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

Rules and Regulations

Federal Register
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Wednesday, November 3, 1999

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. 99–057–1]

Aeration of Imported Logs, Lumber, and Other Unmanufactured Wood Articles That Have Been Fumigated

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: This document amends the regulations for importing unmanufactured wood articles that have been fumigated with methyl bromide or other fumigants by adding a reminder that such articles must be aerated after fumigation in accordance with U.S. Environmental Protection Agency label requirements, the Plant Protection and Quarantine Treatment Manual, and Occupational Safety and Health Administration regulations. Aeration protects port personnel, consignees, and others against possible exposure to dangerous levels of fumigant residue. We are taking this action to increase awareness of the aeration requirement among persons shipping fumigated wood to the United States.

EFFECTIVE DATE: November 3, 1999.

FOR FURTHER INFORMATION CONTACT: Mr. David Reeves, Acting Assistant Director, Port Operations, PPQ, APHIS, 4700 River Road Unit 140, Riverdale, MD 20737–1236; (301) 734–8295.

SUPPLEMENTARY INFORMATION:

Background

The Animal and Plant Health Inspection Service (APHIS) regulates the importation of logs, lumber, and other unmanufactured wood articles to prevent the introduction into the United States of dangerous plant pests, including forest pests. These regulations are contained in 7 CFR 319.40–1 through 319.40–11, ''Subpart—Logs, Lumber, and Other Unmanufactured Wood Articles'' (referred to below as the regulations).

One option for importing certain wood articles involves fumigating the articles with methyl bromide or other fumigants. Section 319.40–7(f) of the regulations contains methyl bromide fumigation standards for logs, lumber, and other regulated wood articles. Other fumigants may be utilized for solid wood packing material from the Peoples Republic of China, including Hong Kong. The Plant Protection and Quarantine (PPQ) Treatment Manual (which is incorporated into the regulations by reference at 7 CFR 300.1) contains fumigation standards for methyl bromide and other fumigants.

When articles are fumigated, the articles must be aerated afterward to ensure that the articles are safe for handling, storage, and transportation. Aeration is required by the Environmental Protection Agency (EPA) in EPA-approved label instructions for all fumigants utilized pursuant to the regulations. Additionally, aeration requirements are set forth in the PPQ Treatment Manual. Furthermore, Occupational Safety and Health Administration (OSHA) regulations contained in title 29 of the Code of Federal Regulations require employers of cargo handlers to determine that the concentration of fumigants is below the level specified as hazardous before the cargo is loaded or discharged.

Recently, APHIS has detected high levels of methyl bromide residue in shipping containers from the Peoples Republic of China, including Hong Kong, that contain fumigated solid wood packing material. These residue levels could pose a health and safety risk to APHIS inspectors at ports of entry and to consignees and other persons who open the shipping containers. APHIS inspectors cannot safely inspect containers with such residues.

Because the recent cases of high levels of residue were all connected with shipments from the Peoples Republic of China, including Hong Kong, APHIS has notified officials in the Peoples Republic of China, including Hong Kong, to remind them of the aeration requirements cited above. However, we believe the requirements would be more apparent to exporters in these and other countries if we stated them explicitly in the regulations.

Therefore, we are adding the following sentence to the introductory paragraph in § 319.40–7(f), which deals with methyl bromide fumigation: ''Following fumigation, fumigated products must be aerated to reduce the concentration of fumigant below hazardous levels, in accordance with the Treatment Manual and label instructions approved by the U.S. Environmental Protection Agency.''

We are making a parallel change to § 319.40–5(g), which requires that solid wood packing material from China ''must be heat treated, fumigated, or treated with preservatives, using a treatment schedule contained in § 319.40–7 or in the Plant protection and Quarantine Treatment Manual.'' This paragraph authorizes fumigation not only with methyl bromide, but with other fumigants authorized by the PPQ Treatment Manual. In each place where the word ''fumigated'' appears, we are changing the word ''fumigated'' to ''fumigated and aerated,'' as a reminder that the PPQ Treatment Manual and EPA-approved label instructions require aeration of all fumigants utilized pursuant to the regulations.

Effective Date

The requirement to aerate fumigated shipments to reduce levels of fumigant to a safe level is already in effect, in the form of EPA-approved label requirements. This requirement is also set forth in the PPQ Treatment Manual. This rule only adds a reference to those requirements to the regulations to increase their visibility to regulated parties. It does not appear that public participation in this rulemaking procedure would make additional relevant information available to the Department.

Accordingly, because the changes contained in this rule are nonsubstantive in nature, we have found that notice and public procedure on this rule are unnecessary. Therefore, pursuant to 5 U.S.C. 553, notice of proposed rulemaking and opportunity to comment are not required, and this rule may be made effective less than 30 days after publication in the **Federal Register**. Further, since this is not a substantive change in the regulations, it is exempt from the provisions of Executive Order 12866 and Executive

Order 12988. Finally, this action is not a rule as defined by Pub. L. 96–354, the Regulatory Flexibility Act, and, thus, is exempt from the provisions of the Act.

Paperwork Reduction Act

This rule contains no 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 319

Bees, Coffee, Cotton, Fruits, Honey, Imports, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, we are amending 7 CFR part 319 as follows:

PART 319—FOREIGN QUARANTINE NOTICES

1. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 150dd, 150ee, 150ff, 151–167, 450, 2803, and 2809; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.2(c).

§ 319.40–5 [Amended]

2. In § 319.40–5, paragraphs (g)(1), (g)(2)(i), (g)(6), and (i) are amended by removing the word ''fumigated,'' each time it appears and adding the phrase ''fumigated and aerated,'' in its place.

§ 319.40–7 [Amended]

3. In § 319.40–7, paragraph (f), the introductory text is amended by adding a third sentence to read as follows: ''Following fumigation, fumigated products must be aerated to reduce the concentration of fumigant below hazardous levels, in accordance with the Treatment Manual and label instructions approved by the U.S. Environmental Protection Agency.''

Done in Washington, DC, this 27th day of October 1999.

Craig A. Reed,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 99–28606 Filed 11–2–99; 8:45 am]

BILLING CODE 3410–34–U

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 928

[Docket No. FV99–928–1 FR]

Papayas Grown in Hawaii; Increased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule increases the assessment rate from $0.0063 to $0.008 per pound of assessable papayas established for the Papaya Administrative Committee (Committee) under Marketing Order No. 928 for the 1999–2000 and subsequent fiscal years. The Committee is responsible for local administration of the marketing order which regulates the handling of papayas grown in Hawaii. Authorization to assess papaya handlers enables the Committee to incur expenses that are reasonable and necessary to administer the program. The fiscal year began on July 1 and ends June 30. The assessment rate will remain in effect indefinitely unless modified, suspended, or terminated.

EFFECTIVE DATE: November 4, 1999.

FOR FURTHER INFORMATION CONTACT: Terry Vawter, Marketing Specialist, California Marketing Field Office, Fruit and Vegetable Programs, AMS, USDA, 2202 Monterey Street, Suite 102B, Fresno, California 93721; telephone: (559) 487–5901; Fax: (559) 487–5906; or George Kelhart, Technical Advisor, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, room 2525–S, P.O. Box 96456, Washington, DC 20090–6456; telephone: (202) 720–2491, Fax: (202) 720–5698. Small businesses may request information on complying with this regulation by contacting Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, P.O. Box 96456, room 2525–S, Washington, DC 20090–6456; telephone (202) 720–2491, Fax: (202) 720–5698, or E-mail: Jay.Guerber@usda.gov.

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Agreement No. 155 and Order No. 928, both as amended (7 CFR part 928), regulating the handling of papayas grown in Hawaii, hereinafter referred to as the ''order.'' The marketing agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

The Department of Agriculture (Department) is issuing this rule in conformance with Executive Order 12866.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the marketing order now in effect, papaya handlers are subject to assessments. Funds to administer the order are derived from such assessments. It is intended that the assessment rate as issued herein will be applicable to all assessable papayas beginning July 1, 1999, and continue until amended, suspended, or terminated. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review the Secretary's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This rule increases the assessment rate established for the Committee for the 1999–2000 and subsequent fiscal years from $0.0063 per pound to $0.008 per pound of assessable papayas.

The papaya marketing order provides authority for the Committee, with the approval of the Department, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. The members of the Committee are producers and handlers of papayas. They are familiar with the Committee's needs and with the costs for goods and services in their local area and are thus in a position to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting. Thus, all directly affected persons have an opportunity to participate and provide input.

For the 1998–1999 and subsequent fiscal years, the Committee recommended, and the Department approved, an assessment rate that would continue in effect from fiscal year to fiscal year unless modified, suspended, or terminated by the Secretary upon recommendation and information submitted by the Committee or other information available to the Secretary.

The Committee met on April 22, 1999, to discuss the crop estimate, budget, and assessment rate for the 1999–2000 fiscal year. On July 15, 1999, the Committee completed a mail ballot on the crop estimate and assessment rate, and on an eight-to-one vote, adopted a crop estimate of 40 million pounds of

assessable papayas and an assessment rate of $0.008 per pound for the 1999–2000 and subsequent fiscal years. The person who voted no objected to the higher assessment rate. The Committee unanimously recommended a 1999–2000 fiscal year budget of $522,500.

The assessment rate of $0.008 is $0.0017 higher than the rate currently in effect. The budgeted expenses are $39,000 less than the $561,500 budgeted for last year. The Committee determined that a higher assessment rate was necessary to meet the recommended expenses and maintain a reserve fund for the 1999–2000 fiscal year. For several fiscal years, money from the reserve fund has been used to meet a portion of budgeted expenses in an effort to keep the assessment rate as low as possible. The Committee believes a further reduction of the reserve fund would not be prudent.

The Committee is authorized to maintain reserve funds in an amount not to exceed approximately one fiscal year's operational expenses. Last year, the reserve fund was $25,200. This year it is expected to be $25,000, which is approximately one percent lower than the previous year and considered adequate by the Committee. After consideration of the estimated crop size and anticipated expenses for the 1999–2000 fiscal year, it was determined that increasing the assessment rate by approximately 27 percent will provide sufficient funds to meet anticipated expenses and maintain an adequate reserve fund.

The major expenditures recommended by the Committee for the 1999–2000 year include $230,000 for marketing and promotion, $90,500 for research and development, and $98,000 for salaries. Budgeted expenses for these items in 1998–99 were $183,000 for marketing and promotion, $171,500 for research and development, and $98,000 for salaries, respectively.

The assessment rate recommended by the Committee was derived by dividing assessment income needed by expected shipments of papayas. Papaya shipments for the year are estimated at 40 million pounds which should provide $320,000 in assessment income. Income derived from handler assessments, when combined with income from the Hawaii Department of Agriculture, State of Hawaii (Research), USDA's Foreign Agricultural Service, County of Hawaii, and the Japanese Inspection program, along with interest income of $16,000, will be adequate to cover budgeted expenses. Funds in the reserve (estimated to be $25,000 at the end of the 1999–2000 fiscal year) will be kept within the maximum permitted in § 928.42(a)(2) of the order. The order authorizes approximately one fiscal year's expenses for the reserve.

The assessment rate established in this rule will continue in effect indefinitely unless modified, suspended, or terminated by the Secretary upon recommendation and information submitted by the Committee or other available information.

Although this assessment rate will be in effect for an indefinite period, the Committee will continue to meet prior to or during each fiscal year to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of Committee meetings are available from the Committee or the Department. Committee meetings are open to the public and interested persons may express their views at these meetings. The Department will evaluate Committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking will be undertaken as necessary. The Committee's 1999–2000 budget and those for subsequent fiscal years would be reviewed and, as appropriate, approved by the Department.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 400 producers of papayas in the production area and approximately 60 handlers subject to regulation under the marketing order. Small agricultural producers have been defined by the Small Business Administration (13 CFR 121.601) as those having annual receipts less than $500,000, and small agricultural service firms are defined as those whose annual receipts are less than $5,000,000.

Based on a reported average f.o.b. price of $1.30 per pound of papayas, a handler would have to ship in excess of 3.85 million pounds of papayas to have annual receipts of $5,000,000. Last year, a majority of the handlers shipped less than 3.85 million pounds of papayas, and, therefore, could be considered small businesses under SBA's definition.

Based on a reported average grower price of $0.45 per pound and industry shipments of 36 million pounds, total grower revenues would be $16.2 million. Average grower revenue would thus be $40,500. Based on the foregoing, the majority of producers of papayas may be classified as small entities.

This rule increases the assessment rate established for the Committee and collected from handlers for the 1999–2000 and subsequent fiscal years from $0.0063 per pound to $0.008 per pound of assessable papayas. The Committee recommended 1999–2000 expenditures for $522,500 and the $0.008 per pound assessment rate. The assessment rate of $0.008 is $0.0017 higher than the 1998–99 rate. The quantity of assessable papayas for the 1999–2000 fiscal year is estimated at 40 million pounds. Thus, the $0.008 rate should provide $320,000 in assessment income. Income derived from handler assessments, the Hawaii Department of Agriculture, State of Hawaii (Research), USDA's Foreign Agricultural Service, County of Hawaii, and the Japanese Inspection program, along with interest income of $16,000, will be adequate to cover budgeted expenses. Funds in the reserve (estimated to be about $25,000 at the end of the 1999–2000 fiscal year) will be kept within the maximum permitted in § 928.42(a)(2) of the order. The order authorizes approximately one fiscal year's expenses for the reserve.

The Committee recommended 1999–2000 expenditures of $522,500. The major expenditures recommended for the 1999–2000 year include $230,000 for marketing and promotion, $90,500 for research and development, and $98,000 for salaries. Budgeted expenses for these items in 1998–99 were $183,000 for marketing and promotion, $171,500 for research and development, and $98,000 for salaries, respectively.

The Committee discussed the alternative of decreasing expenditure levels for marketing and promotion and further reducing research and development expenditures. It determined that the programs should be funded at the recommended levels. The assessment rate of $0.008 per pound of assessable papayas was determined by dividing the assessment income needed by the quantity of assessable papayas, estimated at 40 million pounds for the 1999–2000 fiscal year. This estimate would generate $320,000 in assessment income. When combined with $208,800 in anticipated income from the

previously mentioned sources, and $16,000 in interest income, the Committee will have adequate funds to meet its 1999–2000 expenses.

A review of historical information and preliminary information pertaining to the 1999–2000 fiscal year indicates that the grower price for the season could range between $.30 and $.45 per pound of papayas. Therefore, the estimated assessment revenue for the 1999–2000 fiscal year as a percentage of total grower revenue could range between 1.8 and 2.7 percent.

This action increases the assessment obligation imposed on handlers. While assessments impose some additional costs on handlers, the costs are minimal and uniform on all handlers. Some of the additional costs may be passed on to producers. However, these costs are offset by the benefits derived by the operation of the marketing order. In addition, the Committee's meeting was widely publicized throughout the Hawaii papaya industry and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the April 22, 1999, meeting was a public meeting and all entities, both large and small, were able to express views on this issue.

This rule imposes no additional reporting or recordkeeping requirements on either small or large Hawaii papaya handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

The Department has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

A proposed rule concerning this action was published in the **Federal Register** on September 2, 1999 (64 FR 48115). Copies of the proposed rule were also mailed or sent via facsimile to all papaya handlers. Finally, the proposal was made available through the Internet by the Office of the Federal Register. The period of comments ended October 4, 1999. No comments were received.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at the following web site: http://www.ams.usda.gov/fv/moab.html. Any questions about the compliance guide should be sent to Jay Guerber at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendation submitted by the Committee and other available information, it hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it also found and determined that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because: (1) Handlers are already receiving 1999–2000 crop papayas from growers; (2) the 1999–2000 fiscal year began on July 1 and the order requires that the assessment rate apply to all papayas received during that fiscal year; (3) the Committee needs to have sufficient funds to pay its expenses which are incurred on a continuous basis; (4) handlers are aware of this action which was recommended at a public meeting, and is similar to other assessment rate actions issued in past years; (5) a 30-day comment period was provided for in the proposed rule, and no comments were received.

List of Subjects in 7 CFR Part 928

Marketing agreements, Papayas, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 928 is amended as follows:

PART 928—PAPAYAS GROWN IN HAWAII

1. The authority citation for 7 CFR part 928 continues to read as follows:

Authority: 7 U.S.C. 601–674.

2. Section 928.226 is revised to read as follows:

§ 928.226 Assessment rate.

On and after July 1, 1999, an assessment rate of $0.008 per pound is established for Hawaii papayas.

Dated: October 28, 1999.

Robert C. Keeney,

Deputy Administrator, Fruit and Vegetable Programs.

[FR Doc. 99–28751 Filed 11–2–99; 8:45 am]

BILLING CODE 3410–02–P

FEDERAL ELECTION COMMISSION

[Notice 1999–23]

11 CFR Parts 110, 9004, and 9034

Party Committee Coordinated Expenditures; Costs of Media Travel With Publicly Financed Presidential Campaigns

AGENCY: Federal Election Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: On August 5, 1999, the Commission published the text of revised regulations governing publicly financed Presidential campaigns. These rules address the costs of transportation and ground services that federally funded Presidential primary and general election campaigns may pass on to the news media covering their campaigns, as well as party committee coordinated expenditures that are made before the date their candidates receive the nomination. 64 FR 42579. The Commission announces that these rules are effective as of November 3, 1999.

EFFECTIVE DATE: November 3, 1999.

FOR FURTHER INFORMATION CONTACT: Ms. Rosemary C. Smith, Acting Assistant General Counsel, 999 E Street, N.W., Washington, D.C. 20463, (202) 694–1650 or toll free (800) 424–9530.

SUPPLEMENTARY INFORMATION: The Commission is announcing the effective date of revised regulations at 11 CFR 110.7(d), 9004.6(a) and (b), and 9034.6(a) and (b). New section 11 CFR 110.7(d) addresses party committee coordinated expenditures that are made before the date the party's candidate receives the Presidential nomination. The remaining cited sections address the costs of transportation and ground services that federally funded Presidential primary and general election campaigns may pass on to the news media covering their campaigns.

Section 438(d) of Title 2, United States Code, and sections 9009(c) and 9039(c) of Title 26, United States Code, require that any rules or regulations prescribed by the Commission to carry out the provisions of Title 2 or 26 of the United States Code be transmitted to the Speaker of the House of Representatives and the President of the Senate thirty legislative days prior to final promulgation. These rules were transmitted to Congress on July 30, 1999. Thirty legislative days expired in the Senate and the House of Representatives on October 19, 1999.

Announcement of Effective Date: New 11 CFR 110.7(d) and revised 11 CFR 9004.6(a) and (b) and 9034.6(a) and (b), as published at 64 FR 42579 (August 5, 1999), are effective as of November 3, 1999.

Dated: October 29, 1999.

Scott E. Thomas,

Chairman, Federal Election Commission.

[FR Doc. 99–28703 Filed 11–2–99; 8:45 am]

BILLING CODE 6715–01–U

FEDERAL ELECTION COMMISSION

[Notice 1999–22]

11 CFR Part 9036

Matching Credit Card and Debit Card Contributions in Presidential Campaigns: Documentation

AGENCY: Federal Election Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: On August 5, 1999, the Commission published the text of revised regulations addressing the documentation required to allow contributions made by credit or debit card, including contributions made over the Internet, to be matched under the Presidential Primary Matching Payment Account Act. 64 FR 42584. The Commission announces that these rules are effective retroactive to January 1, 1999.

EFFECTIVE DATE: January 1, 1999.

FOR FURTHER INFORMATION CONTACT: Ms. Rosemary C. Smith, Acting Assistant General Counsel, or Ms. Rita A. Reimer, Attorney, 999 E Street, N.W., Washington, D.C. 20463, (202) 694–1650 or toll free (800) 424–9530.

SUPPLEMENTARY INFORMATION: The Commission is announcing the effective date of new regulations at 11 CFR 9036.1(b) and 9036.2(b) that set out the documentation requirements that must be met before contributions made by credit or debit card, including contributions made over the Internet, may be matched under the Presidential Primary Matching Payment Account Act (''Matching Payment Act''), 26 U.S.C. 9031 *et seq.* ''Matchable contributions'' are those which, when received by candidates who qualify for payments under the Matching Payment Act, are matched by the Federal Government. The new rules require candidates to provide sufficient documentation to the Commission to insure that each contribution submitted for matching was made by a lawful contributor who manifested an intention to make the contribution to the campaign committee that submits it for maching fund payments. They further note that additional information on the documentation required to accompany such contributions will be found in the Commission's Guideline for Presentation in Good Order (''PIGO'').

Section 9039(c) of Title 26, United States Code, requires that any rules or regulations prescribed by the Commission to implement Title 26 of the United States Code be transmitted to the Speaker of the House of Representatives and the President of the Senate thirty legislative days prior to final promulgation. The revisions to 11 CFR 9036.1 and 9036.2 were transmitted to Congress on August 2, 1999. Thirty legislative days expired in the Senate and the House of Representatives on October 19, 1999.

In the Explanation and Justification that accompanied the final rules, the Commission explained that, since many presidential campaigns will have engaged in substantial fundraising by the time these rules take effect, it would retroactively match credit and debit card contributions made on January 1, 1999 and thereafter, if these requirements are met. 64 FR at 42584. Accordingly, these new rules are effective retroactive to January 1, 1999.

Announcement of Effective Date: Amended 11 CFR 9036.1 and 9036.2, as published at 64 FR 42584, are effective retroactive to January 1, 1999.

Dated: October 29, 1999.

Scott E. Thomas,

Chairman, Federal Election Commission.

[FR Doc. 99–28702 Filed 11–2–99; 8:45 am]

BILLING CODE 6715–01–U

FEDERAL RESERVE SYSTEM

12 CFR Part 229

[Regulation CC; Docket No. R–1034]

Availability of Funds and Collection of Checks

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board is adopting amendments to Subpart C of Regulation CC, which contains rules governing the collection and return of checks. The amendments to the regulation and Commentary are intended to provide further clarification as to the extent to which depository institutions and others may vary the terms of the regulation by agreement for the purpose of instituting electronic return systems.

EFFECTIVE DATE: December 15, 1999.

FOR FURTHER INFORMATION CONTACT: Louise Roseman, Director, Division of Reserve Bank Operations and Payment Systems (202/452–2789); Oliver I. Ireland, Associate General Counsel (202/452–3625), Stephanie Martin, Managing Senior Counsel (202/452–3198), Legal Division. For the hearing impaired *only,* contact Diane Jenkins, Telecommunications Device for the Deaf (TDD) (202/452–3544), Board of Governors of the Federal Reserve System, 20th and C Streets, NW, Washington, D.C. 20551.

SUPPLEMENTARY INFORMATION:

Background

In February 1999, the Board requested comment on options for amending provisions in Regulation CC governing when paying or returning banks may send notices instead of returning the original checks.[1] The purpose of the proposal was to explore whether more flexibility is needed to enable check system participants to experiment with methods to return checks electronically.

The collection and return of checks is governed by both Regulation CC and state law (Articles 3 and 4 of the Uniform Commercial Code (U.C.C.)). When a paying bank decides to return a check, the U.C.C. and Regulation CC require it to send the check or a notice within certain deadlines.[2] The U.C.C. and Regulation CC differ on when a bank can return a notice rather than the check itself. If a check is ''unavailable for return,'' U.C.C. 4–301(a) allows a paying bank to charge back the check by revoking its provisional settlement with the presenting bank based on a notice of dishonor or nonpayment. The Official Comment to U.C.C. 4–301 states that a check may be considered unavailable for return if, under a collecting bank check retention plan, presentment is made by a presentment notice and the check is retained by the collecting bank. Presumably, therefore, the U.C.C. would allow a paying bank to return a notice when a check has been truncated. (It is not clear whether a check would be deemed unavailable for return under the U.C.C. if the paying bank, rather than the collecting bank, retains it.)

Regulation CC (§§ 229.30(f) and 229.31(f)) establishes a ''notice in lieu of return,'' which substitutes for the original check and carries value. The notice-in-lieu provisions of Regulation CC provide that the paying (or returning) bank must return the original check unless the check is unavailable, in which case the bank may return a notice that meets certain information requirements. The Regulation CC Commentary states that notice is permitted in lieu of return only when a bank does not have and cannot obtain possession of the check or must retain possession of the check for protest. The Commentary explains that a check is not unavailable for return if it is merely

[1] 64 FR 9105, Feb. 24, 1999.

[2] The paying bank must initiate the return by midnight of the banking day following the day the check was presented (U.C.C. 4–301). The paying bank must return the check so that it reaches the depositary bank expeditiously, in accordance with § 229.30(a) of Regulation CC.

difficult to retrieve from a filing system or from storage by a keeper of checks in a truncation system.

The primary reason for the difference between the U.C.C.''s and Regulation CC's treatment of notices is that there is likely to be less risk for a depositary bank in accepting a notice (instead of the original check) from a bank it knows than from a bank it doesn't know. Under the U.C.C., the paying bank returns a check to the presenting bank, which in turn charges back the check against the prior collecting bank, and so on back up the forward collection chain until the check reaches the depositary bank. Therefore, under the U.C.C., the depositary bank receives returns from the bank to which it had sent the check for collection and with which it has a previously established relationship. One of the purposes of Regulation CC was to speed up the check return system that existed under the U.C.C. Regulation CC eliminated the requirement that returned checks follow the forward collection chain. Under Regulation CC, the paying bank may send the returned check directly to the depositary bank or to any returning bank, even if that bank did not handle the check for forward collection. Therefore, under Regulation CC, depositary banks may receive returned checks from banks with which they have no previous relationship.

Some check system participants asked the Board to clarify the interrelationship between the U.C.C. and Regulation CC in order to provide additional legal certainty for institutions that wish to experiment with electronic return systems, under which they would return images or other notices rather than the checks. These participants were concerned about their ability to bind all relevant parties to an electronic return arrangement under the variation-by-agreement provisions of Regulation CC. Regulation CC (§ 229.37) permits the parties to a check to vary the notice-in-lieu provisions; however, an agreement under Regulation CC cannot affect banks, customers, or others that are not party to the agreement or otherwise bound by it. The Regulation CC variation-by-agreement provision differs from the corresponding language in U.C.C. 4–103 in that the U.C.C. allows clearinghouse rules (as well as Federal Reserve regulations and operating circulars) to be effective as agreements whether or not specifically assented to by all interested parties.[3] Regulation CC does not incorporate the U.C.C.''s special treatment for clearinghouse rules (or for Federal Reserve rules and circulars) but does not affect the status of such under the U.C.C.

This difference in variation-by-agreement provisions exists because Regulation CC does not govern the relationship between banks, their customers, and remote parties to the extent that the U.C.C. does. While Board rules can bind depository institutions, the Board does not appear to have the authority under the Expedited Funds Availability Act to bind depositors or payees to an electronic check return system. Section 611(f) of the Act, which authorizes the Board to establish rules allocating loss and liability in the payments system, applies to loss and liability among depository institutions only. The Act does not authorize such allocations to customers of depository institutions.

Although banks would be able to obtain agreement to the terms of an electronic return arrangement from their customers through account agreements, under Regulation CC they would not be able to bind remote parties to the check, such as non-depositor payees. Some check system participants sought an amendment to Regulation CC that would eliminate the risk that these remote third parties would bring a claim under Regulation CC in the event they suffered losses due to the fact that a check was returned electronically rather than in physical form. A claim could potentially arise under the following circumstances:

Drawer A writes and delivers a check payable to Payee B. Payee B negotiates the check to Depositor C, who deposits the check in his bank. Depositor C's bank presents the check to Drawer A's bank. Both banks are participating in an electronic return system, and Drawer A's bank returns an image of the check to Depositor C's bank, which, in turn, charges Depositor C's account. Depositor C would have to attempt to collect the funds from Payee B or Drawer A without the physical check. Assuming that Depositor C has agreed to the electronic return system through an account agreement, Depositor C would bear the risk that Payee B or Drawer A would not pay without the original check. (Payee B or Drawer A may be concerned about the risk of double payment if the original check is not returned.) If Payee B pays Depositor C in return for the check image or similar notice, Payee B may still be unable to collect from Drawer A without the check and could suffer losses (although Payee B may still have recourse against Drawer A under the U.C.C. even without the original check). Presumably, an electronic return arrangement would allow banks or customers to request the original check within a certain amount of time. If Drawer A becomes insolvent before the original check is retrieved, Payee B would suffer losses. If Payee B would have been able to collect from Drawer A had Payee B originally received the check rather than the notice, then Payee B's losses would likely be attributable to the electronic return system.

Regulation CC imposes a duty on banks to exercise ordinary care and act in good faith in handling checks under Regulation CC. This duty runs to the depositary bank, the depositary bank's customer, the owner of a check, or another party to the check. If a bank violates these duties, resulting in harm to one of these parties, the party may have a claim against the bank for damages. Therefore, if a bank returned a notice-in-lieu when the physical check was deemed ''available'' under Regulation CC, and the return of the notice rather than the physical check caused a party to the check to incur a loss, the bank potentially could be liable for damages. The bank sending the notice could be liable even if it had agreed with the receiving bank to use notices in lieu of return. The injured party would have to show lack of good faith or failure to exercise ordinary care.

The risk of a bank becoming liable to a remote third party under the circumstances described above appears to be low. Nevertheless, some check system participants stated that they were reluctant to begin experimenting with electronic check return systems without additional protection. To flesh out the pros and cons of making regulatory changes in this area, in February 1999 the Board sought commenters' input on two options.[4]

The first option was to amend the Commentary to Regulation CC to state that banks could send a notice of dishonor or nonpayment in accordance with the provisions of U.C.C. 4–301 when they return the notice through the forward collection chain, as contemplated in the U.C.C. The U.C.C. notices would be subject to the Regulation CC expeditious return rules. This proposal would clarify that banks could avail themselves of the U.C.C. rules regarding return of notices to the same extent that they could before Regulation CC was adopted. The Board noted, however, that this proposal may

[3] The Official Comment to U.C.C. 4–103 (note 3) indicates, however, that there are limitations on the scope of clearinghouse rules. The Comment notes that clearinghouses are not authorized to rewrite the basic law generally and that clearinghouse rules should be understood in the light of functions the clearinghouses have exercised in the past.

[4] 64 FR 9105, Feb. 24, 1999.

not provide relief for check truncation or image systems if returns do not follow the forward collection chain and that it could have consequences for the depositors or payees of the checks, who may have difficulty recovering from the drawers without the original checks.

The second option was to delete the Regulation CC Commentary language that explains when a check is unavailable for return. Instead of this language, the Commentary would indicate that notices in lieu of return are permissible whenever they would be permissible under the U.C.C. The Board noted that this option would liberalize the circumstances under which banks could use notices in lieu of return and potentially make it easier for banks to establish electronic check return mechanisms that feature check truncation, but would force depositary banks to accept notices from banks with whom they may have no established relationships. This option could also have consequences for the depositors or payees of the checks as discussed above under option one.

The Board also proposed to delete § 229.36(c) of Regulation CC and its associated Commentary, which states that a bank may present a check electronically under an agreement with the paying bank and that the agreement may not extend return times or otherwise vary the provisions of Regulation CC with respect to persons not party to the agreement. This provision of the regulation is subsumed by the variation-by-agreement provisions in § 229.37, and it may be unnecessary and potentially confusing to retain special provisions regarding a particular type of variation by agreement. The Board proposed to add an example to the Commentary to § 229.37, listing an electronic check presentment agreement as a permissible variation by agreement under Regulation CC. The Board noted that eliminating § 229.36(c) and its Commentary would result in no substantive change to the regulation regarding the validity of electronic presentment agreements.

Summary of Comments

The Board received 72 comments on its proposed options, classified as follows:

Banks/Bank holding cos: 32
Thrifts/Thrift holding cos: 2
Credit unions/Corporate credit unions: 9
Trade associations representing—
  Banks: 5
  Credit unions: 5
  Clearing houses: 2
  Non-banks: 2
Clearing houses/organizations: 9
Federal Reserve Banks: 2
Non-bank service providers: 4

Problems Raised by Notices in Lieu of Returns

Overall, the commenters were supportive of changes that would improve efficiency and reduce risk in the check collection and return system, but were reluctant to support changes that would impose costs on depositary banks, their customers, and other parties to the check without their consent. Thirty-five commenters specifically discussed the problems that would arise if depositors received notices of returned checks instead of the physical checks. Many of these commenters echoed the problems stated by the Board in its proposal, i.e. that customers generally expect checks to be returned to them when their accounts are charged back and that customers have ownership rights in the physical checks. Commenters were concerned about whether their customers would be able to collect from drawers without the original checks and some noted that the drawer's risk of double payment needs to be addressed. Some of these commenters stated that the U.C.C. limits a holder's rights to enforce a check without possession of the physical item. Several commenters raised concerns about whether a notice of a returned check would be sufficient evidence of the return in court, and others noted that law enforcement authorities often require the original check in order to lift fingerprints from the check or examine the handwriting. Four commenters, however, stated that even though the customer, as the legal owner, may have a right to the original check, there may be no practical consequence if an image or other electronic return has legal equivalence under the U.C.C. or the Uniform Electronic Transactions Act.[5]

Twenty-one commenters raised concerns about whether the information provided on a notice-in-lieu-of-return would be sufficient to allow the depositary bank to charge back its customer's account. The commenters listed such necessary information as the indorsement (especially on third-party checks), the check date, the payee, the amount, the reason for return, the teller stamp, trace numbers, and the account number. Some commenters noted that missing information is already a problem for notices-in-lieu under the current regulation. Some of these comments were related to concerns about the quality of the photocopy or image that depositary banks would receive, and others were related to the sufficiency of information in an electronic notice that did not include an image of the check. One commenter suggested that if notices-in-lieu become more permissible, then all of the information requirements of § 229.33(b) should be mandatory and no questions marks allowed.

Costs and Benefits of Electronic Returns

Thirty-one commenters specifically mentioned the benefits of an electronic return system. These commenters generally believe that electronic returns will enable checks to be returned faster and will allow depositary banks and their customers to protect themselves better against check fraud. They stated that an electronic return system would lead to operational savings and make forward check truncation feasible.

On the other hand, eight commenters believed that the costs of an electronic return system could likely outweigh the benefits. The commenters noted that costs could take the form of incomplete information to the depositary bank, potentially resulting in delays in charging back the customer's account, as well as the expense of hardware and software to operate an electronic return system.

Six commenters discussed the potential competitive effects of establishing an electronic return system. These commenters were generally concerned that community banks and other small depository institutions may not be technologically prepared for electronic returns and should not be placed at a disadvantage by any regulatory change.

Option One

Only one commenter expressed a preference for option one. Thirty-two commenters pointed out specific problems that would arise if the Board were to adopt option one. Many stated that application of option one would be too limited in scope to provide sufficient incentive for experimentation in electronic returns. Several commenters believed that certain checks may be impossible to return through the forward collection chain within the expeditious return deadlines. Others commented that the U.C.C. standards are not clear as to what information must be included in a U.C.C. notice of nonpayment and were concerned that the depositary bank would not receive information sufficient to charge the check back to its customer's account.

[5] The Uniform Electronic Transactions Act is a model law drafted and approved by the National Conference of Commissioners on Uniform State Laws and recently adopted in California. It does not provide that a check image or other electronic returned check is legally equivalent to the original check, except for limited record-keeping purposes.

Some commenters believed that adoption of option one would lead to confusion as to when the U.C.C. applied to a returned check rather than Regulation CC, and one commenter noted that state-to-state variation in the meaning of ''unavailable for return'' could lead to confusion with respect to interstate transactions. Commenters raised other questions as to the implementation of option one, such as (1) whether the presenting bank that receives a U.C.C. notice of nonpayment, but holds the truncated physical check, has the option to either send a notice or the check to depositary bank and (2) whether the physical check must be made available to the depositary bank or its customer upon request.

Option Two

Eighteen commenters supported proposed option two, although nearly all of those commenters raised additional issues that they believed should be addressed. The Electronic Check Clearing House Organization (ECCHO) and seventeen other commenters supported option two so long as the regulation made clear that the depositary bank would have to agree to receive electronic notices in lieu of return. These commenters stated that experimentation with electronic notices should be conducted on a voluntary basis, governed by bilateral or multilateral agreements. The commenters stated that the depositary bank would need to know from whom it would be receiving electronic returns and would have to work out such issues as who would own the returns/images, acceptable quality standards, who to contact in case of problems, and what procedures to follow. One supporter of option two, however, did not expect that the receipt of unexpected electronic returns from unfamiliar banks would be widespread. This commenter stated that the issue of the quality of electronic returns from unfamiliar banks would be an operational matter that would likely be self-regulated between paying banks and depositary banks and should be left for the banks to police.

Eleven commenters discussed specific problems regarding option two. Some of these commenters raised issues related to dealing with an unknown returning bank. They stated that accepting notices from banks with which the depositary bank has no relationship could pose significant financial or customer service risk exposure. They also said that handling returned items could become more complex and time-consuming if images are received from multiple sources, and the amount of manual sorting could outweigh the advantages of new technology. Another concern raised by the commenters was that option two could increase the use of notices in lieu of returns, placing the burden on the depositary bank in providing the depositor with the information on the return item when a charge-back occurs without the physical check. The commenters also raised other matters that would need to be addressed under option two, such as (1) Whether the presenting bank that receives a notice but holds the physical check has the option to send either the notice or the check to the depositary bank and (2) whether the physical check must be made available to the depositary bank or its customer on request.

Other Comments on Options.

Seventeen commenters opposed both options. Most of these commenters stated that the proposals would make the return process more complicated, particularly in connection with reconcilement, without a comprehensive all-electronic approach. They stated that the Board should address other issues related to electronic returns before adopting either option. One commenter favored either option, stating that either would accomplish the goal of reconciling Regulation CC with the U.C.C. as to when a check is available for return.

Most of the commenters suggested additions or enhancements to the two options proposed by the Board:

Variation by Agreement.

Nine commenters stated that the Board should permit clearing house rules to vary Regulation CC in same way as they vary the U.C.C. The commenters stated that this would avoid the need to change Regulation CC to accommodate innovations and would put private-sector banks on a more equal footing with non-banks and Federal Reserve Banks.

The Federal Reserve Bank of Atlanta (FRB Atlanta) believed that the concern as to whether § 229.37 of Regulation CC limits the ability of an agreement to bind remote parties is ameliorated by at least two factors: (1) FRB Atlanta stated that the only remote party right under Regulation CC is the right to receive a notice of return, which can be met by an image of sufficient quality to permit the depositary bank to identify its customer; other remote party rights arise under the U.C.C. and can be addressed in the context of agreements under the U.C.C.; and (2) At least one court decision [6] held that the depositary bank, as the collection agent for its customer, can enter into agreements on behalf of the customer without prior consent as long as agreement is reasonable. FRB Atlanta stated that accepting an image return (with the paper check to follow) seems to be reasonable. FRB Atlanta suggested, as an alternative to the proposed options, that the Board revise the Commentary to § 229.37 to provide that depositary bank may agree with paying or returning banks to accept images or other notices of dishonored checks as notices in lieu of return and that those banks may be responsible under other applicable law to parties interested in the check for any losses caused by the handling of check returns under such agreements (except to the extent addressed in effective agreements with those other parties).

U.C.C. Availability Requirement.

Three commenters stated that the proposal's reference to U.C.C. 4–301 is not sufficient because it is not clear what types of check programs are encompassed by the U.C.C.'s Official Comment to 4–301 regarding ''availability'' of checks for return. The commenters suggested that the Regulation CC Commentary should specifically permit notice in lieu of return when a check is difficult to retrieve from a filing system or from storage pursuant to a truncation, image or other check electronification program, provided the receiving bank has agreed to accept notices in lieu of return in such circumstances.

Two commenters raised other questions concerning what sorts of truncation arrangements are contemplated by U.C.C. 4–301(a). These comments reflected the uncertainty as to whether it matters which bank in the collection or return chain is the truncating bank in determining if a check is unavailable for return under the U.C.C.

Three commenters suggested that the Board allow a bank to provide a notice-in-lieu at will, rather than only when the original check is unavailable for return. These commenters noted that such returns may not be permissible under the U.C.C., but they anticipated that the U.C.C. or its state variations may become less restrictive in the future as technology changes.

Address Legal Status of Images.

Five commenters requested that the Board address the legal status of images to provide comfort that an image or electronic notice legally replaces the original check. Some of these commenters suggested that the

[6] *Graubert* v. *Bank Leumi,* 399 N.E. 2d 930 (Ct. App. N.Y. 1979).

Commentary should explicitly state that images are acceptable in the U.S. check collection and return system to bolster banks' ability to convince customers to accept images in lieu of the original check.

Establish Standards.

Fifteen commenters asked the Board to establish standards for an electronic return system. The commenters expressed a need for standards in areas such as image quality, standardized return reason codes, data communication, procedures to verify system integrity and compatibility, and indorsements. Some of these commenters stated that the Board should set time limits for the returning bank to provide the depositary bank with the paper check and procedures for request and retrieval. One commenter stated that the Board should provide for migration to more image-friendly check stock. Another commenter stated that a new regulatory infrastructure is necessary to address detailed issues, even more specifically than the Board's same-day settlement provisions in Regulation CC.

Address Return Deadlines.

Seven commenters stated that the Board should clarify how an electronic return system would affect return deadlines. For example, one commenter suggested that the Board should clarify when the return clock starts if checks are presented electronically and the physical item is necessary to create a return. Other commenters suggested that the Board amend Regulation CC to provide that, if a bank sends image returns under a truncation arrangement where the check was presented electronically, it would not be required to meet the U.C.C. return deadline. The commenters stated that this rule would nurture the development of electronic check presentment and would enable the paying bank to examine the physical check and create an image return without violating the U.C.C. midnight deadline.

Representment.

Eleven commenters stated that the Board should address how a depositary bank could represent a check that had been returned electronically. They said that representment of checks returned electronically would pose technical and operational challenges, including the form of the represented check and what would replace the indorsement audit trail. One commenter suggested that the Board establish redeposit rules allowing for prompt representment of electronic returns to protect consumers from the potential loss from dishonored checks.

Depositary Bank Protections.

Thirteen commenters requested that the Board take steps to protect depositary banks under electronic return systems. Several commenters suggested that the depositary bank should be able to send back an electronic return and require return of the physical check instead. Other commenters suggested providing warranty protection for the depositary bank by requiring the bank that sends an electronic return to indemnify a depositary bank that charges back its customer based on the electronic return. One commenter also stated that the depositary bank and its customers should receive guarantees that the original check will not be returned.

Allow Images Only.

Ten commenters suggested that the Board limit electronic return to images only. One of these commenters stated that the regulation should reflect a preference in favor of check imaging rather than the transmission of a detailed accounting of the check. Another commenter stated that the regulation should discourage the proliferation of written notices, which are often incomplete and expose the depositary bank to undue risk.

Address Coordination Issues.

Two commenters suggested that the Board should address various issues related to the interaction of an electronic return system with other electronic payment initiatives. One commenter asked for clarification as to how a paying bank could return an image if it is receiving check presentment electronically. This commenter also asked how a depositary bank could create ACH returned-check entries (RCKs) without the physical checks. Another commenter suggested that the Board should provide a statement authorizing use of a notice in lieu of return when the check has been processed electronically and returned to its owner at the point of sale. The commenter stated that this would encourage increased experimentation with electronic check truncation at the point of sale.

Comprehensive Approach.

Seven commenters believed that the Board should take the lead in working with the industry on a comprehensive approach to structuring an all-electronic return process. One commenter stated that electronic returns need to be part of a new regulatory approach for overall check electronification. Another commenter stated that the Board should express its willingness to consider and act on appropriate regulatory changes on an ongoing basis during the transition to electronics in check processing. Another commenter suggested that the Board fund a nationwide education and marketing campaign to ensure consumer and corporate acceptance of images in lieu of checks. Finally, one commenter stated that the current return rules hold the check system hostage to the needs of a few payees, and the Board should endorse the notice-in-lieu process more enthusiastically rather than merely condoning it.

Implementation Date.

Seven commenters made statements regarding the implementation date of any rule change. Most of these commenters favored implementation as quickly as possible, but one commenter asked for at least one year lead time to allow for updating of internal systems.

Amendments to §§ 229.36 and 229.37.

Seven commenters explicitly supported the proposed amendments to §§ 229.36 and 229.37 regarding electronic presentment agreements. One commenter suggested that the restriction on the expansion of check return deadlines should be retained explicitly.

Board staff invited all of the public commenters to participate in a meeting on July 26 to discuss issues related to the proposed amendments. Twenty-eight commenters attended the meeting.

Discussion

As indicated in the comment summary, overall, most commenters were open to the idea of an electronic return system but were very concerned about the effects of such a system on depositary banks and their customers. Many commenters were reluctant to support regulatory changes without knowing the details of how an electronic return system would work and how they and their customers would be protected. This concern prompted many commenters to suggest that the Board, in cooperation with banks, establish more detailed rules and standards that would govern such a system. The Board continues to believe that practices and standards would be developed most efficiently through commercial practice and market experimentation rather than by regulation. The Board believes that its appropriate role is to facilitate experimentation by determining whether its rules create barriers to experimentation and if so, whether

those rules can be changed without creating undue adverse affects.

As noted above, under Regulation CC, the inability to bind remote parties to an interbank agreement could lead to liability on the part of banks for relying on electronic returns. Some participants in the July 26 meeting reiterated that it is this potential liability they would like to avoid. ECCHO and various others suggested in their comment letters that the Board adopt option two but permit an electronic return only if the depositary bank agrees to accept it. ECCHO restated its proposal at the July 26 meeting, laying out a 3-part plan for revising option two: (1) All of the banks involved, including the depositary bank, would have to agree to participate in any electronic check return program, (2) a notice in lieu of return, whether specifically permitted under Regulation CC or permitted as part of an interbank agreement on electronic check returns, would satisfy the requirements of Regulation CC to the same extent as the return of the original paper check for all bank and non-bank parties to the check, and (3) banks that are parties to an electronic return agreement may be liable under other law to non-bank parties unless that liability is covered by other agreements.

Most of the discussion at the July 26 meeting focused on the cut-off of rights under ECCHO's point (2), which would shield participating banks against claims by remote parties under Regulation CC but would not operate as a shield against claims under other law. (Presumably, ECCHO and others would rely on their ability to bind remote parties by clearinghouse rules under the U.C.C. to address these potential claims.) The Board's proposed option two would have cut off Regulation CC rights, but those rights would have been cut off for both banks and non-banks. The ECCHO proposal would allow banks to opt out of the electronic return arrangement but would not allow their customers or other parties to the check to do so. Supporters of the ECCHO proposal reasoned that this distinction was justified because depositary banks would have to make operational changes to be able to accept electronic returns, but depositors and others would not necessarily need to make such changes.

Meeting participants were unable to quantify the risk presented by the possibility that non-assenting parties may assert Regulation CC rights if an electronic return program caused them to incur losses. In general, participants agreed that, because banks can generally obtain assent from their customers through deposit agreements, the most serious risks would be from potential claims by remote third parties, such as non-depositor payees, unless those rights are cut off. ECCHO and some of the bank representatives stated that the uncertainty as to the size of this risk was preventing banks from investing in pilot electronic return programs. Without quantifying this risk, some banks stated that they are unable to judge whether the benefits of an electronic return system outweigh the risks, although some bank representatives said that they had not made a focused attempt to determine the magnitude of the risk. At the close of the meeting representatives from ECCHO and certain banks stated that they would take a closer look at the risks of claims from non-assenting parties under Regulation CC to determine whether those risks are actually outweighed by the perceived benefits to banks of electronic returns.

In a subsequent letter to the Board, ECCHO reiterated its support for a Regulation CC amendment that would incorporate its proposal as outlined at the meeting.[7] In its letter, ECCHO argued that its proposal would result in increased efficiency in the check return system that would benefit banks as well as depositors in terms of protection against check fraud. ECCHO believes that customer service incentives will lead banks to make the original paper checks available to customers within a reasonable window of time and that banks that are not comfortable with the arrangement can opt out.

ECCHO's proposal would eliminate the risks of potential Regulation CC claims against banks that participate in electronic check return systems. The risk would, in effect, be shifted from depositary banks to their customers and remote third parties. Those who favor this proposal have not demonstrated the magnitude of this risk. They state that the risk is significant enough to prevent banks from experimenting with electronic returns. On the other hand, they state that shifting the risk to non-bank parties is justified by the efficiencies and cost-savings that an electronic return system would bring. The Board's proposed option 2 would also, in effect, shift this risk to non-bank parties to the check, as well as to depositary banks. The Board believes that the risk of Regulation CC claims by remote third parties is quite low and finds it difficult to justify shifting that risk to the remote third parties to benefit banks that have agreed among themselves to return checks electronically. The barrier that the current regulation presents to electronic check return does not appear to be significant enough to warrant shifting risks to non-assenting parties. Further, the commenters indicated that proposed option one would not be useful in many situations where checks are not returned back through the forward collection chain.

Instead, the Board has taken a different approach, similar to that suggested by FRB Atlanta. The Board has revised the Commentary to § 229.37 to clarify that depositary banks may agree with paying or returning banks to accept images or other notices in lieu of returned checks even when the checks are available for return under Regulation CC. Except to the extent that other parties interested in the checks assent to or are bound by the banks' agreements, banks entering into such agreements may be liable under Regulation CC or other applicable law to other interested parties for any losses caused by the handling of returned checks under such agreements. This revision leaves the rights of depositary banks, depositors, and remote parties intact under both Regulation CC and the U.C.C., avoiding the potential consumer issues of the proposed options and the ECCHO proposal.

Given the Board's action, the final analysis of any electronic return system will be driven by a cost decision on the part of the banks involved. If the cost savings of an electronic return system will be as great as some check system participants expect, then the risk of Regulation CC claims by non-assenting remote third parties may be outweighed by those savings and could be absorbed by participating banks. The Board notes that banks have taken on these risks in other contexts. For example, the banks that are participating in the Federal Reserve electronic return pilot in Montana have agreed to assume the risk of claims by non-assenting parties.[8]

The Board believes that the best long-term solution to this particular electronic return issue, as well as other

[7] The Board received five other follow-up letters from organizations that attended the July 26 meeting. The letters supported the ECCHO proposal in general, but some stated that the Board should seek additional comment before adopting the ECCHO proposal.

[8] In other electronic payment experimental programs, banks have been willing to assume risks that appear to be more significant than the risk presented in this instance. For example, under recently adopted National Automated Clearing House Association rules that allow check payees to collect the funds from the checks through the automated clearing house (ACH) under certain circumstances, the bank that originates the ACH transaction warrants that all signatures on the check are genuine and that the underlying paper check will not be presented, even though the bank itself may not have possession of or control over the check.

issues related to the electronic collection and return of checks, would best be addressed in a coordinated effort to bring subpart C of Regulation CC and the U.C.C. into conformance. The Board is pursuing this solution with the National Conference of Commissioners on Uniform State Laws.

In addition, as proposed, the Board has removed the electronic presentment agreement provisions from § 229.36(c) and its related Commentary and added a corresponding example to the Commentary to § 229.37. These amendments will not have any substantive effect.

Regulatory Flexibility Act Certification

In accordance with section 605 of the Regulatory Flexibility Act, (12 U.S.C. 605), the Board certifies that the amendments to Regulation CC and its Commentary will not have a significant economic impact on a substantial number of small entities. The amendments will clarify the extent to which banks may agree to vary the terms of Regulation CC by agreement to experiment with electronic return systems, but will not affect any entities who have not agreed.

List of Subjects in 12 CFR Part 229

Banks, banking, Federal Reserve System, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 12 CFR Part 229 is amended as set forth below:

PART 229—AVAILABILITY OF FUNDS AND COLLECTION OF CHECKS (REGULATION CC)

1. The authority citation for part 229 continues to read as follows:

Authority: 12 U.S.C. 4001 *et seq.*

§ 229.36 [Amended]

2. In § 229.36, paragraph (c) is removed and reserved.

3. In Appendix E, under section XXII, paragraph C. is removed and reserved.

4. In Appendix E, under section XXIII, new paragraphs C.9. and C.10. are added to read as follows:

Appendix E to Part 229—Commentary

* * * * *

XXIII. Section 229.37 Variations by Agreement

* * * * *

C. * * *

9. A presenting bank and a paying bank may agree that presentment takes place when the paying bank receives an electronic transmission of information describing the check rather than upon delivery of the physical check. (See § 229.36(b).)

10. A depositary bank may agree with a paying or returning bank to accept an image or other notice in lieu of a returned check even when the check is available for return under this part. Except to the extent that other parties interested in the check assent to or are bound by the variation of the notice-in-lieu provisions of this part, banks entering into such an agreement may be responsible under this part or other applicable law to other interested parties for any losses caused by the handling of a returned check under the agreement. (See §§ 229.30(f), 229.31(f), 229.38(a).)

* * * * *

By order of the Board of Governors of the Federal Reserve System, October 27, 1999.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 99–28580 Filed 11–2–99; 8:15 am]

BILLING CODE 6210–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99–SW–12–AD; Amendment 39–11397; AD 99–23–01]

RIN 2120–AA64

Airworthiness Directives; Robinson Helicopter Company (Robinson) Model R44 Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to Robinson Model R44 helicopters, that currently requires removing and replacing the pilot's cyclic control grip assembly (grip assembly) with an airworthy grip assembly. This amendment requires the same actions as the current AD but would change a part number (P/N) referenced in the current AD. This amendment is prompted by the discovery of an error in the P/N of the current AD. The actions specified by this AD are intended to prevent use of a grip assembly that may crack, resulting in failure of the grip assembly and subsequent loss of control of the helicopter.

EFFECTIVE DATE: December 8, 1999.

FOR FURTHER INFORMATION CONTACT: Fred Guerin, Aerospace Engineer, FAA, Los Angeles Aircraft Certification Office, Airframe Branch, 3960 Paramount Boulevard, Lakewood, California 90712, telephone (562) 627–5232, fax (562) 627–5210.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding AD 98–21–36, Amendment 39–10845, Docket No. 97–SW–01–AD, (63 FR 55783, October 19, 1998), which is applicable to Robinson Model R44 helicopters, was published in the **Federal Register** on August 4, 1999 (64 FR 42296). That action proposed to require removing the grip assembly, P/N A756–6, Revision N or prior revision, and replacing it with an airworthy grip assembly other than P/N A765–6, Revision A through N.

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received on the proposal or the FAA's determination of the cost to the public. The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

The FAA estimates that 5 helicopters of U.S. registry will be affected by this AD, that it will take approximately 4 work hours per helicopter to accomplish the required actions, and that the average labor rate is $60 per work hour. Required parts will cost approximately $576 per helicopter. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $4,080.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the

Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (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. Section 39.13 is amended by removing Amendment 39–10845 (63 FR 55783), and by adding a new airworthiness directive (AD), Amendment 39–11397, to read as follows:

AD 99–23–01 Robinson Helicopter Company: Amendment 39–11397. Docket No. 99–SW–12–AD. Supersedes AD 98–21–36, Amendment 39–10845, Docket No. 97–SW–01–AD.

Applicability: Model R44 helicopters, serial numbers (S/N) 0001 through 0159, except S/N's 0143, 0150, and 0156, with pilot's cyclic control grip assembly (grip assembly), part number (P/N) A756–6, Revision N or prior revision, installed, certificated in any category.

Note 1: This AD applies to each helicopter identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Within 25 hours time-in-service or 30 calendar days, whichever occurs first, unless accomplished previously.

To prevent use of a grip assembly that may crack, resulting in failure of the grip assembly and subsequent loss of control of the helicopter, accomplish the following:

(a) Remove the grip assembly, P/N A756–6, Revision A through N, and replace it with an airworthy grip assembly other than P/N A756–6, Revision A through N.

Note 2: Robinson KI–112 R44 Pilot's Grip Assembly Upgrade Kit instructions, dated December 20, 1996, pertain to the subject of this AD.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles Aircraft Certification Office. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Los Angeles Aircraft Certification Office.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles Aircraft Certification Office.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be accomplished.

(d) This amendment becomes effective on December 8, 1999.

Issued in Fort Worth, Texas, on October 26, 1999.

Eric Bries,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 99–28655 Filed 11–2–99; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–SW–60–AD; Amendment 39–11398; AD 99–23–02]

RIN 2120–AA64

Airworthiness Directives; Eurocopter France Model SA–365N, SA–365N1, and AS–365N2 Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to Eurocopter France Model SA–365N, SA–365N1, and AS–365N2 helicopters, that requires replacing certain defective electrical modules with airworthy electrical modules. This amendment is prompted by the discovery of several defective electrical modules. The actions specified by this AD are intended to prevent loss of electrical continuity, which could cause loss of critical rotorcraft electrical systems and subsequent loss of control of the helicopter.

EFFECTIVE DATE: December 8, 1999.

FOR FURTHER INFORMATION CONTACT: Robert McCallister, Aerospace Engineer, FAA, Rotorcraft Directorate, Rotorcraft Standards Staff, Fort Worth, Texas 76193–0110, telephone (817) 222–5121, fax (817) 222–5961.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that is applicable to Eurocopter France Model SA–365N, SA–365N1, and AS–365N2 helicopters was published in the **Federal Register** on August 4, 1999 (64 FR 42295). That action proposed to require replacing certain defective electrical modules with airworthy electrical modules.

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received on the proposal or the FAA's determination of the cost to the public. The FAA has determined that air safety and the public interest require the adoption of the rule as proposed except for two nonsubstantive changes that have been made to paragraph (b) and Note 3 of the AD. In paragraph (b), the NPRM incorrectly states that alternative methods of compliance (AMOC) or adjustments of the compliance time may be approved by the ''Manager, Rotorcraft Standards Staff, Rotorcraft Directorate.'' This is incorrect and has been changed to state that the Manager, Regulations Group, Rotorcraft Directorate, is responsible for approving any AMOC or adjustment of the compliance time. Note 3 of the NPRM states that information concerning the existence of approved AMOC may be obtained from the ''Rotorcraft Standards Staff''; this is also incorrect and has been changed to state that information may be obtained from the ''Regulations Group.'' The FAA has determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

The FAA estimates that 41 helicopters of U.S. registry will be affected by this AD, that it will take approximately 300 work hours per helicopter to replace all affected modules, and that the average labor rate is $60 per work hour. Required parts would cost approximately $29,520, but the helicopter manufacturer has stated that the parts will be provided at no cost. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $738,000 to replace all affected modules.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3)

will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (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. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

AD 99–23–02 Eurocopter France: Amendment 39–11398. Docket No. 98–SW–60–AD.

Applicability: Model SA–365N, SA–365N1, and AS–365N2 helicopters, certificated in any category.

Note 1: This AD applies to each helicopter identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required within 200 hours time-in-service (TIS) or within the next 3 calendar months, whichever occurs first, unless accomplished previously.

To prevent loss of electrical continuity, which could cause loss of critical rotorcraft electrical systems and subsequent loss of control of the helicopter, accomplish the following:

(a) Remove and replace each ''CONNECTRAL'' green electrical module that does not have a white dot on the face and that has a manufacturing code of 95/16 through 96/21 with an airworthy electrical module.

Note 2: Eurocopter France Service Bulletin No. 01.00.47R1, dated December 18, 1998, pertains to the subject of this AD.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Regulations Group, Rotorcraft Directorate, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Regulations Group.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Regulations Group.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be accomplished.

(d) This amendment becomes effective on December 8, 1999.

Note 4: The subject of this AD is addressed in Direction Generale De L'Aviation Civile (France) AD No. 1998–253–044(A)R1, dated February 10, 1999.

Issued in Fort Worth, Texas, on October 26, 1999.

Eric Bries,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 99–28654 Filed 11–2–99; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 99–ACE–46]

Amendment to Class E Airspace; Mountain View, MO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; request for comments.

SUMMARY: This action amends Class E airspace area at Mountain View Airport, Mountain View, MO. A review of the Class E airspace area for Mountain View Airport indicates it does not comply with the criteria for 700 feet Above Ground Level (AGL) airspace required for diverse departures as specified in FAA Order 7400.2D. The Class E airspace has been enlarged to conform to the criteria of FAA Order 7400.2D.

In addition, a minor revision to the Airport Reference Point (ARP) is included in this document.

The intended effect of this rule is to provide additional controlled Class E airspace for aircraft operating under Instrument Flight Rules (IFR), revise the ARP, and comply with the criteria of FAA Order 7400.2D.

DATES: Effective date: 0901 UTC, February 24, 2000.

Comments for inclusion in the Rules Docket must be received on or before December 5, 1999.

ADDRESSES: Send comments regarding the rule in triplicate to: Manager, Airspace Branch, Air Traffic Division, ACE–520, DOT Regional Headquarters Building, Federal Aviation Administration, Docket Number 99–ACE–46, 901 Locust, Kansas City, MO 64106.

The official docket may be examined in the Office of the Regional Counsel for the Central Region at the same address between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

An informal docket may also be examined during normal business hours in the Air Traffic Division at the same address listed above.

FOR FURTHER INFORMATION CONTACT: Kathy Randolph, Air Traffic Division, Airspace Branch, ACE–520C, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329–2525.

SUPPLEMENTARY INFORMATION: This amendment to 14 CFR 71 revises the Class E airspace at Mountain View, MO. A review of the Class E airspace for Mountain View Airport, MO, indicates it does not meet the criteria for 700 feet AGL airspace required for diverse departures as specified in FAA Order 7400.2D. The criteria in FAA Order 7400.2D for an aircraft to reach 1200 feet AGL is based on a standard climb gradient of 200 feet per mile plus the distance from the ARP to the end of the outermost runway. Any fractional part of a mile is converted to the next higher tenth of a mile. The amendment at Mountain View Airport, MO, will provide additional controlled airspace for aircraft operating under IFR, revise the ARP, and comply with the criteria of FAA Order 7400.2D. The area will be depicted on appropriate aeronautical charts. Class E airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9G, dated September 10, 1999, and effective September 16, 1999, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Direct Final Rule Procedure

The FAA anticipates that this regulation will not result in adverse or negative comment and, therefore, is issuing it as a direct final rule. Previous actions of this nature have not been controversial and have not resulted in adverse comments or objections. The amendment will enhance safety for all flight operations by designating an area where VFR pilots may anticipate the presence of IFR aircraft at lower altitudes, especially during inclement weather conditions. A greater degree of safety is achieved by depicting the area on aeronautical charts. Unless a written adverse or negative comment, or a written notice of intent to submit an adverse or negative comment is received with the comment period, the regulation will become effective on the date specified above. After the close of the comment period, the FAA will publish a document in the **Federal Register** indicating that no adverse or negative comments were received and confirming the date on which the final rule will become effective. If the FAA does receive, within the comment period, an adverse or negative comment, or written notice of intent to submit such a comment, a document withdrawing the direct final rule will be published in the **Federal Register**, and a notice of proposed rulemaking may be published with a new comment period.

Comments Invited

Although this action is in the form of a final rule and was not preceded by a notice of proposed rulemaking, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended or withdrawn in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of this action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy-related aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this action will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 99–ACE–46.'' The postcard will be date stamped and returned to the commenter.

Agency Findings

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is noncontroversial and unlikely to result in adverse or negative comments. For the reasons discussed in the preamble, I certify that this regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

Accordingly, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9G, Airspace Designations and Reporting Points, dated September 10, 1999, and effective September 16, 1999, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ACE MO E5 Mountain View, MO [Revised]

Mountain View Airport, MO
(Lat 36°59′34″ N., long. 91°42′52″ W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Mountain View Airport and within 2.6 miles each side of the 108° bearing from the Mountain View Airport, extending from the 6.5-mile radius to 7 miles east of the airport.

Issued in Kansas City, MO, on October 13, 1999.

Herman J. Lyons, Jr.,

Manager, Air Traffic Division, Central Region.

[FR Doc. 99–27927 Filed 11–2–99; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

15 CFR Part 285

[Docket No. 990927264.9264.01]

National Voluntary Laboratory Accreditation Program; Amendment of Regulations

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Final rule.

SUMMARY: On February 20, 1996, the Director of NIST delegated certain designated authorities under the National Voluntary Laboratory Accreditation Program (NVLAP) regulations to the Chief of the Laboratory Accreditation Program at NIST. This document amends the NVLAP regulations to reflect the delegation of authority. The amendments will only affect Agency organization, procedure and practice.

EFFECTIVE DATE: November 3, 1999.

FOR FURTHER INFORMATION CONTACT: Chief, Laboratory Accreditation Program, National Institute of Standards and Technology, 100 Bureau Drive, Stop 2140, Gaithersburg, MD, 20899–2140; or, by e-mail at *nvlap@nist.gov*.

SUPPLEMENTARY INFORMATION:

Background

Title 15 Part 285 of the Code of Federal Regulations sets out procedures and general requirements under which the National Voluntary Laboratory

Accreditation Program (NVLAP) operates as an unbiased third party to accredit both calibration laboratories and testing laboratories. NVLAP accredits laboratories in response to (a) mandates by the Federal Government; (b) requests from a government agency; and (c) requests from a private sector organization.

The NVLAP procedures were first published in the **Federal Register** on February 25, 1976, and have been revised several times since then. Certain authorities under the NVLAP regulations were given to the Director of NIST. In accordance with 15 CFR subpart A, section 285.5, the Director of NIST delegated these authorities to the Chief of the National Voluntary Laboratory Accreditation Program on February 20, 1996, in a memorandum to the Director of the Office of Standards Services. The delegation of authority was not extended to the conclusion of any agreements with the governments of other countries referenced in Section 285.11(f) of Title 15 of the Code of Federal Regulations.

Purpose

The purpose of this rule is to amend Part 285 of Title 15 of the CFR so that it conforms to the current delegation of authority.

Rulemaking Requirements

Under Title 5 United States Code Section 553, this rule is not subject to the notice and comment requirements of the Administrative Procedure Act. This rule only relates to Agency organization, management or personnel (5 USC 553 (a)(2)).

PRA Clearance. This rule does not contain a collection of information for purposes of the Paperwork Reduction Act.

Executive Order 12866: This rule is exempt under Section 3(d)(3) of E.O. 12866.

Regulatory Flexibility Act. This action is exempt from the analytical requirements of the Regulatory Flexibility Act because notice and comment are not required for this action by Section 553 of the Administrative Procedure Act or any other law.

List of Subjects in 15 CFR Part 285

Business and industry, Commerce, Laboratories, Measurement standards.

Dated: October 26, 1999.

Karen H. Brown,

Deputy Director.

For the reasons set forth in the preamble, Title 15 of the Code of Federal Regulations (CFR), part 285 is amended as follows:

PART 285—NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM

1. The authority citation for 15 CFR part 285 continues to read as follows:

Authority: 15 U.S.C. 272 et seq.

§ 285.3 [Amended]

2. In § 285.3(c) remove the phrase, ''Director of the National Institute of Standards and Technology (NIST)'' and add, in its place, the phrase ''Chief of NVLAP.''

§ 285.11 [Amended]

3. In § 285.11 (a) and (d) introductory text, remove the phrase, ''Director of NIST'' and add, in its place, the phrase ''Chief of NVLAP.''

4. In § 285.11(e) introductory text, remove the phrase, ''Director'' and add, in its place, the phrase ''Chief of NVLAP.''

§ 285.12 [Amended]

5. In § 285.12(a) introductory text, (b) introductory text (twice), (c), (d), and (e), remove the phrase, ''Director of NIST'' and add, in its place, the phrase ''Chief of NVLAP.''

§ 285.13 [Amended]

6. In 285.13 (a) and (d), remove the phrase, ''Director of NIST'' and add, in its place, the phrase ''Chief of NVLAP.''

§ 285.14 [Amended]

7. In § 285.14(a) introductory text and (d), remove the phrase, ''Director of NIST'' and add, in its place, the phrase ''Chief of NVLAP.''

§ 285.19 [Amended]

8. In § 285.19(a) (twice) and (c) (twice), remove the phrase, ''Director of NIST'' and add, in its place, the phrase ''Chief of NLAP.''

[FR Doc. 99–28665 Filed 11–2–99; 8:45 am]

BILLING CODE 3510–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Office of the Commissioner and the Center for Drug Evaluation and Research

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the delegations of authority statement that covers general redelegations of authority from the Commissioner of Food and Drugs to other officers of FDA. The amendment delegates authority to perform all functions relating to waivers or reductions of prescription drug user fees under the Prescription Drug User Fee Act of 1992 (PDUFA), as originally enacted and as reauthorized by the FDA Modernization Act of 1997 (the Modernization Act), to the Director, Center for Drug Evaluation and Research (CDER) and to the Associate Director for Policy, CDER, except for the functions that pertain to situations where ''the fees will exceed the anticipated present and future costs.'' The authority to waive or reduce user fees, previously redelegated to the Chief Mediator and Ombudsman/User Fee Waiver Officer, the Deputy Chief Mediator and Ombudsman, and the Deputy User Fee Waiver Officer is hereby revoked, except the authority to act upon requests for reconsideration of any user fee decision made by such officers prior to July 1, 1999. Also, as a result of the June 20, 1999, FDA reorganization, the Office of Operations component and the Deputy Commissioner for Operations position were abolished; therefore, the Deputy Commissioner will assume the role of the User Fee Appeals Officer and perform the associated functions.

EFFECTIVE DATE: July 1, 1999.

ADDRESSES: As of July 1, 1999, submit all requests for waivers, refunds, and reductions in user fees under PDUFA, originally enacted and reauthorized by the Modernization Act, to the Associate Director for Policy, Center for Drug Evaluation and Research (HFD–5), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, Attn: User Fee Waiver Office. Submit requests sent via a courier that requires a street address to the Associate Director for Policy, Center for Drug Evaluation and Research (HFD–5), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, Attn: User Fee Waiver Office. Submit requests for reconsideration of user fee waiver determinations made prior to the effective date of this document to the Office of the Chief Mediator and Ombudsman, (HF–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Beverly J. Friedman, User Fee Staff (HFD–5), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041, or

Donna G. Page, Division of Management Programs (HFA–340),

Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4816.

SUPPLEMENTARY INFORMATION: FDA is amending the delegations of authority under § 5.20 *General redelegations of authority from the Commissioner to other officers of the Food and Drug Administration* (21 CFR 5.20) by revising § 5.20(h) to revoke the authority of the Chief Mediator and Ombudsman/User Fee Waiver Officer, the Deputy Chief Mediator and Ombudsman, and the Deputy User Fee Waiver Officer to waive or reduce user fees under the waiver provisions of PDUFA as originally enacted and as amended by the Modernization Act (section 736(d) and (a)(1)(G) of the Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379h(d) and (a)(1)(G)), except the authority to act upon requests for reconsideration of any user fee decision made by such officers prior to July 1, 1999. FDA is also revising the section to reflect that the Deputy Commissioner is designated as the User Fee Appeals Officer and in the case of a vacancy in the position, to reflect the designation of the Senior Associate Commissioner, Office of the Commissioner as the User Fee Appeals Officer.

FDA is adding § 5.101 *Authority relating to waivers or reductions of prescription drug user fees* to reflect redelegation of certain user fee-related authorities under section 736(d) and (a)(1)(G) of the act, as amended, to the Director, CDER and to the Associate Director for Policy, CDER. CDER will exercise the authority now being delegated to resolve requests for waivers, reductions, or refunds of assessable fees relating to human drug products reviewed and regulated by CDER, the Center for Biologics Evaluation and Research, and any other FDA center.

Authority delegated to a position by title may be exercised by a person officially designated to serve in such a position in an acting capacity or on a temporary basis, unless prohibited by a restriction in the document designating him/her as ''acting'' or unless not legally permissible. These authorities may not be further redelegated.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; 15 U.S.C. 1451–1461; 21 U.S.C. 41–50, 61–63, 141–149, 321–394, 467f, 679(b), 801–886, 1031–1309; 35 U.S.C. 156; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1; 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11921, 41 FR 24294, 3 CFR, 1977 Comp., p. 124–131; E.O. 12591, 52 FR 13414, 3 CFR, 1988 Comp., p. 220–223.

2. Section 5.20 is amended by revising paragraph (h) to read as follows:

§ 5.20 General redelegations of authority from the Commissioner to other officers of the Food and Drug Administration.

* * * * *

(h)(1) The Chief Mediator and Ombudsman and the Deputy Chief Mediator and Ombudsman are authorized to act upon requests for reconsideration of any user fee decisions (under 21 U.S.C. 379h(d)) made by such officers and the former Deputy User Fee Waiver Officer prior to July 1, 1999. This authority may not be further redelegated. (See § 5.101 for the user fee-related redelegation to officials within the Center for Drug Evaluation and Research.)

(2) The Deputy Commissioner for Management and Systems and the Director, Office of Financial Management are authorized to perform the functions of the Commissioner under 21 U.S.C. 379h(d)(1)(C), as amended, to waive or reduce prescription drug user fees in situations where he/she finds that ''the fees will exceed the anticipated present and future costs.'' This authority may not be further redelegated.

(3) The Deputy Commissioner or, in the event of a vacancy in that position, the Senior Associate Commissioner, Office of the Commissioner, is designated as the User Fee Appeals Officer. The User Fee Appeals Officer is authorized to hear and decide user fee waiver appeals. The decision of the User Fee Appeals Officer will constitute final agency action on such matters. This authority may not be further redelegated.

3. Section 5.101 is added to subpart C to read as follows:

§ 5.101 Authority relating to waivers or reductions of prescription drug user fees.

The Director, Center for Drug Evaluation and Research (CDER), and the Associate Director for Policy, CDER, are authorized to perform all functions of the Commissioner of Food and Drugs relating to waivers or reductions of prescription drug user fees under the Prescription Drug User Fee Act of l992, as originally enacted and as reauthorized by the FDA Modernization Act of l997, except for the functions under 21 U.S.C. 379h(d)(1)(C) that pertain to situations where ''the fees will exceed the anticipated present and future costs,'' on behalf of CDER, the Center for Biologics Evaluation and Research, and any other FDA center. This authority pertains to waivers requested under the public health waiver provision (21 U.S.C. 379h(d)(1)(A)); the barrier to innovation waiver provision (21 U.S.C. 379h(d)(1)(B)); the applications submitted under section 505(b)(1) and (b)(2) of the Federal Food, Drug, and Cosmetic Act waiver provision (21 U.S.C. 379h(d)(1)(D)); the small business waiver provision (21 U.S.C. 379h(d)(1)(E)); and to requests for refunds of fees if an application or supplement is withdrawn after filing (21 U.S.C. 379h(a)(1)(G)); as well as waivers, reductions, or refunds requested on any other basis except fees exceeding the cost. These authorities may not be further redelegated. (See § 5.20(h)(1) for the authority to reconsider any user fee decisions made by the Chief Mediator and Ombudsman, the Deputy Chief Mediator and Ombudsman, and/or the former Deputy User Fee Waiver Officer prior to July 1, 1999.)

* * * * *

Dated: October 25, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–28562 Filed 11–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. 99N–2550]

Medical Devices; Hearing Aids; Technical Data Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations governing hearing aid labeling to reference the most recent version of the consensus standard used to determine the technical data to be included in labeling for hearing aids. This amendment is being made in order that manufacturers may use state-of-the-art methods to address technical data in hearing aid labeling. FDA is amending

the regulations in accordance with its direct final rule procedures. Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule under FDA's usual procedures for notice and comment to provide a procedural framework to finalize the rule in the event the agency receives a significant adverse comment and withdraws this direct final rule.

DATES: This regulation is effective March 17, 2000. Submit written comments on or before January 17, 2000. If FDA receives no significant adverse comments within the specified comment period, the agency intends to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this direct final rule ends. If timely significant adverse comments are received, the agency will publish a document in the **Federal Register** withdrawing this direct final rule before its effective date. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in § 801.420(c)(4) (21 CFR 801.420(c)(4)), effective March 17, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: David A. Segerson, Center for Devices and Radiological Health (HFZ–460), Food And Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2080.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 15, 1977 (42 FR 9286), FDA published final regulations establishing requirements for professional and patient labeling of hearing aids (§ 801.420) and governing conditions for sale of hearing aids (§ 801.421 (21 CFR 801.421)). The regulations became effective on August 15, 1977. Section 801.421(b)(1) of the regulations provides that, before the sale of a hearing aid to a prospective user, a hearing aid dispenser is to provide the prospective user with a copy of the User Instructional Brochure. Section 801.420(c)(4) requires that technical data useful in selecting, fitting, and checking the performance of a hearing aid be provided in the brochure or in separate labeling that accompanies the device. The regulation further required that the technical data values provided in the brochure or other labeling be determined according to the test procedures established by the Acoustical Society of America (ASA) in the ''American National Standard Specification of Hearing Aid Characteristics,'' ANSI S3.22–1976 (ASA 70–1976), which was incorporated by reference in the regulation.

ANSI S3.22 (ASA 70–1976) established measurement methods and specifications for several definitive hearing aid characteristics, and provided a method of ascertaining whether a hearing aid, after being manufactured and shipped, met the specifications and design parameters stated by the manufacturer for a particular model, within the tolerance stated by the standard.

In 1982, ASA revised the standard (ANSI S3.22–1982) (ASA 70–1982). In a final rule published in the **Federal Register** of July 24, 1985 (50 FR 30153). FDA incorporated the revised standard into § 801.420(c)(4). ASA revised the standard again in 1987 (ANSI S3.22–1987) (ASA 70–1987). In a final rule published in the **Federal Register** of December 21, 1989 (54 FR 52395), FDA incorporated the newly revised standard into § 801.420(c)(4).

In 1996, ASA revised the standard again (ANSI S3.22–1996) (ASA 70–1996). The standard describes air-conduction hearing aid measurement methods that are particularly suitable for specification and tolerance purposes. Among the test methods described are output sound pressure level (SPL with a 90-dB input SPL, full-on gain, frequency response, harmonic distortion, equivalent input noise, current drain, induction-coil sensitivity, and static and dynamic characteristics of automatic gain control hearing aids. The standard gives specific configurations for measuring the input SPL to a hearing aid. The standard also describes allowable tolerances in relation to values specified by the manufacturer for certain parameters. Appendices are provided to describe an equivalent substitution method, characteristics of battery simulators, and additional tests to characterize the electroacoustic performance of hearing aids more completely.

FDA is now incorporating the 1996 standard into § 801.420(c)(4). This will allow hearing aid manufacturers to use the up-to-date methods to determine the technical data values for hearing aids. In addition, FDA is removing from § 801.420(c)(4) the address for ''American National Standard Institute'' and is adding in its place the address for ''Acoustical Society of America.''

II. Rulemaking Action

In the **Federal Register** of November 21, 1997 (62 FR 62466), FDA described when and how FDA will employ direct final rulemaking. FDA believes that this rule is appropriate for direct final rulemaking because FDA views this rule as a noncontroversial amendment and anticipates no significant adverse comments. Consistent with FDA's procedures on direct final rulemaking, FDA is publishing elsewhere in this issue of the **Federal Register** a companion proposed rule to amend part 801 (21 CFR part 801). The companion proposed rule and the direct final rule are substantively identical. The companion proposed rule provides a procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of a significant adverse comment. The comment period for the direct final rule runs concurrently with the companion proposed rule. Any comments to the companion proposed rule will be considered as comments regarding the direct final rule.

FDA is providing a comment period on the direct final rule until January 17, 2000. If the agency receives a significant adverse comment, FDA intends to withdraw this final rule by publication in the **Federal Register** within 30 days after the comment period ends. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. For example, a comment requesting a change in provisions of the hearing aid rule unrelated to the subject matter addressed in the ANSI standard will not be considered a significant adverse comment, because it is outside the scope of the rule. On the other hand, a comment recommending an additional change to the rule may be considered a significant adverse comment if the comment demonstrates why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule and that provision can be

severed from the remainder of the rule, FDA may adopt as final those provisions of the rule that are not the subject of a significant adverse comment.

If FDA withdraws the direct final rule, all comments received will be considered under the proposed rule in developing a final rule in accordance with usual Administrative Procedure Act notice-and-comment procedures.

If FDA receives no significant adverse comment during the specified comment period, FDA intends to publish a confirmation document within 30 days after the comment period ends confirming the effective date.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impact of this direct final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this direct final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, this direct final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The direct final rule amends the existing hearing aid regulation to refer to the updated consensus standard that is used to determine the technical data in hearing aid labeling. Communications from manufacturers to FDA show that they are prepared to be in compliance with this standard immediately. The agency, therefore, certifies that this final rule will not have a significant economic impact on a substantial number of small entities. This direct final rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in an expenditure of $100 million or more by State, local, or tribal governments in the aggregate, or by the private sector, in any one year.

V. Paperwork Reduction Act of 1995

This direct final rule contains no collection of information. Therefore clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is no required.

VI. Request for Comments

Interested persons may, on or before January 17, 2000, submit to the Docket Management Branch (address above) written comments regarding this direct final rule. The comment period runs concurrently with the comment period for the companion proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. All comments received will be considered as comments regarding the companion proposed rule and this direct final rule. In the event the direct final rule is withdrawn, all comments received regarding the companion proposed rule and this direct final rule will be considered comments on the proposed rule.

List of Subjects in 21 CFR Part 801

Hearing aids, Incorporation by reference, Medical devices, Professional and patient labeling.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 801 is amended as follows:

PART 801—LABELING

1. The authority section for 21 CFR part 801 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360i, 360j, 371, 374.

2. Section 801.420 is amended by revising the second and third sentences in paragraph (c)(4) to read as follows:

§ 801.420 Hearing aid devices; professional and patient labeling.

* * * * *

(c) * * *

(4) * * * The determination of technical data values for the hearing aid labeling shall be conducted in accordance with the test procedures of the American National Standard ''Specification of Hearing Aid Characteristics,'' ANSI S3.22–1996 (ASA 70–1996) (Revision of ANSI S3.22–1987), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Standards Secretariat of the Acoustical Society of America, 120 Wall St., New York, NY 10005–3993, or are available for inspection at the Regulations Staff, CDRH (HFZ–215), FDA, 1350 Piccard Dr., rm. 240, Rockville, MD 20850, and at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. * * *

* * * * *

Dated: October 19, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–28209 Filed 11–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 982

[Docket No. FR–4428–F–05]

RIN 2577–AB91

Housing Choice Voucher Program; Amendment

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Final rule.

SUMMARY: On October 21, 1999, HUD published a final rule implementing the statutory merger of the Section 8 tenant-based certificate and voucher programs. This rule makes an amendment to the October 21, 1998 final rule concerning the 40 percent of adjusted monthly income initial rent burden limit. HUD is making this change based upon its reconsideration of the statutory language and legislative history regarding this requirement.

DATES: Effective Date: December 3, 1999.

FOR FURTHER INFORMATION CONTACT: Gerald J. Benoit, Office of Public and Indian Housing, Department of Housing and Urban Development, Room 4210, 451 Seventh Street, SW, Washington, DC 20410; telephone (202) 708–0477. (This is not a toll-free number.) Hearing or speech-impaired individuals may access this number via TTY by calling

the toll-free Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

On October 21, 1999 (64 FR 56894), HUD published a final rule implementing the statutory merger of the Section 8 tenant-based certificate and voucher programs. The October 21, 1999 final rule implemented section 545 of the Quality Housing and Work Responsibility Act of 1998 (Title V of the FY 1999 HUD Appropriations Act; Pub. L. 105–276, approved October 21, 1998) (referred to as the ''Public Housing Reform Act''). The new tenant-based program (known as the Housing Choice Voucher program) has features of the previously authorized certificate and voucher programs, plus new features. Interested persons should consult the preamble to the October 21, 1999 final rule for additional details. This final rule makes an amendment to new Housing Choice Voucher Program regulations at 24 CFR part 982.

The Public Housing Reform Act provides that at the time a family initially receives tenant based assistance under the Housing Choice Voucher Program with respect to any dwelling unit:

> [T]he total amount that a family may be required to pay for rent may not exceed 40 percent of the monthly adjusted income of the family. (42 U.S.C. 1437f(o)(3), as amended by section 545 of the Public Housing Reform Act)

This statutory provision is currently implemented by § 982.508.

This final rule provides that the initial rent burden restriction at § 982.508 applies only to a family who leases a unit at a gross rent which exceeds the applicable payment standard for the family. This final rule provides that at the time the Public Housing Agency (PHA) approves a tenancy for initial occupancy of a dwelling unit by a family with assistance under the voucher program, *and where the gross rent of the unit exceeds the applicable payment standard for the family,* the family share of gross rent must not exceed 40 percent of the family's monthly adjusted income. Under this final rule, the initial rent burden restriction will not apply to a family that rents a unit for a gross rent (rent to owner plus tenant-paid utilities) at or below the payment standard for the family.

In the Housing Choice Voucher Program, the monthly assistance payment for a family that rents for a gross rent below the payment standard for the family is the gross rent minus the total tenant payment (TTP), as computed by a statutory formula. The TTP is *the highest of:*

1. 30 percent of monthly adjusted income;
2. 10 percent of monthly income;
3. In ''as-paid'' States (where the welfare housing grant is adjusted in accordance with actual housing cost), the portion of welfare assistance designated for housing; or
4. The PHA's minimum rent (from $0 to $50, as determined by the PHA).

Under the last three branches of this formula, the TTP (which is not covered by the voucher subsidy payment) for a family may exceed 40 percent of adjusted monthly income. HUD previously advised that such families may not rent a unit for a gross rent that exceeds the 40 percent initial rent burden limit.

On reconsideration of the statute and legislative history, HUD believes that the statute is only intended to place a restriction on the rent burden of a family who chooses to lease a unit for a rent that exceeds the payment standard applicable to the family.

The exact language later enacted as the initial rent burden restriction in the Public Housing Reform Act originated in the predecessor of the Public Housing Reform Act, as reported by the Senate Banking Committee in May, 1997 (Sen. Report 105–21, May 23, 1997). The Committee report specifies that the 40 percent rent burden limitation applies ''if the initial rent on a unit exceeds the payment standard'' (Sen. Report 105–21, page 34; see also, page 35). The Committee report also states that ''if the tenant wishes to lease a unit where the initial rent on a unit exceeds the payment standard'' tenants may pay the difference up to 40 percent of adjusted income (Sen. Report 105–21, page 56). The Committee report clearly indicates that the 40 percent rent burden limitation is not intended to apply for a family that rents below the payment standard, and whose statutory total tenant payment exceeds 40 percent of adjusted income.

Although this final rule will not take effect until December 3, 1999, PHAs are advised that the amendment made by this final rule better reflects the intent of the Congress in enacting the ''40 percent rent burden limit.'' PHAs should, therefore, immediately begin to conform their practices and procedures to the language of § 982.508, as amended by this final rule. In the meantime, pending the effective date of this rule, HUD does not anticipate imposing sanctions against PHAs that rely on the course set out here as a ''safe harbor.''

II. Justification for Final Rulemaking

In general, HUD publishes a rule for public comment before issuing a rule for effect, in accordance with its own regulations on rulemaking at 24 CFR part 10. Part 10, however, does provide for exceptions from that general rule where HUD finds good cause to omit advance notice and public participation. The good cause requirement is satisfied when the prior public procedure is ''impracticable, unnecessary, or contrary to the public interest'' (24 CFR 10.1). HUD finds that good cause exists to publish this rule for effect without first soliciting public comment, in that prior public procedure would be contrary to the public interest. This final rule amends the Housing Choice Voucher Program regulations at 24 CFR part 982 to more accurately reflect the Congressional intent regarding the ''40 percent initial rent burden.'' Upon reconsideration of the relevant statutory language and legislative history, HUD has determined that its initial interpretation (codified at § 982.505) may contradict the intent of the Congress in enacting this provision. It is necessary for this rule not to be delayed to solicit public comments in order to correct any potential confusion on the part of PHAs and assisted families regarding the scope and applicability of this statutory requirement. Accordingly, HUD is publishing this rule for effect without prior public participation.

III. Findings and Certifications

Environmental Impact

A Finding of No Significant Impact with respect to the environment was made on HUD's May 14, 1999 interim rule implementing the statutory merger of the tenant-based Section 8 certificate and voucher programs, in accordance with HUD regulations in 24 CFR part 50 that implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4223). That Finding remains applicable to this final rule and is available for public inspection between 7:30 a.m. and 5:30 p.m. weekdays in the Office of the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (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 final rule does not impose any Federal mandates on any State,

local, or tribal governments or the private sector within the meaning of Unfunded Mandates Reform Act of 1995.

Impact on Small Entities

The Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)) (the RFA), has reviewed and approved this final rule and in so doing certifies that this rule would not have a significant economic impact on a substantial number of small entities. The final rule is exclusively concerned with public housing agencies that administer tenant-based housing assistance under Section 8 of the United States Housing Act of 1937. Specifically, the final rule would establish requirements governing tenant-based assistance for an eligible family. The final regulatory amendment would not change the amount of funding available under the Section 8 voucher program. Accordingly, the economic impact of this rule will not be significant, and it will not affect a substantial number of small entities.

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 final rule does not have federalism implications and does not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive Order.

Catalog of Domestic Assistance Numbers

The Catalog of Domestic Assistance numbers for the programs affected by this final rule are 14.855 and 14.85.

List of Subjects in 24 CFR Part 982

Grant programs—housing and community development, Housing, Rent subsidies.

For the reasons described in the preamble, HUD is amending 24 CFR part 982 as follows:

PART 982—SECTION 8 TENANT BASED ASSISTANCE: HOUSING CHOICE VOUCHER PROGRAM

1. The authority citation for 24 CFR part 982 continues to read as follows:

Authority: 42 U.S.C. 1437f and 3535(d).

2. Revise § 982.305(a)(5) to read as follows:

§ 982.305 PHA approval of assisted tenancy.

(a) * * *

(5) At the time a family initially receives tenant-based assistance for occupancy of a dwelling unit, and where the gross rent of the unit exceeds the applicable payment standard for the family, the family share does not exceed 40 percent of the family's monthly adjusted income.

* * * * *

3. Revise § 982.508 to read as follows:

§ 982.508 Maximum family share at initial occupancy.

At the time the PHA approves a tenancy for initial occupancy of a dwelling unit by a family with tenant-based assistance under the program, and where the gross rent of the unit exceeds the applicable payment standard for the family, the family share must not exceed 40 percent of the family's adjusted monthly income. The determination of adjusted monthly income must be based on verification information received by the PHA no earlier than 60 days before the PHA issues a voucher to the family.

Dated: October 28, 1999.

Harold Lucas,

Assistant Secretary for Public and Indian Housing.

[FR Doc. 99–28790 Filed 11–1–99; 8:51 am]

BILLING CODE 4210–33–U

DEPARTMENT OF JUSTICE

Parole Commission

28 CFR Part 2

Paroling, Recommitting, and Supervising Federal Prisoners: Rescission Guidelines

AGENCY: United States Parole Commission, Justice.

ACTION: Interim rule; amendments.

SUMMARY: The Commission is amending its regulation regarding sanctioning of disciplinary infractions and new criminal behavior by prisoners who have applied for parole or who have received grants of parole. The amendment clarifies the Commission's longstanding policy that this regulation applies to all misconduct committed by a prisoner while confined, whether before or after the sentence is imposed. It also clarifies the applicability of the rule to parolees when they are confined for new crimes committed while on parole.

DATES: *Effective Date:* December 3, 1999. Comments must be received by December 31, 1999.

ADDRESSES: Send comments to Office of General Counsel, U.S. Parole Commission, 5550 Friendship Blvd., Chevy Chase, Maryland 20815.

FOR FURTHER INFORMATION CONTACT: Pamela A. Posch, Office of General Counsel, U.S. Parole Commission, 5550 Friendship Blvd., Chevy Chase, Maryland 20815, telephone (301) 492–5959.

SUPPLEMENTARY INFORMATION: The Commission's regulation at 28 CFR § 2.36 provides in pertinent part that the rescission guidelines contained therein ''shall apply to the sanctioning of disciplinary infractions or new criminal behavior committed by a prisoner subsequent to the commencement of his sentence and prior to his release on parole.'' 28 CFR 2.36(a). The Commission's regulation regarding guidelines for parole decisionmaking provides in pertinent part that ''for criminal behavior committed while in confinement see § 2.36.'' 28 CFR 2.20(i). The Commission's longstanding interpretation of its rescission guidelines is therefore that they apply to all misconduct and new criminal behavior committed by an offender ''in confinement''. In order to clarify the language of § 2.36(a), (which, standing alone, appears to limit rescission guidelines to conduct after a prisoner has begun service of an imposed sentence) the Commission is amending § 2.36(a). The amended rule will make clear that the rescission guidelines apply to new criminal conduct committed by any offender who is in confinement, whether as a pretrial detainee, as a prisoner serving an imposed sentence, or as a prisoner who has been transferred to another institution pending trial or sentencing on another matter. The amended rule also makes clear that the rescission guidelines apply to disciplinary infractions or further crimes committed by a parolee after he has been confined on a new criminal charge, whether before or after the Commission revokes his parole. This inclusive policy reflects the Commission's view that disciplinary infractions are always relevant to the parole decisionmaking process, and that new crimes committed while in official confinement of any type share are a significant indicant of the offender's lack of suitability for parole or reparole.

The rescission guidelines therefore apply to conduct committed while in confinement regardless of the venue of confinement; new criminal conduct in a halfway house or jail, as well as in a

prison, falls within the ambit of § 2.36(a).

Implementation

The amended rule is made effective as an interim rule pending the public comment process because of the public and law enforcement interest in not placing in doubt the many parole decisions made in accordance with 28 CFR 2.36 and 2.20(i).

Regulatory Assessment Requirements

The U.S. Parole Commission has determined that this amended interim rule is not a significant rule within the meaning of Executive Order 12866. The amended interim rule will not have a significant economic impact upon a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 605(b), and is deemed by the Commission to be a rule of agency practice that does not ''substantially affect the rights or obligations of non-agency parties'' pursuant to Section 804(3)(C) of the Congressional Review Act.

List of Subjects in 28 CFR Part 2

Administrative practice and procedure, Probation and parole, Prisoners.

The Amendments

Accordingly, the U.S. Parole Commission is adopting the following amendments to 28 CFR Part 2.

PART 2—[AMENDED]

1. The authority citation for 28 CFR Part 2 continues to read as follows:

Authority: 18 U.S.C. 4203(a)(1) and 4204(a)(6).

2. Section 2.36 is amended by revising the first sentence of paragraph (a) to read as follows:

§ 2.36 Rescission guidelines.

(a) The following guidelines shall apply to the sanctioning of disciplinary infractions or new criminal conduct committed by a prisoner during any period of confinement that is credited to his current sentence (whether before or after sentence is imposed), but prior to his release on parole; and by a parole violator during any period of confinement prior to or following the revocation of his parole (except when such period of confinement has resulted from initial parole to a detainer). * * *

* * * * *

Dated: October 25, 1999.

Michael J. Gaines,

Chairman, Parole Commission.

[FR Doc. 99–28587 Filed 11–2–99; 8:45 am]

BILLING CODE 4410–31–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD07–99–068]

RIN 211–AE46

Special Local Regulations: City of Augusta, GA

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: Temporary Special Local Regulations are being adopted for the Augusta Port Authority's Head of the South Rowing Regatta. The event will be held from 7 a.m. to 6 p.m. Eastern Standard Time (EST) on November 13 and 14, 1999, on the Savannah River in Augusta, GA. These regulations are needed to provide for the safety of life on navigable waters during the event.

DATES: These regulations become effective at 6:30 a.m. November 13, 1999, and terminate at 6:30 p.m. on November 14, 1999.

FOR FURTHER INFORMATION CONTACT: Mr. William Tole (706) 722–4114.

SUPPLEMENTARY INFORMATION:

Background and Purpose

These regulations are required to provide for the safety of life on navigable waters during the Head of the South Rowing Regatta to be held in Augusta, GA. The regulations are intended to promote safe navigation on the Savannah River immediately before, during, and after the race by controlling the traffic entering, exiting, and travelling within the regulated area. The anticipated number of participant and spectator vessels poses a safety concern which is addressed in these special local regulations. There will be approximately 3000 participants racing single, double, four and eight person rowing shells on a fixed course. The event will take place in an area of limited commercial traffic on the Savannah River at Augusta GA, between mile marker 187.5 and 203.

In accordance with 5 U.S.C. 553, a notice of proposed rulemaking has not been published for these regulations and good cause exists for making them effective in less than 30 days from the date of publication. Information concerning the exact date and times of the event were only recently received by the U.S. Coast Guard, leaving insufficient time for a full comment period and delayed effective date.

Regulatory Evaluation

This regulation is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(f) of that order. The Office of Management and Budget has excepted it from review under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT 44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this proposal to be so minimal that a full regulatory evaluation under paragraph 10e of the regulated policies and procedures of DOT is unnecessary. The regulated area encompasses less than 3 nautical miles on the Savannah River with little commercial usage, entry into which is prohibited for only twelve hours on each day of the event.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) the Coast Guard must consider whether this rulemaking will have a significant economic impact on a substantial number of small entities. Small entities include small business, not-for-profit organizations that are independently owned and operated and are not dominant under their fields, and governmental jurisdictions with populations of less then 50,000.

Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities, as the regulations will only be in effect for two days in a limited area of the Savannah River that is seldom used for commerce.

Collection of Information

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

Federalism

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this rulemaking does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environmental Assessment

The Coast Guard has considered the environmental impact of this action and has determined under Figure 2–1, paragraph 34(h) of Commandant Instruction M16475.1C, that this rule is categorically excluded from further environmental documentation.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

Temporary Regulations

In consideration of the foregoing, the Coast Guard amends part 100 of Title 33, Code of Federal Regulations as follows:

PART 100—[AMENDED]

1. The authority citation for Part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.49 CFR 1.46, and 33 CFR 100.35.

2. Add temporary § 100.35T–07–068 to read as follows:

§ 100.35T–07–068 Head of the South Rowing Regatta; Savannah River, Augusta, GA

(a) *Regulated Area:* A regulated area is established on that portion of the Savannah River at Augusta GA, between mile markers 187 and 200.2. The regulated area encompasses the width of the Savannah River between these two points.

(b) *Coast Guard Patrol Commander.* The Coast Guard Patrol Commander is a commissioned, warrant, or petty officer of the Coast Guard who has been designated by Commanding Officer, Group Charleston, SC.

(c) *Special Local Regulations.* Entry into the regulated area by other than event participants is prohibited, unless otherwise authorized by the Patrol Commander. After termination of the Head of the South Rowing Regatta, all vessels may resume normal operations.

(d) *Dates:* These regulations become effective at 6:30 a.m. and terminate at 6:30 p.m. on November 13 and 14, 1999.

Dated: October 27, 1999.

G.W. Sutton,

Captain U.S.Coast Guard, Commander, Seventh Coast Guard District Acting.

[FR Doc. 99–28748 Filed 11–2–99; 8:15 am]

BILLING CODE 4910–15–U

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD05–98–111]

RIN 2115–AE47

Drawbridge Operation Regulations; Debbies Creek, New Jersey

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is changing the regulations governing the operation of the Monmouth County highway bridge, at mile 0.4, across Debbies Creek, at Manasquan, New Jersey. This rule will continue to provide the current opening schedule, except that from January 1 through April 1, from 4:30 p.m. to 8 a.m., a four-hour advance notice will be required. This change is intended to relieve the bridge owner of the burden of having a bridge tender staff the bridge during periods when there are few or no requests for openings, while still providing for the reasonable needs of navigation.

DATES: This final rule is effective December 3, 1999.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket CGD05–98–111 and are available for inspection or copying at the office of Commander (Aowb), Fifth Coast Guard District, Federal Building, 4th Floor, 431 Crawford Street, Portsmouth, Virginia 23704–5004, between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. The telephone number is (757) 398–6222.

FOR FURTHER INFORMATION CONTACT: Ann Deaton, Bridge Administrator, Fifth Coast Guard District, (757) 398–6222.

SUPPLEMENTARY INFORMATION:

Regulatory History

On January 22, 1999, we published a Notice of Proposed Rulemaking (NPRM) entitled ''Drawbridge Operation Regulations; Debbies Creek, New Jersey'' in the **Federal Register** (64 FR 3464). We received 10 letters commenting on the proposed rulemaking. One of the comments included a request for a public hearing, but after reading and considering the comments, we determined that a public hearing would provide no additional information and would not aid the rulemaking process.

On July 6, 1999, we published a Supplemental Notice of Proposed Rulemaking (SNPRM) entitled ''Drawbridge Operation Regulations; Debbies Creek, New Jersey'' in the **Federal Register** (64 FR 36318). We received no comments on the supplemental notice of proposed rulemaking. No public hearing was requested, and none was held.

Background and Purpose

The Monmouth County highway bridge is owned and operated by the Board of Chosen Freeholders of the County of Monmouth (BCFCM) in New Jersey. Title 33 Code of Federal Regulations (CFR) part 117.715 requires the bridge to open on signal, except that, from Memorial Day through Labor Day from 7 a.m. to 8 p.m., the draw need be opened only on the hour and the half hour if any vessels are waiting to pass.

The BCFMC had initially requested a change in the regulation by requiring a 24-hour advance notice for bridge openings from January 1 through March 31. Bridge logs from 1989 through 1997 revealed a total of 496 bridge openings in the months of January, February and March. During this period, bridge tenders received an average of approximately 18 bridge-opening requests per month. Considering the minimal number of openings identified by the bridge logs, the Coast Guard believed that the initial proposal would more fairly balance the competing needs of vehicular and vessel traffic. However, the Coast Guard received 10 comments objecting to the proposed rule. After consideration of the comments and further discussions with BCFCM, the Coast Guard determined that since vessel use from January 1 through March 31 was primarily during the daylight hours, an alternative proposal, as set forth in the SNPRM was appropriate. The Coast Guard also believes that enumeration and rewording will clarify the current regulation.

Discussion of Comments and Changes

The Coast Guard received 10 comments on the NPRM in opposition to a 24-hour advance notice for vessel openings from January 1 to March 31. Nine comments opposed the proposed change as unreasonable and unfair. The remaining comment suggested manning the bridge between the hours of 8 a.m. and 4:30 p.m. during January and February, and between 8 a.m. and 6 p.m. or 7 p.m. in the month of March with a 24-hour advance notice at all other times. All commenters generally indicated that a 24-hour advance notice would be inconvenient and was excessive due to the unpredictable weather conditions. Further review of the bridge logs from 1995 through 1997 revealed a total of 61 bridge openings for vessels from January 1 to March 31, from 4:30 p.m. to 8 a.m. During the same timeframes, bridge logs from 1989 to 1997 showed a total of 104 vessel openings. The Coast Guard responded to the comments by reducing the 24-hour advance notice requirement in our original proposal to only four hours.

The Coast Guard received no comments opposing our new proposal and is amending 33 CFR 117.715 by inserting a new provision requiring a four-hour advance notice for bridge openings from January 1 through April

1, between the hours of 4:30 p.m. to 8 a.m. Additionally, to ensure clarity and consistency of the operating regulation, the text of the current 33 CFR 117.715 will be enumerated and reworded.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979).

The Coast Guard reached this conclusion based on the fact that the final rule will not prevent mariners from transiting the bridge, but merely require mariners to plan their transits and to provide the four-hour advance notice to the bridge tender.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), we considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This conclusion is based on the fact that this rule will continue to provide openings to mariners on a schedule they are accustomed to, and merely require advance notice for openings during nighttime transits.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1966 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effect on them and participate in the rulemaking process. This was accomplished by publication of a NPRM in the **Federal Register**, consideration of comments received in response to the NPRM, and subsequent issuance of a SNPRM based on those comments.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act (44 U.S.C. 3501–3520).

Federalism

We have analyzed this rule under Executive Order 12612 and have determined that this rule does not have sufficient implications for federalism to warrant the preparation of a Federalism Assessment.

Unfunded Mandates Reform Act and Enhancing the Intergovernmental Partnership

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) and E.O. 12875, Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993) govern the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal Government's having first provided the funds to pay those unfunded mandate costs. This rule will not impose an unfunded mandate.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Environment

We considered the environmental impact of this rule and concluded that, under figure 2–1, paragraph (32e) of Commandant Instruction M16475.1C, this rule is categorically excluded from further environmental documentation. This rule only deals with the operating schedule of an existing drawbridge, and will have no effect on the environment. A ''Categorical Exclusion Determination'' is available in the docket for inspection or copying where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g); Section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. Section 117.715 is revised to read as follows:

§ 117.715 Debbies Creek.

(a) The draw of the Monmouth County highway bridge, mile 0.4 at Manasquan, shall open on signal, except as follows:

(1) From 4:30 p.m. January 1 through 8 a.m. April 1, from 4:30 p.m. to 8 a.m., the draw need open only if at least four-hours advance notice is given.

(2) From Memorial Day through Labor Day from 7 a.m. to 8 p.m., the draw need open only on the hour and half hour if any vessels are waiting to pass.

(b) The owners of the bridge shall provide and keep in good legible condition two board gauges painted white with black figures not less than eight inches high to indicate the vertical clearance under the closed draw at all stages of the tide. The gauges shall be so placed on the bridge that they are plainly visible to operators of vessels approaching the bridge either up or downstream.

Dated: October 20, 1999.

John E. Shkor,

Vice Admiral, U. S. Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. 99–28612 Filed 11–2–99; 8:15 am]

BILLING CODE 4910–15–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[TN–158–2–9942(a); TN–211–1–9943(a); TN–215–1–9944(a); TN–221–1–9945(a); FRL–6452–8]

Approval and Promulgation of Implementation Plans; Tennessee: Approval of Revisions to the Knox County Portion of the Tennessee SIP Regarding Use of LAER for Major Modifications and Revisions to the Tennessee SIP Regarding the Coating of Miscellaneous Metal Parts

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The EPA is acting on revisions to Section 46.2 and 46.3.A. of the Knox County portion of the Tennessee State Implementation Plan (SIP) which were submitted by the Tennessee Department of Air Pollution Control (TDAPC), on May 23, 1995, and November 13, 1998, for purposes of revising the definition for Volatile Organic Compounds (VOC) and requiring the use of Lowest Achievable Emission Rate (LAER) for major modifications to existing sources of VOC. The EPA is also approving revisions to the Tennessee SIP which were submitted by TDAPC on February 12, 1999, and May 17, 1999, for purposes of revising Rule 1200–3–18–.20 (Coating of Miscellaneous Metal Parts) to include a standard for the touch-up of heavy-duty trucks and revise the definition of ''high performance architectural coating.''

DATES: This direct final rule is effective January 3, 2000 without further notice, unless EPA receives adverse comment by December 3, 1999. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: All comments should be addressed to: Allison Humphris at the EPA, Region 4 Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303.

Copies of the State submittal(s) are available at the following addresses for inspection during normal business hours:

Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460

Environmental Protection Agency, Region 4, Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303–8960. Allison Humphris, 404/562–9030

Tennessee Department of Environment and Conservation, Division of Air Pollution Control, L & C Annex, 9th Floor, 401 Church Street, Nashville,

Tennessee 37243–1531.615/532–0554

Knox County Department of Air Quality Management, City-County Building, Room 339, 400 West Main Street, Knoxville, Tennessee, 37902–2405. 423/215–2488

FOR FURTHER INFORMATION CONTACT: Allison Humphris at 404/562–9030.

SUPPLEMENTARY INFORMATION:

I. Background

A. Knox County SIP Revisions

The EPA is approving the most recently received revisions to Section 46.2 (Definitions) and Section 46.3 (Regulation of Volatile Organic Compounds/Standards for New Sources) of the Knox County Portion of the Tennessee SIP, which were submitted by TDAPC on November 13, 1998. Section 46.2.A.34 is being revised to incorporate by reference the definition for VOC contained in 40 CFR Part 51 Subpart F. The existing paragraph A of Section 46.3 requires all new major VOC sources and all modifications to existing major VOC sources to use LAER. On May 23, 1995, TDAPC submitted a revision to this paragraph that allowed director's discretion in determining whether or not to apply LAER to modifications to existing major VOC sources. On November 13, 1998, following EPA notification that this revision was unapprovable, TDAPC submitted replacement language for Section 46.3.A that requires use of LAER for all new VOC sources and all major modifications to existing VOC sources. EPA is taking action on both submittals by approving the most recently submitted revision.

B. Tennessee SIP Revisions

The EPA is also approving revisions to Rule 1200–3–18–.20 (Coating of Miscellaneous Metal Parts) of the Tennessee SIP which were submitted on February 12, 1999, and May 17, 1999. The February 12, 1999, submittal amends Rule 1200–3–18–.20(2) and (3)(b) to include a definition and an emission limit for ''heavy-duty truck touch-up.'' The May 17, 1999, submittal revises the definition for ''High Performance Architectural Coating'' contained in Rule 1200–3–18–.20(2). The revisions also include appropriate renumbering of the definitions section of the rule.

II. Analysis of State's Submittal

A. Knox County SIP Revisions

Section 46.2.A.34 is amended to revise the definition for VOC by exempting 16 compounds (per 62 FR 44900) and methyl acetate (per 63 FR 17331) from regulation as VOC due to EPA's determination that they do not contribute significantly to ozone formation. Section 46.3.A is being revised to ensure that the Knox County Portion of the Tennessee SIP contains requirements for applying LAER to VOC sources that: (i) Are at least as stringent as the existing local SIP requirements, (ii) will help to ensure Knox County's maintenance of the National Ambient Air Quality Standard (NAAQS) for ozone, and (iii) are consistent with Clean Air Act (CAA) requirements. The language being approved by this notice is as stringent as existing local SIP requirements, since it will require use of LAER for all major modifications, instead of allowing director's discretion to determine the appropriate controls. The language is also consistent with Section 173(a)(2) of the CAA and Chapter 1200–3–9–.01(5)(b)2.(iii) of the Tennessee SIP, both of which specify that new or modified major stationary sources located in a nonattainment area must comply with LAER in order to be issued construction or operating permits. Knox County is currently a maintenance area for the one-hour ozone NAAQS. However, Section 46 was contained in the SIP while the county was designated nonattainment for ozone. Implementation of Section 46 requirements was therefore critical to Knox County's attainment of the ozone NAAQS in 1991, as explained in EPA's September 27, 1993 redesignation notice (58FR50271).

B. Tennessee SIP Revisions

Several changes and additions to Rule 1200–3–18–.20 are being approved by this notice. The first revision, submitted February 12, 1999, establishes an emission limit of 4.8 pounds per gallon for ''heavy-duty truck touch-up'' that satisfies Reasonably Available Control Technology (RACT) requirements. As noted in August 15, 1996, correspondence from EPA to Tennessee, this limit is consistent with EPA's guidance on final repair, as specified in the Control Technology Guideline (CTG) document: Control of Volatile Organic Emissions from Existing Stationary Sources—Volume II: Surface Coating of Cans, Coils, Paper, Fabrics, Automobiles and Light-Duty Trucks (May 1977). This submittal also addresses EPA's disapproval (60FR10504) of a previous revision of this chapter that included a less stringent emission limit for ''heavy-duty truck touch-up.'' This disapproval was part of an action in which EPA approved the majority of SIP revisions submitted by Tennessee on May 18, 1993, to satisfy RACT ''Catch Up'' requirements contained in the amended CAA.

The second revision, submitted May 17, 1999, revises the definition for ''High Performance Architectural Coating'' by deleting language that limits the applicability of this standard to a specific county. Upon EPA approval of this revision, the emission limit of 6.2 pounds per gallon for this coating type,

as provided in 1200–3–18–.20(3), will become applicable to all Tennessee counties. This limit is consistent with the National Volatile Organic Compound Emission Standards for Architectural Coatings—Final Rule (63 FR 48848), which specifies a maximum allowable VOC content of 6.7 pounds per gallon for extreme high durability coatings.

III. Final Action

EPA is approving the aforementioned changes to the SIP because they are consistent with Clean Air Act and EPA requirements.

The EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should adverse comments be filed. This rule will be effective January 3, 2000 without further notice unless the Agency receives adverse comments by December 3, 1999.

If the EPA receives such comments, then EPA will publish a document withdrawing the final rule and informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period. Parties interested in commenting should do so at this time. If no such comments are received, the public is advised that this rule will be effective on January 3, 2000 and no further action will be taken on the proposed rule.

IV. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order (E.O.) 12866, entitled ''Regulatory Planning and Review.''

B. Executive Orders on Federalism

Under E.O. 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a state, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected state, local, and tribal governments, the nature of their concerns, copies of written communications from the governments, and a statement supporting the need to issue the regulation.

In addition, E.O. 12875 requires EPA to develop an effective process permitting elected officials and other representatives of state, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.'' Today's rule does not create a mandate on state, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of E.O. 12875 do not apply to this rule.

On August 4, 1999, President Clinton issued a new executive order on federalism, Executive Order 13132, [64 FR 43255 (August 10, 1999),] which will take effect on November 2, 1999. In the interim, the current Executive Order 12612 [52 FR 41685 (October 30, 1987)] on federalism still applies. This rule will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 12612. The rule affects only one State, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act.

C. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to E.O. 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

D. Executive Order 13084

Under E.O. 13084, EPA may not issue a regulation that is not required by statute, that significantly affects or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation.

In addition, E.O. 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) 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. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions.

This final rule will not have a significant impact on a substantial number of small entities because SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities.

Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

F. Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated annual costs to State, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated annual costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

G. Submission to Congress and the Comptroller General

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

H. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use ''voluntary consensus standards'' (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this action. Today's action does not require the public to perform activities conducive to the use of VCS.

I. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 3, 2000. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements.

Dated: September 23, 1999.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

Part 52 of chapter I, title 40, *Code of Federal Regulations*, is amended as follows:

PART 52—[AMENDED]

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

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

Subpart RR—Tennessee

2. Section 52.2239(c), is amended by adding paragraph (c)(168) to read as follows:

§ 52.2239 Original identification of plan section.

* * * * *

(c) * * *

(168) Revisions to the Knox County portion of the Tennessee state implementation plan submitted to EPA by the State of Tennessee on November 13, 1998, concerning VOC and use of LAER for major modifications to existing sources were approved.

(i) Incorporation by reference.

(A) Section 46.2.A.34 of the Knox County Air Pollution Control Regulation ''Volatile Organic Compounds/ Definitions'' effective November 10, 1998.

(B) Section 46.3.A of the Knox County Air Pollution Control Regulation ''Volatile Organic Compounds/ Standards for New Sources'' effective November 10, 1998.

(ii) Other material. None.

3. Section 52.2220(c) is amended by revising the entry for Section 1200–3–18–.20 to read as follows:

§ 52.2220 Identification of plan.

* * * * *

(c) * * *

EPA APPROVED TENNESSEE REGULATIONS FOR TENNESSEE

State citation	Title/subject	Adoption date	EPA approval date	Federal Register notice
* *	*	*	*	* *
Chapter 1200–3–18	Volatile Organic Compounds.			
* *	*	*	*	* *
Section 1200–3-18–.20	Coating of Miscellaneous Metal Parts.	01/26/99	November 3, 1999	[Insert citation of this FEDERAL REGISTER Notice when published]
* *	*	*	*	* *

[FR Doc. 99–27195 Filed 11–2–99; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[OK–8–1–5772a; FRL–6457–7]

Approval and Promulgation of Implementation Plans; Oklahoma; Recodification of Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The EPA is taking direct final action approving into the Oklahoma State Implementation Plan (SIP), subchapters of the Oklahoma Department of Environmental Quality (ODEQ) Air Pollution Control Rules adopted by the State Legislature on March 30, 1994. These Rules, submitted by the Governor to EPA on May 16, 1994, replace most of the existing ODEQ regulations in the Oklahoma SIP. The EPA is taking no action on subchapters of the submittal that are either not equivalent to, or are not in, the current Oklahoma SIP-approved regulations. Approval of this action will make the numbering format and administrative terms of the subchapters being approved consistent with that of the current ODEQ air quality control regulations. The changes are administrative in nature and do not substantively revise the current SIP.

DATES: This rule is effective on January 3, 2000 without further notice, unless EPA receives adverse comment by December 3, 1999. If EPA receive such comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Written comments on this action should be addressed to Mr. Thomas H. Diggs, Chief, Air Planning Section (6PD–L), at the EPA Region 6 Office listed below. Copies of documents relevant to this action are available for public inspection during normal business hours at the following locations. Anyone wanting to examine these documents should make an appointment with the appropriate office at least two working days in advance.

Environmental Protection Agency, Region 6, Air Planning Section (6PD–L), 1445 Ross Avenue, Dallas, Texas 75202–2733

Oklahoma Department of Environmental Quality, Air Quality Division, 707 North Robinson, P.O. Box 1677, Oklahoma City, Oklahoma 73101–1677

Documents which are incorporated by reference are available for public inspection at the Air and Radiation Docket and Information Center, Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Bill Deese of the EPA Region 6 Air Planning Section at (214) 665–7253.

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we'' is used, we mean EPA.

I. What Is the Purpose of This Action?

This action approves a recodification of the ODEQ regulations in the Oklahoma SIP adopted by the Oklahoma Legislature on March 30, 1994, and submitted by the Governor of Oklahoma on May 16, 1994, as a revision to the Oklahoma SIP. The EPA is approving subchapters of the submittal that are equivalent to the current SIP-approved regulations replaced. The EPA is taking no action on subchapters that have not previously been approved into the Oklahoma SIP or are not equivalent to the existing SIP-approved regulations.

II. Why Is EPA Taking This Action?

The ODEQ has used four different numbering systems for its air quality control regulations since the original Oklahoma SIP was approved by EPA on May 31, 1972 (37 FR 10887). Regulations in the current Oklahoma SIP have been approved under three of these numbering systems.

The ODEQ air quality control regulations approved with the original Oklahoma SIP were numbered with a one or two digit number such as Regulation Number 4 and Regulation Number 15. Regulations approved by EPA under this numbering system were approved in 40 CFR part 52, §§ 52.1920(b) to 52.1920(c)(21). Some ODEQ regulations approved under this system are still in the Oklahoma SIP.

Between 1981 and 1991, the ODEQ used a numbering system such as Regulation 1.1, Regulation 1.4.4, and Regulation 4.1 for its air quality control regulations. Regulations were approved by EPA under this numbering system at 40 CFR 52.1920(c)(24) to 52.1920(c)(41) and 52.1920(c)(47).

In 1990 the Oklahoma State Legislature passed the Oklahoma Administrative Procedures Act which mandated a common format for all Oklahoma rules and regulations. To meet the requirements of the Administrative Procedures Act, the Air Quality Service of the Oklahoma State Department of Health recodified the Oklahoma air pollution control regulations into the Oklahoma Administrative Code, Title 310, Chapter 200 (OAC:310:200), Oklahoma Air Pollution Control Rules. As required by the Oklahoma Administrative Procedures Act, the Oklahoma Air Pollution Control Rules contained no substantive changes, but was a change in format only. The Governor of Oklahoma submitted the recodified regulations to EPA on July 1, 1992, as a revision to the Oklahoma SIP.

The EPA has approved two revisions to the ODEQ regulations in the Oklahoma SIP in this numbering system submitted after the July 1, 1992, submittal. The revisions were submitted to EPA on December 10, 1992, and May 16, 1994. Subchapter 31 (OAC:310:200–31), Control of Emissions of Sulfur Compounds, adopted by the State March 24, 1993, and submitted by the Governor on December 10, 1992, was approved by EPA on July 15, 1993 (58 FR 38060), at 40 CFR 52.1920(c)(43). Subchapter 23 (OAC:310:200–23), Control of Emissions from Cotton Gins, adopted by the State on March 24, 1993, and submitted by the Governor on May 16, 1994, was approved by EPA on May 14, 1997 (62 FR 26393), at 40 CFR 52.1920(c)(44).

(**Note:** The May 16, 1994, submittal of Subchapter 23 (OAC:310:200–23) was a completely separate submittal from the May 16, 1994, submittal being acted upon in this action.)

Before EPA could take action on the recodified regulations submitted July 1, 1992, the Air Quality Service, in 1993, became the Air Quality Division of the newly created ODEQ. This necessitated the transfer of the Air Pollution Control Rules from OAC:310:200 to new OAC:252:100. The recodification of the regulations to OAC:252:100 was adopted by the Oklahoma Legislature on March 30, 1994, published in the *Oklahoma Register* on May 16, 1994, effective May 26, 1994, and submitted by the Governor of Oklahoma to EPA as a revision to the Oklahoma SIP on May 16, 1994. There were no substantive changes in the regulations. No regulations or revisions to regulations in the Oklahoma SIP have been approved under this numbering system.

The intent of this **Federal Register** action is to approve the regulations in the May 16, 1994, submittal that are equivalent to the current SIP-approved regulations. The EPA is taking no action on subchapters of the submittal that are not equivalent to the current SIP-approved regulations being replaced, or on subchapters that have not previously been approved into the SIP.

III. What Regulations in the May 16, 1994, Submittal Are Not Being Acted Upon in This Action?

Subchapter 8 (Operating Permits), subchapter 11 (Alternative Emissions Reduction Permits), subchapter 21 (Particulate Matter Emissions from Wood-Waste Burning Equipment), and appendix D (Particulate Matter Emission Limits for Wood Waste Burning Equipment) are not being acted upon in this action because equivalent regulations are not in the current Oklahoma SIP.

Subchapter 7 (Permits) is not being approved in this recodification because it is a substantial revision to the current SIP-approved regulation. As a result, the following ODEQ regulation remains in the Oklahoma SIP: Regulation 1.4 (Air Resources Management Permits Required) as approved by EPA on August 25, 1983 (48 FR 38636), at § 52.1920(c)(26); January 31, 1991 (56 FR 03781), at § 52.1920(c)(38); and July 23, 1991 (56 FR 33717), at § 52.1920(c)(41). This subchapter will be addressed in a future rulemaking.

Subchapter 41 (Control of Emission of Hazardous and Toxic Air Contaminants) is not being acted on in this rulemaking because it is not equivalent to the current SIP-approved regulations. As a result, the following ODEQ regulation remains in the Oklahoma SIP: Regulation 3.8, (Control of Emission of Hazardous Air Contaminants), as approved by EPA on August 15, 1983 (48 FR 36819), at § 52.1920(c)(27).

IV. What Oklahoma SIP Regulations Are Being Replaced by This Action?

The table below cross-references subchapters in the May 16, 1994, submittal of OAC:252:100 that EPA is approving in this action with previous citations of the regulations. The third (1992) codification is not shown because it is identical to the current codification except that ''252:100'' in the current codification was ''310:200'' in the third codification. The titles shown are the proposed new SIP titles. In some cases these titles are different from the current SIP-approved titles. The current SIP-approved regulations are shown with an ''*'' following the regulation numbers. In some cases, such as new subchapter 1, parts of two former codifications are in the current SIP. An ''*'' in the first column means the current SIP regulations were approved under the 1992 ''310–200'' codification.

Proposed New SIP Citation, (Subchapter of 252:100)	Proposed New SIP Title	1982 to 1991 State Citation (Regulation)	Before 1982 State Citation (Regulation No.)
1.	General Provisions	1.1*	3*
3.	Air Quality Standards and Increments	1.2*	3
5.	Registration of Air Contaminant Sources	1.3	4*
9.	Excess Emission and Malfunction Reporting Requirements	1.5*	11
13.	Prohibition of Open Burning	2.1	1
15.	Motor Vehicle Pollution Control Devices	2.2	2*
17.	Incinerators	2.3	5*
19.	Particulate Matter Emissions from Fuel-Burning Equipment	2.4	6*
23.*	Control of Emissions from Cotton Gins	Did not exist	Did not exist
25.	Smoke, Visible Emissions and Particulates	3.1*	7
27.	Particulate matter Emissions from Industrial and Other Processes and Operations.	3.2	8*
29.	Control of Fugitive Dust	3.3	9*
31.*	Control of Emissions of Sulfur Compounds	3.4	16
33.	Control of Emissions of Nitrogen Oxides	3.5	18*
35.	Control of Emission of Carbon Monoxide	3.6	17*
37.	Control of Emission of Organic Materials	3.7*	15*
39.	Control of Emission of Organic Materials in Nonattainment Areas	3.7*	15*
43.	Sampling and Testing Methods	4.1*	12*
45.	Monitoring of Emissions	5.1	13*
Appendix A. (Cited in Subchapter 17).	Allowable Emissions for Incinerators with Capacities in Excess of 100 lbs/hr	2.3 Figure 1	5 Figure 1*
Appendix B. (Cited in Subchapter 17).	Allowable Emissions for Incinerators with Capacities Less Than 100 lbs/hr	2.3 Figure 1	5 Figure 1*
Appendix C. (Cited in Subchapter 19).	Particulate Matter Emission Limits for Fuel-Burning Equipment	2.4 Figure 1	6 Figure 1*
Appendix E. (Cited in Subchapter 3).	Primary Ambient Air Quality Standards	1.2(1) Table 1*	3, Table 1a
Appendix F. (Cited in Subchapter 3).	Secondary Ambient Air Quality Standards	1.2(1) Table 2*	3, Table 1b
Appendix G. (Cited in Subchapter 27).	Allowable Rate of Emissions	3.2 Table 1	8 Table 1*

V. What Changes Have Been Made to the Regulations?

This section summarizes changes to the regulations initially made in OAC:300:200 and carried over into OAC:252:100.

A. Format Changes

The new numbering system is considerably different from the first two numbering systems. A subchapter number has been assigned to the group of rules previously identified by regulation numbers. Some subchapters are further divided into parts. The numbers initially assigned to subchapters and parts are all odd numbers to allow for future expansions of the rules.

Subchapters and parts are divided into groups of related sections. A section may be further subdivided into subsections, paragraphs, subparagraphs, units, and subunits.

B. Administrative Wording Changes

The regulations also underwent administrative wording changes necessitated by the transfer of the

administration of the regulations to the newly created ODEQ and the resultant transfer of the Oklahoma Air Pollution Control Regulations to OAC:252:100 as well as style changes to be consistent with that preferred by the State. For example, the term ''Executive Director'' replaced the word ''Commissioner'' and the terms ''Chapter'' and ''Subchapter'' replaced the word ''Regulation.'' Two tables in the support document for this action show the administrative wording changes versus the terms replaced.

C. Changes to Definition Sections

Subchapter 1, General Provisions, contains definitions for Chapter 100. Almost all definitions previously approved by EPA in other ODEQ SIP-approved regulations are included in subchapter 1, section 1–3, Definitions, as well as in the subchapter, part, or section they apply to. Some individual terms and terms with more than one definition in section 1–3 are restricted to specific subchapters, parts, or sections.

All definitions in Chapter 100 have a standard introductory paragraph which gives the part or section the definitions pertain to. All defined terms are in double quotes followed by the word ''means'' followed by the definition of the term. Terms within each definitions section have been placed in alphabetical order. Definitions not previously approved by EPA in the State General Definitions section were approved into the SIP in the Regulations they apply to.

D. Other Changes

A Purpose section is the first section of each subchapter. Some regulations in the earlier codifications did not have a Purpose section.

Most sections and subsections and some paragraphs and subparagraphs formerly without titles have been given titles.

Most of the tables in the old regulations are in appendices at the end of Chapter 100. New sections in the subchapters reference the tables in the appendices.

VI. Final Action

The EPA is approving ODEQ Air Pollution Control Rules (OAC:252:100) adopted by the State on March 30, 1994, and submitted by the Governor on May 16, 1994, except for subchapters 7, 8, 11, 21, 41, and appendix D. The regulations being approved replace the current ODEQ regulations in the Oklahoma SIP except for Regulation 1.4 (Air Resources Management Permits Required) and Regulation 3.8 (Control of Emission of Hazardous Air Contaminants). The changes are administrative in nature and do not substantively revise the current SIP.

The EPA is publishing this rule without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comments. However, in the ''Proposed Rules'' section of today's **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the SIP revision if adverse comments are received. This rule will be effective on January 3, 2000 without further notice unless we receive adverse comment by December 3, 1999. If EPA receives adverse comments, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. We will address all public comments in a subsequent final rule based on the proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

VII. Administrative Requirements

A. Executive Order (E.O.) 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from E.O. 12866, entitled ''Regulatory Planning and Review.''

B. Executive Order 12875

Under E.O. 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments, or EPA consults with those governments. If EPA complies by consulting, E.O. 12875 requires EPA to provide to the OMB a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, E.O. 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create a mandate on State, local, or tribal governments. The rule does not impose any enforceable rules on any of these entities. This action does not create any new requirements but simply approves requirements that the State is already imposing. Accordingly, the requirements of section 1(a) of E.O. 12875 do not apply to this rule.

C. Executive Order 13045

Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

The EPA interprets E.O. 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This final rule is not subject to E.O. 13045 because it approves a State program.

D. Executive Order 13084

Under E.O. 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, E.O. 13084 requires EPA to provide to the OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, E.O. 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of

section 3(b) of E.O. 13084 do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 600 *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. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This final rule will not have a significant impact on a substantial number of small entities because SIP approvals under section 110 and subchapter I, part D of the Federal Clear Air Act (the Act) do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities. Moreover, due to the nature of the Federal-State relationship under the Act, preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Act forbids EPA to base its actions concerning SIPs on such grounds. *See Union Electric Co.* v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

F. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995, signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated annual costs to State, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

The EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated annual costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

G. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major'' rule as defined by 5 U.S.C. 804(2). This rule will be effective January 3, 2000.

H. Petitions for Judicial Review

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 3, 2000. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. See section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: September 23, 1999.

Jerry Clifford,

Acting Regional Administrator, Region 6.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

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

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

Subpart LL—Oklahoma

2. Section 52.1920 is amended by adding paragraph (c)(48) to read as follows:

§ 52.1920 Identification of plan.

* * * * *

(c) * * *

(48) Revisions to Oklahoma Department of Environmental Quality (ODEQ) regulations in the Oklahoma SIP adopted by the Oklahoma Legislature on March 30, 1994, effective May 26, 1994, and submitted by the Governor on May 16, 1994.

(i) Incorporation by reference.

(A) *Oklahoma Register*, May 16, 1994, pages 2031 and 2032, approving the transfer of the Oklahoma Air Quality Control Rules into Title 252, Chapter 100, of the Oklahoma Administrative Code.

(B) Oklahoma Administrative Code, Title 252, Chapter 100 (OAC:252:100), Oklahoma Air Quality Control Rules, adopted by the Oklahoma Legislature on March 30, 1994, effective May 26, 1994.

(1) Subchapter 1, General Provisions.

(2) Subchapter 3, Air Quality Standards and Increments.

(3) Subchapter 5, Registration of Air Contaminant Sources.

(4) Subchapter 9, Excess Emissions and Reporting Requirements.

(5) Subchapter 13, Prohibition of Open Burning.

(6) Subchapter 15, Motor Vehicle Pollution Control Devices.

(7) Subchapter 17, Incinerators.

(8) Subchapter 19, Particulate Matter Emissions from Fuel-Burning Equipment.

(9) Subchapter 23, Control of Emissions from Cotton Gins.

(10) Subchapter 25, Smoke, Visible Emissions and Particulates.

(11) Subchapter 27, Particulate Matter Emissions from Industrial and Other Processes and Operations.

(12) Subchapter 29, Control of Fugitive Dust.

(13) Subchapter 31, Control of Emission of Sulfur Compounds.

(14) Subchapter 33, Control of Emission of Nitrogen Oxides.

(15) Subchapter 35, Control of Emission of Carbon Monoxide.

(16) Subchapter 37, Control of Emissions of Organic Materials.

(17) Subchapter 39, Control of Emission of Organic Materials in Nonattainment Areas

(18) Subchapter 43, Sampling and Testing Methods.

(19) Subchapter 45, Monitoring of Emissions.

(20) Appendix A, Allowable Emissions for Incinerators with Capacities in Excess of 100 lbs/hr.

(21) Appendix B, Allowable Emissions for Incinerators with Capacities Less Than 100 lbs/hr.

(22) Appendix C, Particulate Matter Emission Limits for Fuel-Burning Equipment.

(23) Appendix E, Primary Ambient Air Quality Standards.

(24) Appendix F, Secondary Ambient Air Quality Standards.

(25) Appendix G, Allowable Rate of Emissions.

(ii) The following previously approved ODEQ regulations remain in the Oklahoma SIP:

(A) Regulation 1.4, ''Air Resources Management Permits Required,'' as approved by EPA on: August 25, 1983 (48 FR 38636), at 52.1920(c)(26); April 2, 1984 (49 FR 13039), at 52.1920(c)(29); July 27, 1984 (49 FR 30185), at 52.1920(c)(31); August 20, 1990 (55 FR 33907), at 52.1920(c)(34); February 12, 1991 (56 FR 5655), at 52.1920(c)(38); and July 23, 1991 (56 FR 33717), at 52.1920(c)(41).

(B) Regulation 3.8, ''Control of Emission of Hazardous Air Contaminants,'' approved by EPA on August 15, 1983 (48 FR 36819), at 52.1920(c)(27).

(iii) Additional materials—None.

[FR Doc. 99–27541 Filed 11–2–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[AL–050–9953(a); FRL–6461–8]

Approval and Promulgation of Implementation Plans: Revisions to the Alabama Department of Environmental Management (ADEM) Administrative Code for the Air Pollution Control Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The EPA is approving revisions to the Alabama Department of Environmental Management's (ADEM) Administrative Code submitted on April 22, 1999, by the State of Alabama. These revisions were made to comply with the regulations set forth in the Clean Air Act (CAA). Included in this document are revisions to Chapter 335–3–1—General Provisions which establishes Credible Evidence regulations and Chapter 335–3–14—Air Permits which allows exemptions for projects which are found to be beneficial to the environment.

DATES: This direct final rule is effective January 3, 2000 without further notice, unless EPA receives adverse comment by December 3, 1999. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: All comments should be addressed to: Kimberly Bingham at the EPA, Region 4 Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303.

Copies of the State submittal(s) are available at the following addresses for inspection during normal business hours:

Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

Environmental Protection Agency, Region 4, Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303–8960.

Alabama Department of Environmental Management, 400 Coliseum Boulevard, Montgomery, Alabama 36110–2059.

FOR FURTHER INFORMATION CONTACT: Kimberly Bingham of the EPA Region 4, Air Planning Branch at (404) 562–9038 and at the above address.

SUPPLEMENTARY INFORMATION:

I. Analysis of State's Submittal

Listed below is a summary of the revisions to the Alabama State implementation plan (SIP) on which EPA is taking action in this document.

Chapter 335–3–1—General Provisions

Rule 335–3–1–.13—Credible Evidence

On February 24, 1997, EPA promulgated regulations under sections 113(a) and 113(e)(1) of the CAA that gave EPA the authority to use all available data to prove CAA violations (See 62 FR 8314–8328). EPA required states to incorporate provisions into their SIPs to ensure that the states have the ability to use any available data or ''credible evidence'' to determine violations. To comply, the ADEM submitted rule 335–3–1–.13 to EPA Region 4 for approval. This new rule allows the use of any credible evidence that is both reference test data and comparable non-reference test data. The data will be used to prove or disprove violations of the State of Alabama's regulations in enforcement actions.

Chapter 335–3–14—Air Permits Authorizing Construction in Clean Air Areas [Prevention of Significant Deterioration Permitting (PSD)]

Rule 335–3–14.04(2)(ff)

ADEM is revising its PSD rules to allow an exemption for modifications or projects that are proven to be beneficial to the environment. These regulations would require that an ambient air quality analysis be completed before the project can be approved. Class 1 areas must also not be affected by the new project. Moreover, the public notification requirements of the PSD regulations would also have to be met.

Rule 335–3–14.04(2)(gg)

The rule was revised to include a definition for Pollution Prevention Projects that can also be exempted if proven to be environmentally beneficial. ADEM defines Pollution Prevention Projects as any activity that through process changes, product reformulation or substitution of less polluting raw materials, eliminates or reduces the release of air pollutants (including fugitive emissions) and other pollutants to the environment prior to recycling, treatment, or disposal. It does not mean recycling (other than certain ''in process recycling'' practices), energy recovery, treatment, or disposal.

Rule 335–3–14–.04(8)(m)

This rule lists the PSD exemptions for projects that are environmentally beneficial.

II. Final Action

EPA is approving the aforementioned changes to the State of Alabama's SIP because they are consistent with the CAA and EPA policy. The EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should adverse comments be filed. This rule will be effective January 3, 2000 without further notice unless the Agency receives adverse comments by December 3, 1999.

If the EPA receives such comments, then EPA will publish a document withdrawing the final rule and informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period. Parties interested in commenting should

do so at this time. If no such comments are received, the public is advised that this rule will be effective on January 3, 2000 and no further action will be taken on the proposed rule.

III. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order (E.O.) 12866, entitled ''Regulatory Planning and Review.''

B. Executive Orders on Federalism

Under E.O. 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a state, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected state, local, and tribal governments, the nature of their concerns, copies of written communications from the governments, and a statement supporting the need to issue the regulation.

In addition, E.O. 12875 requires EPA to develop an effective process permitting elected officials and other representatives of state, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.'' Today's rule does not create a mandate on state, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of E.O. 12875 do not apply to this rule.

On August 4, 1999, President Clinton issued a new executive order on federalism, Executive Order 13132, (64 FR 43255 (August 10, 1999),) which will take effect on November 2, 1999. In the interim, the current Executive Order 12612 (52 FR 41685 (October 30, 1987)) on federalism still applies. This rule will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 12612. The rule affects only one State, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act.

C. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to E.O. 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

D. Executive Order 13084

Under E.O. 13084, EPA may not issue a regulation that is not required by statute, that significantly affects or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation.

In addition, E.O. 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) 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. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions.

This final rule will not have a significant impact on a substantial number of small entities because SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities.

Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

F. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated annual costs to State, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated annual costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

G. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small

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

H. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use ''voluntary consensus standards'' (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this action. Today's action does not require the public to perform activities conducive to the use of VCS.

I. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 3, 2000. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: October 5, 1999.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

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

PART 52—[AMENDED]

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

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

EPA APPROVED ALABAMA REGULATIONS

State citation	Title subject	Adoption date	EPA approval date	Federal Register notice
Chapter No. 335–3–1—General Provision				
* *	* *	*	*	*
Section 335–3–1–.13	Credible Evidence	04/13/99	11/03/99	[Insert citation of publication]
Chapter No. 335–3–14—Air Permits				
Section 335–3–14–.04(ff–gg)	Air Permits Authorizing Construction in Clean Air Areas [Prevention of Significant Deterioration (PSD)].	04/13/99	11/03/99	[Insert citation of publication]
Section335–3–14–.04(8)(m)	Air Permits Authorizing Construction in Clean Air Areas [Prevention of Significant Deterioration (PSD)].	04/13/99	11/03/99	[Insert citation of publication]
* *	* *	*	*	*

Subpart B—Alabama

2. Section 52.50 is amended by revising the table heading and adding three new entries in the table in paragraph (c) to read as follows:

§ 52.50 Identification of plan.

* * * * *

(c) EPA approved regulations.

* * * * *

[FR Doc. 99–27539 Filed 11–2–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[VA 097–5041; FRL–6459–9]

Approval and Promulgation of Air Quality Implementation Plans; Virginia; Control of VOC Emissions From Solvent Metal Cleaning Operations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving State Implementation Plan (SIP) revisions submitted by the Commonwealth of Virginia. The revisions pertain to and clarify the Commonwealth's regulation to control of volatile organic compound (VOC) emissions from solvent metal cleaning operations using non-halogenated solvents, and update another of its regulations to incorporate certain federal regulations by reference. The intended effect of this action is to approve the Commonwealth's request to approve these SIP revisions pertaining to solvent metal cleaning operations.

DATES: This final rule is effective on December 20, 1999 without further notice, unless EPA receives adverse

comments by December 3, 1999. If EPA receives adverse comments, we will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Written comments should be addressed to David Arnold, Chief, Ozone and Mobile Sources Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; the Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and Virginia Department of Environmental Quality, P.O. Box 10009, 629 East Main Street, Richmond, Virginia 23219.

FOR FURTHER INFORMATION CONTACT: Janice M. Lewis, (215) 814–2185, at EPA Region III address above or via e-mail at lewis.janice@epa.gov. While information may be requested by e-mail, any comments must be submitted in writing to the EPA Region III address above.

SUPPLEMENTARY INFORMATION:

I. Background

On April 22, 1996 the Virginia Department of Environmental Quality (VADEQ) submitted a revised version of Rule 4–24 (9 VAC 5–40–3260 et seq) Emission Standards for Solvent Metal Cleaning Operations Using Non-Halogenated Solvents as adopted on December 19, 1995, published in the Virginia Register of Regulations (Volume 12, Issue 11) on February 19, 1996, and effective on April 1, 1996. The VADEQ originally adopted this regulation in 1979 to satisfy the Clean Air Act's (the Act's) requirement that states impose reasonably available control technology (RACT) requirements on sources of volatile organic compound (VOC) emissions located in ozone nonattainment areas. In accordance with the Act's requirements, this RACT regulation applies in the Virginia portion of the Metropolitan Washington DC ozone nonattainment area and also applies in the previously designated ozone nonattainment areas of Richmond and Hampton Roads which have been redesignated to attainment for the one-hour ozone ambient air quality standard. The redesignations do not alter the Act's requirements that RACT be imposed on sources of VOC located in the of the Richmond and Hampton Roads areas. On December 19, 1995, Virginia adopted amendments to the regulation to update it to conform to recently issued EPA guidance, and on April 22, 1996 submitted it to EPA for approval as SIP revision.

On October 9, 1998, VADEQ submitted an amendment to the 9 VAC 5–40–3260 Applicability and designation of affected facility portion of Rule 4–24 (9 VAC 5–40–3260 et seq) Emission Standards for Solvent Metal Cleaning Operations Using Non-Halogenated Solvents. Although the title of the December 19, 1995 version of Rule 4–24 specifically referred to sources using non-halogenated solvents, the portion of the regulation entitled Applicability and designation of affected facility did not. Therefore, to clarify any potential for confusion, Virginia adopted a technical amendment to add language to the 9 VAC 5–40–3260 Applicability and designation of affected facility portion of Rule 4–24 to specify that it applies to facilities using non-halogenated solvents. This amendment was adopted on January 8, 1997, published in the Virginia Register of Regulations (Volume 13, Issue 14) on March 31, 1997 and effective on April 1, 1997.

EPA has determined that Rule 4–24 (9 VAC 5–40–3260 et seq) Emission Standards for Solvent Metal Cleaning Operations Using Non-Halogenated Solvents as originally submitted on April 22, 1996, and as revised by the October 9, 1998 submittal, meets all federal guidance for approval.

As a separate matter, the Commonwealth's October 9, 1998 submittal also included requests that EPA approve revisions made to Rule 6–2 (9 VAC 5–60–90 et seq) pertaining to the use of halogenated solvents as a source category subject to maximum available control technology (MACT) to control air toxics. For the Commonwealth to maintain its delegation of authority for the MACT standard, and to make this federal rule part of the SIP to establish RACT for halogenated solvent sources, Virginia adopted the relevant federal regulations found at 40 CFR Part 63.460 through 40 CFR Part 63.469 by incorporating them by reference into Rule 6–2 at 9 VAC 5–60–100, Subpart T. The Commonwealth also amended Rule 6–2 at 9 VAC 5–60–90 to update its dated citation of the Code of Federal Regulations from which regulations have been incorporated by reference from the 1994 version to the 1996 version. EPA is approving both of these revisions.

II. Final Action

EPA is approving the SIP revisions pertaining to solvent metal cleaning submitted by the VADEQ on April 22, 1996 and October 9, 1998.

EPA is approving these SIP revisions without a prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separated document that will serve as the proposal to approve the SIP revisions should adverse or critical comments be filed. This SIP revision will be effective December 20, 1999 without further notice unless the Agency receives adverse comments by December 3, 1999. If EPA receives such comments, then EPA will publish a document withdrawing the final action and informing the public that the action will not take effect. All public comments received will then be addressed in a subsequent final action based on the proposed rule. EPA will not institute a second comment period on the rule. Parties interested in commenting on this action should do so at this time. If no such comments are received, the public is advised that this SIP revision will be effective on December 20, 1999 and no further action will be taken on the proposed rule.

III. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from review under E.O. 12866, entitled ''Regulatory Planning and Review.''

B. Executive Orders on Federalism

Under E.O. 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a state, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If EPA complies by consulting, E.O. requires EPA to provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected state, local, and tribal governments, the nature of their concerns, copies of written communications from the governments, and a statement supporting the need to issue the regulation. In addition, E.O. 12875 requires EPA to develop an effective process permitting elected officials and other representatives of state, local, and tribal governments ''to

provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.'' Today's rule does not create a mandate on state, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of E.O. 12875 do not apply to this rule. On August 4, 1999, President Clinton issued a new executive order on federalism, Executive Order 13132, [64 FR 43255 (August 10, 1999),] which will take effect on November 2, 1999. In the interim, the current Executive Order 12612, [52 FR 41685 (October 30, 1987),] on federalism still applies. This rule will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 12612. The rule affects only one State, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act.

C. Executive Order 13045

E.O. 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), applies to any rule that the EPA determines (1) is ''economically significant,'' as defined under E.O. 12866, and (2) the environmental health or safety risk addressed by the rule has a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. This final rule is not subject to E.O. 13045 because it is not an economically significant regulatory action as defined by E.O. 12866, and it does not address an environmental health or safety risk that would have a disproportionate effect on children.

D. Executive Order 13084

Under E.O. 13084, EPA may not issue a regulation that is not required by statute, that significantly affects or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) 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. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This final rule will not have a significant impact on a substantial number of small entities because conditional approvals of SIP submittals under section 110 and subchapter I, part D of the CAA do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

F. Unfunded Mandates

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

G. Submission to Congress and the Comptroller General

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

H. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action to approve revisions to the Virginia SIP pertaining to solvent metal cleaning operations in the Commonwealth must be filed in the United States Court of Appeals for the appropriate circuit by January 3, 2000. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action to approve revisions to the Virginia SIP pertaining to solvent metal cleaning operations may not be challenged later

in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Ozone.

Dated: September 30, 1999.

Thomas C. Voltaggio,

Acting Regional Administrator, Region III.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

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

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

Subpart VV—Virginia

2. Section 52.2420 is amended by adding paragraph (c)(130) to read as follows:

§ 52.2420 Identification of plan.

* * * * *

(c) * * *

(130) Revisions to the State Implementation Plan submitted on April 22, 1996 and October 9, 1998 by the Virginia Department of Environmental Quality regarding regulations for reasonably available control technology requirements to control volatile organic compound emissions from solvent metal cleaning operations using non-halogenated solvents.

(i) Incorporation by reference.

(A) The letters dated April 22, 1996 and October 9, 1998 from the Virginia Department of Environmental Quality transmitting revisions to the Virginia State Implementation Plan pertaining to Rule 4–24 (9 VAC 5–40–3260 et seq.) of 9 VAC 5 Chapter 40.

(B) The amended version of Rule 4–24 (9 VAC 5–40–3260 et seq.) Emission Standards for Solvent Metal Cleaning Operations Using Nonhalogenated Solvents as adopted on December 19, 1995, published in the Virginia Register of Regulations (Volume 12, Issue 11) on February 19, 1996, and effective on April 1, 1997.

(C) Amendments to 9 VAC 5–40–3260 *Applicability and designation of affected facility* of Rule 4–24 (9 VAC 5–40–3260 et seq.) Emission Standards for Solvent Metal Cleaning Operations Using Non-Halogenated Solvents adopted on January 8, 1997, published in the Virginia Register of Regulations (Volume 13, Issue 14) on March 31, 1997 and effective on April 1, 1997.

(ii) Additional Materials—The remainders of the April 22, 1996 and October 1998 submittals which pertain to Rule 4-24 (9 VAC 5–40–3260 et seq.) Emission Standards for Solvent Metal Cleaning Operations Using Non-Halogenated Solvents.

3. Section 52.2423 is amended by adding paragraph (q) to read as follows:

§ 52.2423 Approval status.

* * * * *

(q) EPA approves as part of the Virginia State Implementation Plan the following revisions to the Virginia Regulations for the Control and Abatement of Pollution submitted by the Virginia Department of Environmental Quality on October 9, 1998:

(1) Subpart T of 9 VAC 5–60–100 *Designated emission standards* of Rule 6–2 (9 VAC 5–60–90 et seq.) of 9 VAC 5 Chapter 60 amended to adopt 40 CFR 63.460 through 63.469 by reference. This amendment was adopted on January 8, 1997, published in the Virginia Register of Regulations on March 31, 1997 and effective on May 1, 1997.

(2) Revised date reference to 40 CFR part 63 (July 1, 1996) contained in 9 VAC 5–60–90 (General), as it pertains to the documents listed in 9 VAC 5–60–100, Subpart T.

[FR Doc. 99–27675 Filed 11–2–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[Region 2 Docket No. NJ35–2–195a FRL–6461–7]

Approval and Promulgation of Air Quality Implementation Plans; New Jersey; Approval of National Low Emission Vehicle Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve a State Implementation Plan (SIP) revision submitted by the State of New Jersey on February 22, 1999. That revision committed that the State will accept compliance with the National Low Emission Vehicle (National LEV) program requirements as a compliance option for new motor vehicles sold in the State. New Jersey has previously adopted the California Low Emission Vehicle (CAL LEV) program, but the State has made clear that National LEV is the preferred motor vehicle control program. Auto manufacturers have agreed to sell cleaner vehicles meeting the National LEV standards throughout New Jersey for the duration of the manufacturers' commitments to the National LEV program. This SIP revision is required as part of the agreement between states and automobile manufacturers to ensure the continuation of the National LEV program to supply clean cars throughout most of the country, beginning with 1999 model year vehicles in Northeastern states and extending to other states beginning with 2001 model year vehicles.

DATES: This rule is effective on January 3, 2000 without further notice, unless EPA receives adverse comment by December 3, 1999. If we receive such comment, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Comments may be mailed to: Raymond Werner, Acting Chief, Air Programs Branch, Environmental Protection Agency, Region 2, 290 Broadway, 25th Floor, New York, NY 10007–1866.

Copies of the State submittal are available for public inspection during normal business hours, by appointment, at the following addresses:

Environmental Protection Agency, Region 2, Air Programs Branch, 290 Broadway, 25th Floor, New York, NY 10007–1866.

New Jersey Department of Environmental Protection, Bureau of Air Quality Planning, 401 East State Street, CN027, Trenton, New Jersey 08625

FOR FURTHER INFORMATION CONTACT: Michael P. Moltzen, Air Programs Branch, Environmental Protection Agency, 290 Broadway, 25th Floor, New York, NY 10007–1866, (212) 637–3710.

SUPPLEMENTARY INFORMATION:

Table of Contents

1. What Action Is EPA Taking Today?

The EPA is approving New Jersey's State Implementation Plan (SIP) revision, submitted on February 22, 1999, which fulfills the State's obligation to incorporate its commitment to the National Low Emission Vehicle (National LEV) program in the SIP. The submittal contains amendments, adopted on February 3, 1999, to the State's ''Ozone Transport Commission—Low Emission

Vehicle'' (OTC-LEV) program rules at N.J.A.C. 7:27–26. These changes complete New Jersey's process of agreeing to participate in, or ''opting into'' the National LEV program.

The State's commitment to opt into the National LEV program was stated by Governor Christine Todd Whitman in her January 28, 1998 letter to the EPA Administrator. New Jersey's regulations now provide that the National LEV program is an acceptable compliance option, in addition to the California low emission vehicle (CAL LEV) program, for new motor vehicles sold in the State.

New Jersey had previously adopted the CAL LEV program, but had also specified that National LEV would be the State's preferred motor vehicle control program if it became effective. Based on the opt-ins and commitments of the auto manufacturers and the Northeastern states, on March 2, 1998, EPA determined that National LEV is in effect. New Jersey's SIP revision is required as part of the agreement between states and automobile manufacturers to ensure the continuation of this program to bring clean cars throughout the country, beginning with 1999 model year vehicles in the Northeast.

The final National LEV rule stated that if states submitted SIP revisions containing language substantively identical to the language in the National LEV regulations without additional conditions, and if the submissions met the Clean Air Act requirements for approvable SIP submissions, we would not need to go through notice-and-comment rulemaking to approve the SIP revisions. In the National LEV rulemaking, we provided full opportunity for public comment on the language for the SIP revisions. Thus, as discussed in more detail in the final rule, the requirements for EPA approval are easily verified objective criteria. See 63 FR 936 (January 7, 1998). While we believe that we could have appropriately approved the New Jersey submittal without providing for additional notice and comment, we nonetheless decided to take this action as a direct final rulemaking, which allows an opportunity for further public comment. Here, we are not under a timing constraint that would support a shorter rulemaking process, and thus we decided there was no need to deviate from EPA's usual procedures for SIP approvals.

2. What Is the National Low Emission Vehicle Program?

The National Low Emission Vehicle (National LEV) program is a voluntary nationwide clean car program, designed to reduce smog and other pollution from new motor vehicles. On January 7, 1998, (63 FR 926) EPA published a final rule outlining the National LEV program. The National LEV regulations allow auto manufacturers to commit to meet tailpipe standards for cars and light light-duty trucks that are more stringent than EPA can mandate. The regulations provided that the program would come into effect only if Northeastern states and the auto manufacturers voluntarily signed up for it. On March 9, 1998 (63 FR 11374), EPA published a notice finding that nine Northeastern states (New Jersey, New Hampshire, Rhode Island, Connecticut, Pennsylvania, Maryland, Virginia, Delaware and the District of Columbia) and 23 manufacturers had opted into the National LEV program and that the program is in effect. Now that it is in effect, National LEV is enforceable in the same manner as any other federal new motor vehicle program.

National LEV will achieve significant air pollution reductions nationwide. In addition, the program provides substantial harmonization of federal and California new motor vehicle standards and test procedures, which enables manufacturers to design and test vehicles to one set of standards nationwide. The National LEV program demonstrates how cooperative, partnership efforts can produce a smarter, cheaper program that reduces regulatory burden while increasing protection of the environment and public health.

The National LEV program will result in substantial reductions in non-methane organic gases (NMOG) and nitrous oxides (NO_X), which contribute to unhealthy levels of smog in many areas across the country. National LEV vehicles are 70% cleaner than today's model requirements under the Clean Air Act. This voluntary program provides auto manufacturers flexibility in meeting the associated standards as well as the opportunity to harmonize their production lines and make vehicles more efficiently.

National LEV vehicles were estimated to cost an additional $76 above the price of vehicles otherwise required today, but it is expected that due to factors such as economies of scale and historical trends related to emission control costs, the per vehicle cost will be even lower. This incremental cost is less than 0.5% of the price of an average new car. In addition, the National LEV program will help ozone nonattainment areas across the country improve their air quality as well as reduce pressure to make further, more costly emission reductions from stationary industrial sources.

Because it is a voluntary program, National LEV was set up to come into effect, and will remain in effect, only if the Northeastern state and auto manufacturer participants commit to the program and abide by their commitments. The states and manufacturers initially committed to the program through opt-in notifications to EPA, which were sufficient for EPA to find that National LEV had come into effect. The National LEV regulations provide that the second stage of the state commitments is to be made through SIP revisions that incorporate the state commitments to National LEV in state regulations, which EPA will approve into the federally-enforceable SIPs. The National LEV regulations laid out the elements to be incorporated in the SIP revisions, the timing for such revisions, and the language (or substantively similar language) that needs to be included in a SIP revision to allow EPA to approve the revision as adequately committing the state to the National LEV program. In today's action, EPA is approving the National LEV SIP revision for New Jersey as adequately committing the State to the program. EPA expects to take similar action for the other states that have elected to join the National LEV program in the future.

3. What Is New Jersey's Role in the National LEV Program?

Along with eight other Northeast states, New Jersey has chosen to participate in and accept National LEV as an alternative motor vehicle control program. New Jersey has adopted state clean vehicle rules which include provisions for a program identical to the California low emission vehicle (CAL LEV) program, pursuant to section 177 of the Clean Air Act. The motor vehicle program rules, originally adopted on November 22, 1995, are titled ''Ozone Transport Commission—Low Emission Vehicle program'' (OTC–LEV) and are codified at N.J.A.C. 7:27–26. These rules explicitly provide that motor vehicle manufacturers could comply with a national program as an alternative to the CAL LEV program in New Jersey.

The State adopted amendments, on February 3, 1999, to its OTC–LEV program rules. Those amendments, transmitted in the SIP submittal we are acting on today, modify the OTC–LEV rule to accept compliance with National LEV, specifically, as the auto manufacturers' alternative to compliance with the section 177 CAL LEV requirements. The State's regulations now provide that for the duration of New Jersey's participation in

National LEV, manufacturers may comply with National LEV or equally stringent mandatory federal standards in lieu of compliance with the CAL LEV program adopted pursuant to section 177. The regulations accept National LEV as a compliance alternative for requirements applicable to passenger cars, light light-duty trucks, and light-duty trucks designed to operate on gasoline. The regulations further provide that New Jersey's participation in National LEV conditionally extends until model year 2006. The condition is that by the end of calendar year 2000, EPA must adopt mandatory standards at least as stringent as the National LEV standards. Such standards would apply to new motor vehicles beginning in model year 2004, 2005 or 2006. If EPA does not adopt such standards by that date, the State's participation in National LEV would extend only until model year 2004. Through this regulation and its amendments, the State has adequately committed to the National LEV program, as provided in the final National LEV rule.

4. Final Action

EPA has evaluated the SIP revision submitted by New Jersey and have determined it is consistent with the EPA National LEV regulations and meets the Clean Air Act section 110 requirements for SIP approvals. Therefore, EPA is approving the New Jersey ''OTC–LEV'' program rules as amended on February 3, 1999, and submitted on February 22, 1999, into the New Jersey SIP.

EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. However, in the ''Proposed Rules'' section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should adverse comments be filed. This rule will be effective January 3, 2000 without further notice unless the Agency receives adverse comment by December 3, 1999.

If EPA receives adverse comment, then EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments received in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

5. Administrative Requirements

A. Executive Order 12866

Regulatory Impact Analysis

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order (E.O.) 12866, entitled ''Regulatory Planning and Review.''

B. Executive Orders on Federalism

Under Executive Order 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a state, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 12875 requires EPA to provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected state, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of state, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create a mandate on state, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

On August 4, 1999, President Clinton issued a new executive order on federalism, Executive Order 13132, (64 FR 43255 (August 10, 1999),) which will take effect on November 2, 1999. In the interim, the current Executive Order 12612 (52 FR 41685 (October 30, 1987)) on federalism still applies. This rule will not have a substantial direct effect on states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 12612. The rule affects only one state, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act.

C. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to E.O. 13045 because it is not ''economically significant'' as defined under E. O. 12866, and does not involve an action that addresses environmental or safety risks.

D. Executive Order 13084

Consultation and Coordination With Indian Tribal Governments

Under E.O. 13084, EPA may not issue a regulation that is not required by statute, that significantly uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to the OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

E. Impact on Small Entities

The Regulatory Flexibility Act (RFA) 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. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This final rule will not have a significant impact on a substantial number of small entities because SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities. Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

F. Unfunded Mandates

Under sections 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated annual costs to state, local, or tribal governments in the aggregate, or to the private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that this final approval action does not include a Federal mandate that may result in estimated annual costs of $100 million or more to either state, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under state or local law, and imposes no new requirements. Accordingly, no additional costs to state, local, or tribal governments, or to the private sector, result from this action.

G. Submission to Congress and the Comptroller General

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

H. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 3, 2000. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: September 27, 1999.

William J. Muszynski,

Acting Regional Administrator, Region 2.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

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

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

Subpart FF—New Jersey

2. Section 52.1570 is amended by adding new paragraph (c)(67) to read as follows:

§ 52.1570 Identification of plan.

* * * * *

(c) * * *

* * * * *

(67) Revision to the New Jersey State Implementation Plan (SIP) for ozone, submitting amended New Jersey Ozone Transport Commission—Low Emission Vehicle (OTC–LEV) program, Opting into the National Low Emission Vehicle (National LEV) Program, dated February 22, 1999, submitted by the New Jersey Department of Environmental Protection (NJDEP).

(i) Incorporation by reference: Title 7, Chapter 27, Subchapter 26, ''Ozone Transport Commission—Low Emission Vehicles Program,'' effective March 1, 1999.

(ii) Additional information: Letter from the New Jersey Department of Environmental Protection Commissioner Shinn, dated February 22, 1999, submitting a revision to the New Jersey State Implementation Plan for the National Low Emission Vehicle program.

3. Section 52.1605 is amended by revising the entry for ''Subchapter 26'' under the heading ''Title 7, Chapter 27'' in numerical order to read as follows:

§ 52.1605 EPA-approved New Jersey regulations.

State regulation	State effective date	EPA approved date	Explanation
*	*	*	*
Title 7, Chapter 27			
*	*	*	*

State regulation	State effective date	EPA approved date	Explanation
* *	*	*	* * *
Subchapter 26, ''Ozone Transport Commission—Low Emission Vehicles Program''.	March 1, 1999	Nov. 3, 1999	Provides that for the duration of New Jersey's participation in National Low Emission Vehicle (LEV), manufacturers may comply with National LEV or equally stringent mandatory federal standards in lieu of compliance with the California LEV program adopted pursuant to section 177. The regulations accept National LEV as a compliance alternative for requirements applicable to passenger cars, light light-duty trucks, and light-duty trucks designed to operate on gasoline.
* *	*	*	* * *

[FR Doc. 99–27793 Filed 11–2–99; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[IN106–1a; FRL–6446–5]

Approval and Promulgation of Implementation Plan; Indiana

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving an Indiana request to amend the Stage II Vapor Recovery rule as a revision to the State Implementation Plan (SIP). Indiana submitted the SIP revision request on April 6, 1999. The revision affects gasoline dispensing facilities in Clark, Floyd, Lake, and Porter Counties. Stage II Vapor Recovery systems lower Volatile Organic Compound (VOC) emissions from vehicle refueling operations. VOC emissions are a precursor of ground-level ozone, commonly known as smog.

DATES: This rule is effective on January 3, 2000, unless EPA receives adverse written comments by December 3, 1999. If adverse written comment is received, EPA will publish a timely withdrawal of the rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Written comments should be sent to: J. Elmer Bortzer, Chief, Regulation Development Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Copies of the revision request for this rulemaking action are available for inspection at the following address: U.S. Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. (It is recommended that you telephone Francisco J. Acevedo at (312) 886–6061 before visiting the Region 5 Office).

FOR FURTHER INFORMATION CONTACT: Francisco J. Acevedo, Environmental Protection Specialist, at (312) 886–6061.

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we,'' ''us,'', or ''our'' are used we mean EPA.

Table of Contents

I. What Action Is EPA Proposing in This Rulemaking?

We are approving Indiana's April 6, 1999, SIP revision request to amend the Stage II Vapor Recovery rules promulgated by Indiana in 1993 and approved by us on April 28, 1994. The amendments we are approving clarify the applicability of definitions pertaining to gasoline dispensing facilities.

II. Why Are the Amendments to the Stage II Vapor Recovery Rule Approvable?

This SIP revision does not impact the stringency of the SIP. The definitions specific to the Stage II Vapor Recovery rules promulgated by Indiana in 1993 and approved by us on April 28, 1994 were incorrectly incorporated into the general provisions for all of the volatile organic compound rules contained in Indiana rule 326 IAC Article 8. To rectify this error and avoid future confusion, Indiana amended the Stage II rules and relocated the definitions specific to gasoline dispensing facilities from 326 IAC 8–1–0.5 to 326 IAC 8–4–6. Indiana did not make any other substantive changes to the Stage II rule; and this revision does not change the requirements of the Stage II program originally approved. For these reasons, the amendments to the Stage II Vapor Recovery rule are approvable.

III. Where Are the Rules for This SIP Revision Codified?

The Stage II Vapor Recovery rule amendments are codified under 326 IAC 8–1–0.5: Definitions, and 326 IAC 8–4–6: Gasoline dispensing facilities.

The rules were published in the Indiana Register on November 1, 1995 (19 In. Reg. 202). The effective date of the rules is October 18, 1995.

IV. What Public Hearing Opportunities Were Provided for This SIP Revision?

Indiana held public hearings on March 1, 1995, and on May 3, 1995, in Indianapolis, Indiana.

V. Final Rulemaking Action

In this rulemaking action, we are approving the April 6, 1999, SIP revision request, which includes technical amendments to the Stage II Vapor recovery rule affecting gasoline dispensing facilities.

The EPA is publishing this action without prior proposal because EPA views this as a noncontroversial revision and anticipates no adverse comments. However, in a separate document in this **Federal Register** publication, the EPA is proposing to approve the SIP revision should adverse written comments be received. This action will be effective without further notice unless EPA receives relevant adverse written comment by December 3, 1999. Should the Agency receive such comments, it will publish a timely withdrawal informing the public that this action will not take effect. Any parties interested in commenting on this action should do so at this time. If no

such comments are received, the public is advised that this action will be effective on January 3, 2000.

VI. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order (E.O.) 12866, entitled ''Regulatory Planning and Review.''

B. Executive Order 12875

Under E.O. 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a state, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected state, local, and tribal governments, the nature of their concerns, copies of written communications from the governments, and a statement supporting the need to issue the regulation. In addition, E.O. 12875 requires EPA to develop an effective process permitting elected officials and other representatives of state, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.'' Today's rule does not create a mandate on state, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of E.O. 12875 do not apply to this rule.

C. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to E.O. 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

D. Executive Order 13084

Under E.O. 13084, EPA may not issue a regulation that is not required by statute, that significantly affects or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, E.O. 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) 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. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This final rule will not have a significant impact on a substantial number of small entities because SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities. Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.*, v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

F. Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated annual costs to State, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated annual costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

G. Submission to Congress and the Comptroller General

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

H. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act

(NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use ''voluntary consensus standards'' (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this action. Today's action does not require the public to perform activities conducive to the use of VCS.

I. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 3, 2000. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: September 17, 1999.

Francis X. Lyons,

Regional Administrator, Region 5.

For the reasons stated in the preamble, part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

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

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

Subpart P—Indiana

2. Section 52.770 is amended by adding paragraph (c)(125) to read as follows:

§ 52.770 Identification of Plan.

* * * * *

(c) * * *

(125) On April 6, 1999, Indiana submitted amended rules for the control of volatile organic compound emissions from vehicle refueling in Clark, Floyd, Lake, and Porter Counties as a revision to the State Implementation Plan.

(i) Incorporation by reference.

326 Indiana Administrative Code 8–1: General Provisions, Section 0.5: Definitions and 326 Indiana Administrative Code 8–4: Petroleum Sources, Section 6: Gasoline Dispensing Facilities. Adopted by the Indiana Air Pollution Control Board May 3, 1995. Filed with the Secretary of State September 18, 1995. Published at Indiana Register, Volume 19, Number 2, November 1, 1995. Effective October 18, 1995.

[FR Doc. 99–28039 Filed 11–2–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[KY–75–1–9910a; KY–97–1–9911a; FRL–6465–6]

Approval and Promulgation of Implementation Plans, Kentucky: Approval of Revisions to the Kentucky State Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule; Withdrawal.

SUMMARY: On September 13, 1999, EPA published a direct final rule (64 FR 49404) approving, and an accompanying proposed rule (64 FR 4925) proposing to approve the Louisville 15 Percent Rate-of-Progress Plan (15 percent plan) which was submitted on November 12, 1993, and amended on June 30, 1997. As stated in the **Federal Register** document, if adverse or critical comments were received by October 13, 1999, the effective date would be delayed and timely notice would be published in the **Federal Register**. Therefore, due to receiving adverse comments within the comment period, EPA is withdrawing the direct final rule and will address all public comments received in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this document.

DATE: The direct final rule published on September 13, 1999 (64 FR 49404) is withdrawn as of November 3, 1999.

FOR FURTHER INFORMATION CONTACT: Scott M. Martin, Regulatory Planning Section, Air Planning Branch, Air, Pesticides & Toxics Management Division, Region 4 Environmental Protection Agency, 61 Forsyth Street, SW, Atlanta, Georgia 30303–3104. The telephone number is (404) 562–9036.

SUPPLEMENTARY INFORMATION: See the information provided in the direct final rule located in the final rules section of the September 13, 1999, **Federal Register** (64 FR 49404).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements.

Dated: October 19, 1999.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

[FR Doc. 99–28390 Filed 11–2–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR PART 52

[OH 129–1a; FRL–6464–5]

Approval and Promulgation of Maintenance Plan Revisions; Ohio

AGENCY: United States Environmental Protection Agency (USEPA).

ACTION: Direct final rule.

SUMMARY: USEPA is approving an August 19, 1999, request from Ohio for a State Implementation Plan (SIP) revision of the Columbiana County ozone maintenance plan. The maintenance plan revision establishes a new transportation conformity mobile source emissions budget for the year 2005. USEPA is approving the allocation of a portion of the safety margin for oxides of nitrogen (NO_X) to the area's 2005 mobile source emissions budget for transportation conformity purposes. This allocation will still maintain the total emissions for the area at or below the attainment level required by the transportation conformity regulations. The transportation conformity budget for volatile organic compounds will remain the same as previously approved in the maintenance plan.

DATES: This rule is effective on January 3, 2000, unless USEPA receives adverse written comments by December 3, 1999. If adverse comment is received, USEPA will publish a timely withdrawal of the rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Send written comments to: J. Elmer Bortzer, Chief, Regulation Development Section, Air Programs Branch, (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West

Jackson Boulevard, Chicago, Illinois, 60604.

You may inspect copies of the documents relevant to this action during normal business hours at the following location:

Regulation Development Section, Air Programs Branch, (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois, 60604.

Please contact Patricia Morris at (312) 353–8656 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT:

Patricia Morris, Environmental Scientist, Regulation Development Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–8656.

SUPPLEMENTARY INFORMATION:

Throughout this document wherever ''we'', ''us'', or ''our'' are used we mean USEPA.

This Supplementary Information section is organized as follows:

What action is USEPA taking today?
Who is affected by this action?
How did the State support its request?
What is transportation conformity?
What is an emissions budget?
What is a safety margin?
How does this action change the Columbiana County ozone maintenance plan?
Why is the request approvable?
USEPA Action.
Administrative Requirements.

What Action is USEPA Taking Today?

In this action, we are approving a revision to the ozone maintenance plan for Columbiana County, Ohio. The revision will change the mobile source emissions budget for NO_X that is used for transportation conformity purposes. The revision will keep the total emissions for the area at or below the attainment level required by law. This action will allow State or local agencies to maintain air quality while providing for transportation growth.

Who Is Affected by This Action?

Primarily, the transportation sector represented by Ohio Department of Transportation and persons needing to travel through Columbiana County will be affected by this revision. A proposed project to build a new 4 lane highway through a portion of Columbiana County would produce higher emissions than currently allowed in the maintenance plan. The conformity rule, however, provides that if a ''safety margin'' exists in the maintenance plan, then the safety margin can be allocated to the transportation sector via the mobile source budget.

How Did the State Support This Request?

On August 19, 1999, Ohio submitted to USEPA a SIP revision request for the Columbiana County ozone maintenance area. A public hearing on this proposal was held on September 22, 1999. No one from the public commented on the proposed revisions. At the public hearing Ohio officially changed the request from 1 ton per day of NO_X to 0.5 ton per day of NO_X to be allocated to the mobile source budget.

In the submittal, Ohio requested to establish a new 2005 mobile source emissions budget for NO_X for the Columbiana County, Ohio, ozone maintenance area. The State originally requested that 1 ton per day of NO_X be allocated from the maintenance plan's safety margin. After comment from USEPA, however, the request was changed to 0.5 ton per day of NO_X. The 0.5 ton per day change will accommodate the proposed highway and leave a safety margin for future use. The mobile source budgets are used for transportation conformity purposes.

What Is Transportation Conformity?

Transportation conformity means that the level of emissions from the transportation sector (cars, trucks and buses) must be consistent with the requirements in the SIP to attain and maintain the air quality standards. The Clean Air Act, in section 176(c), requires conformity of transportation plans, programs and projects to an implementation plan's purpose of attaining and maintaining the National Ambient Air Quality Standards. On November 24, 1993, USEPA published a final rule establishing criteria and procedures for determining if transportation plans, programs and projects funded or approved under Title 23 U.S.C. or the Federal Transit Act conform to the SIP.

The transportation conformity rules require an ozone maintenance area, such as Columbiana County, to compare the actual projected emissions from cars, trucks and buses on the highway network, to the mobile source emissions budget established by a maintenance plan. The Columbiana County area has an approved ozone maintenance plan. Our approval of the maintenance plan established the mobile source emissions budgets for transportation conformity purposes.

What Is an Emissions Budget?

An emissions budget is the projected level of controlled emissions from the transportation sector (mobile sources) that is estimated in the SIP. The SIP controls emissions through regulations, for example, on fuels and exhaust levels for cars. The emissions budget concept is further explained in the preamble to the November 24, 1993, transportation conformity rule (58 FR 62188). The preamble also describes how to establish the mobile source emissions budget in the SIP and how to revise the emissions budget. The transportation conformity rule allows the mobile source emissions budget to be changed as long as the total level of emissions from all sources remains below the attainment level.

What Is a Safety Margin?

A ''safety margin'' is the difference between the attainment level of emissions (from all sources) and the projected level of emissions (from all sources) in the maintenance plan. The attainment level of emissions is the level of emissions during one of the years in which the area met the air quality health standard. For example: Columbiana County was monitoring attainment of the one hour ozone standard during the 1988–1990 time period. The State uses 1990 as the attainment level of emissions for Columbiana County. The emissions from County point, area and mobile sources in 1990 equaled 23.98 tons per day of VOC and 11.66 tons per day of NO_X. The Ohio Environmental Protection Agency projected emissions out to the year 2005 and projected a total of 18.70 tons per day of VOC and 10.02 tons per day of NO_X from all sources in Columbiana County. The safety margin for the County is calculated to be the difference between these amounts or 5.28 tons per day of VOC and 1.64 tons per day of NO_X. Table 1 gives detailed information on the estimated emissions from each source category and the safety margin calculation.

The 2005 emission projections reflect the point, area and mobile source reductions and are illustrated in Table 1.

TABLE 1.—NO_X and VOC Emissions Budget; and Safety Margin Determinations, Columbiana County

[Tons/day]

Source Category	1990	2005
	VOC Emission	
Point	1.89	2.25
Mobile	11.69	5.65
Area	10.40	10.80
Totals	23.98	18.70

TABLE 1.—NO_X and VOC Emissions Budget; and Safety Margin Determinations, Columbiana County—Continued

[Tons/day]

Source Category	1990	2005
Safety Margin = 1990 total emissions—2005 total emissions = 5.28 tons/day VOC		
	NO_X Emissions	
Point	0.06	0.07
Mobile	7.00	5.05
Area	4.60	4.90
Totals	11.66	10.02
Safety Margin = 1990 total emissions—2005 total emissions = 1.64 tons/day NO_X		

The emissions are projected to maintain the area's air quality consistent with the air quality health standard. The safety margin credit can be allocated to the transportation sector. The total emission level, even with this allocation will be below the attainment level or safety level and thus is acceptable. The safety margin is the extra safety [points] that can be allocated as long as the total level is maintained.

How Does This Action Change the Columbiana County Zone Maintenance Plan?

It raises the NO_X emissions budget for mobile sources. The maintenance plan is designed to provide for future growth while still maintaining the ozone air quality standard. Growth in industries, population, and traffic is offset with reductions from cleaner cars and other emission reduction programs. Through the maintenance plan the State and local agencies can manage and maintain air quality while providing for growth.

In the submittal, Ohio requested to allocate part of the area's safety margin to the mobile source emissions budget. The Columbiana County area's safety margin is the difference between the 1990 attainment inventory year and the 2005 projected emissions inventory (5.28 tons /day VOC safety margin, and 1.64 tons/day NO_X safety margin) as shown in Table 1. The SIP revision requests the allocation of 0.5 ton/day NO_X, into the area's mobile source NO_X emissions budget from the safety margin. The 2005 mobile source NO_X emissions budget showing the safety margin allocations are outlined in Table 2. The mobile source NO_X emissions budget in Table 2 will be used for transportation conformity purposes.

Table 2 below illustrates that the requested portion of the safety margin can be allocated to the 2005 mobile source budget and that total emissions will still remain at or below the 1990 attainment level of total emissions for the Columbiana County maintenance area. Since the area would still be at or below the 1990 attainment level for the total emissions, this allocation is allowed by the conformity rule. The VOC budget and safety margin will remain the same.

TABLE 2.—ALLOCATION OF SAFETY MARGIN TO THE 2005 MOBILE SOURCE EMISSIONS BUDGET, COLUMBIANA COUNTY

[Tons/day]

Source category	1990	2005
	NO_X Emissions	
Point	0.06	0.07
Mobile	7.00	5.55
Area	4.60	4.90
Total	11.66	10.52

Remaining Safety Margin = 1990 total emissions − 2005 total emissions = 1.14 tons/day NO_X

Why is the Request Approvable?

After review of the SIP revision request, USEPA finds that the requested allocation of the safety margin for the Columbiana County area is approvable because the new mobile source emissions budget for NO_X maintains the total emissions for the area at or below the attainment year inventory level as required by the transportation conformity regulations. This allocation is allowed by the conformity rule since the area would still be at or below the 1990 attainment level for the total emissions.

USEPA Action

USEPA is approving the requested allocation of the safety margin to the mobile source NO_X emission budget for the Columbiana County ozone maintenance area.

USEPA is publishing this action without prior proposal because USEPA views this as a noncontroversial revision and anticipates no adverse comments. However, in a separate document in this **Federal Register** publication, USEPA is proposing to approve the SIP revision should adverse written comments be filed. This action will be effective without further notice unless USEPA receives relevant adverse written comment by December 3, 1999. Should the Agency receive such comments, it will publish a final rule informing the public that this action will not take effect. Any parties interested in commenting on this action should do so at this time. If no such comments are received, the public is advised that this action will be effective on January 3, 2000.

Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order (E.O.) 12866, entitled ''Regulatory Planning and Review.''

B. Executive Orders on Federalism

Under E.O. 12875, USEPA may not issue a regulation that is not required by statute and that creates a mandate upon a state, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, USEPA must provide to the Office of Management and Budget a description of the extent of USEPA's prior consultation with representatives of affected state, local, and tribal governments, the nature of their concerns, copies of written communications from the governments, and a statement supporting the need to issue the regulation.

In addition, E.O. 12875 requires USEPA to develop an effective process permitting elected officials and other representatives of state, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.'' Today's rule does not create a mandate on state, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of E.O. 12875 do not apply to this rule.

On August 4, 1999, President Clinton issued a new executive order on federalism, Executive Order 13132 (64 FR 43255 (August 10, 1999),) which will take effect on November 2, 1999. In the interim, the current Executive Order 12612 [52 FR 41685 (October 30, 1987),] on federalism still applies. This rule will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 12612. The rule affects only one State, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act.

C. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be ''economically

significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that USEPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to E.O. 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

D. Executive Order 13084

Under E.O. 13084, USEPA may not issue a regulation that is not required by statute, that significantly affects or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, USEPA must provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of USEPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation.

In addition, E.O. 13084 requires USEPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) 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. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions.

This final rule will not have a significant impact on a substantial number of small entities because SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities.

Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.,* v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

F. Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, USEPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated annual costs to State, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under Section 205, USEPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires USEPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

USEPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated annual costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

G. Submission to Congress and the Comptroller General

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

H. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, USEPA must consider and use ''voluntary consensus standards'' (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

USEPA believes that VCS are inapplicable to this action. Today's action does not require the public to perform activities conducive to the use of VCS.

I. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 3, 2000. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Intergovernmental relations, Ozone, Nitrogen oxides, Transportation conformity.

Dated: October 20, 1999.

Francis X. Lyons,

Regional Administrator.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

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

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

Subpart KK—Ohio

2. Section 52.1885 is amended by adding paragraph (a)(13) to read as follows:

§ 52.1885 Control Strategy: Ozone.

(a) * * *

(13) Approval—On August 19, 1999, Ohio submitted a revision to the ozone maintenance plan for the Columbiana County area. The revision consists of allocating a portion of the Columbiana County area's NO_X safety margin to the transportation conformity mobile source emissions budget. The mobile source emissions budgets for transportation conformity purposes for the Columbiana County area are now: 5.65 tons per day of volatile organic compound emissions for the year 2005 and 5.55 tons per day of oxides of nitrogen emissions for the year 2005. This approval only changes the NO_X transportation conformity emission budget for Columbiana County.

[FR Doc. 99–28386 Filed 11–2–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[MD054–3044a; FRL–6456–6]

Approval and Promulgation of State Air Quality Plans for Designated Facilities and Pollutants; Maryland; Revision to Section 111(d) Plan Controlling Total Reduced Sulfur Emissions From Existing Kraft Pulp Mills

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: This action approves the section 111(d) plan revision submitted by the State of Maryland regarding revised monitoring procedures test methods used to determine compliance of total reduced sulfur (TRS) emissions from existing kraft pulp mills. The plan revision was submitted in accordance with the requirements of the Clean Air Act (the Act). EPA is approving this plan revision because Maryland's revised procedures meet current EPA requirements for monitoring and testing TRS emissions.

DATES: This final rule is effective January 3, 2000 unless by December 3, 1999 adverse or critical comments are received. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public the rule will not take effect.

ADDRESSES: Comments may be mailed to Harold A. Frankford, Office of Air Programs, Mail Code 3AP20, Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the documents relevant to this action are available for public inspection during normal business hours at the following locations: Air Protection Division, Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; and the Maryland Department of the Environment, 2500 Broening Highway, Baltimore, Maryland, 21224.

FOR FURTHER INFORMATION CONTACT: Harold A. Frankford at (215) 814–2108, or by e-mail at frankford.harold@epamail.gov.

SUPPLEMENTARY INFORMATION: Throughout this document, wherever ''we'', ''us'', or ''our'' is used, we mean EPA.

What Action is EPA Taking?

We are approving a revision to Maryland's section 111(d) plan for the control of total reduced sulfur (TRS) emissions from kraft pulp mills.

What Does the Revision Consist Of?

Maryland has revised COMAR 26.11.14.05 (monitoring and reporting requirements for control of kraft pulp mills TRS emissions) to incorporate Method 16B of Technical Memorandum 91–01 as the method for continuous monitoring of TRS emissions from recovery boilers (COMAR 26.11.14.05A.), and once-a-month grab sampling from smelt dissolving tanks (COMAR 26.11.14.05B). According to documents supplied by Maryland accompanying this revision, Method 16B of Technical Memorandum 91–01 consists of cross-references to the Method 16B provisions found in 40 CFR part 60, Appendix A.

What Actions Did the State Take to Satisfy the Federal Public Hearing Requirements?

Maryland certified that public hearings on the revisions to COMAR 26.11.14.05 were held in Baltimore on November 25, 1991 in accordance with the requirements of 40 CFR 60.23(d).

What is EPA Evaluation?

The April 2, 1992 revisions to COMAR 26.11.14.05 replace provisions found in TM–116, Method 12 [Revised 1980] submitted with the State's original Section 111(d) plan controlling TRS from kraft pulp mills. We had approved these test methods on May 11, 1982 (47 FR 20127). Since then, we have revised the monitoring and testing provisions of 40 CFR part 60 as they apply to measuring TRS emissions from kraft pulp mills—May 20, 1986 (51 FR 18545) for emissions monitoring, February 14, 1990 (55 FR 5212) for test methods and procedures. We have determined that Maryland's revised provisions found in COMAR 26.11.14.05 reflect our current requirements for monitoring and testing TRS emissions from recovery boilers and smelt dissolving tanks.

Final Action

We are approving the revisions to COMAR 26.11.14.05 regarding monitoring procedures and test methods for measuring TRS emissions from affected facilities. We are publishing this rule without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comment. However, in the ''Proposed Rules'' section of today's **Federal Register**, we are publishing a separate document that will serve as the proposal to approve the revision to Maryland's Section 111(d) plan for controlling TRS emissions from kraft pulp mills if adverse comments are filed. This rule will be effective on January 3, 2000 without further notice unless we receive adverse comment by December 3, 1999. If we receive adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. We will address all public comments in a subsequent final rule based on the proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

III. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from review under E.O. 12866, entitled ''Regulatory Planning and Review.''

B. Executive Orders on Federalism

Under E.O. 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a state, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If EPA complies by consulting, E.O. requires EPA to provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives

of affected state, local, and tribal governments, the nature of their concerns, copies of written communications from the governments, and a statement supporting the need to issue the regulation. In addition, E.O. 12875 requires EPA to develop an effective process permitting elected officials and other representatives of state, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.'' Today's rule does not create a mandate on state, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of E.O. 12875 do not apply to this rule.

On August 4, 1999, President Clinton issued a new executive order on federalism, Executive Order 13132 (64 FR 43255 (August 10, 1999), which will take effect on November 2, 1999. In the interim, the current Executive Order 12612 (52 FR 41685 (October 30, 1987)), on federalism still applies. This rule will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 12612. The rule affects only one State, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act.

C. Executive Order 13045

E.O. 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), applies to any rule that the EPA determines (1) is ''economically significant,'' as defined under E.O. 12866, and (2) the environmental health or safety risk addressed by the rule has a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This final rule is not subject to E.O. 13045 because it is not an economically significant regulatory action as defined by E.O. 12866, and it does not address an environmental health or safety risk that would have a disproportionate effect on children.

D. Executive Order 13084

Under E.O. 13084, EPA may not issue a regulation that is not required by statute, that significantly affects or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) 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. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This final rule will not have a significant impact on a substantial number of small entities because approvals under section 111(d) of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities. Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning section 111(d) plans on such grounds. *Union Electric Co.* v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

F. Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated annual costs to State, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated annual costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

G. Submission to Congress and the Comptroller General

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

H. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 3, 2000. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and

shall not postpone the effectiveness of such rule or action. This action to approve revised test methods for Maryland's section 111(d) plan controlling TRS emissions from existing kraft pulp mills may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 62

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements, Total reduced sulfur.

Dated: September 30, 1999.

Thomas Voltaggio,

Acting Regional Administrator, EPA Region III.

40 CFR Part 62 is amended as follows:

PART 62—[AMENDED]

Subpart V—Maryland

1. The authority citation for Part 62 continues to read as follows:

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

2. Under the following undesignated centerhead, § 62.5100 is amended by adding paragraph (d) to read as follows:

Plan for Control of Designated Pollutants From Existing Facilities (Section 111(d) Plan)

* * * * *

§ 62.5100 Identification of plan.

* * * * *

(d) *Submittal of plan revisions*—On April 2, 1992, Maryland submitted revisions to COMAR 26.11.14.05A. and .05B. governing the testing, monitoring, and reporting of total reduced sulfur (TRS) emissions from kraft pulp mills.

[FR Doc. 99–26851 Filed 11–2–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 63 and 68

[FRL–6465–7]

Approval of Delegation of the Accidental Release Prevention Requirements: Risk Management Programs Under Clean Air Act Section 112(r)(7): State of Ohio

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: This action approves delegation of the Clean Air Act (CAA) section 112(r)(7) accidental release prevention requirements to the State of Ohio, Environmental Protection Agency (OEPA), Division of Air Pollution Control (DAPC), for all applicable Ohio sources. DAPC requested the section 112(r)(7) delegation on July 23, 1999. Section 112(r)(7) requires owners and operators of stationary sources subject to the requirements to submit a risk management plan (RMP) to detect and prevent or minimize accidental releases of regulated substances.

In the proposed rule section of this **Federal Register**, EPA is proposing approval of, and soliciting comments on, the proposed delegation. If adverse comments are received on this action, EPA will withdraw this final rule and address the comments received in response to this action in a final rule on the related proposed rule. A second public comment period will not be held. Parties interested in commenting on this action should do so at this time.

DATES: This direct final rule will be effective January 3, 2000, unless EPA receives adverse or critical comments by December 3, 1999. If adverse comment is received, EPA will publish a timely withdrawal of the rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Written Comments on this action should be sent concurrently to: Bob Mayhugh, U.S. Environmental Protection Agency, Region 5, 77 W. Jackson Blvd., (SC–6J), Chicago, IL 60604–3590, *mayhugh.robert@epa.gov*, and Sherri Swihart, Ohio Environmental Protection Agency, 1800 WaterMark Dr., Columbus, Ohio 43215–1099, *sherri.swihart@epa.state.ohio.us.*

Copies of Ohio's section 112(r) delegation request letter and accompanying documents are available for public review during the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, at the addresses listed above. If you would like to review these documents, please make an appointment with the appropriate office at least 24 hours before visiting day.

FOR FURTHER INFORMATION CONTACT: Bob Mayhugh, U.S. Environmental Protection Agency, Region 5, Superfund Division, Office of Chemical Emergency Preparedness and Prevention, 60604–3590, (telephone 312/886–5929), *mayhugh.robert@epa.gov*, or Sherri Swihart, Ohio Environmental Protection Agency, 1800 WaterMark Dr., Columbus, Ohio 43215–1099 (telephone 614/644–3594), *sherri.swihart@epa.state.oh.us.*

SUPPLEMENTARY INFORMATION: The 1990 CAA Amendments added section 112(r) to provide for the prevention and mitigation of accidental chemical releases. Section 112(r) (3)–(5) mandates that EPA promulgate a list of ''regulated substances,'' with threshold quantities. Processes at stationary sources that contain a threshold quantity of a regulated substance are subject to accidental release prevention regulations promulgated under CAA section 112(r)(7). Pursuant to section 112(r)(7), EPA published the risk management program regulations on June 20, 1996 (61 FR 31668), and subsequently amended the regulations on January 6, 1999 (64 FR 963). The risk management program regulations are set forth at 40 CFR part 68. The regulations require, among other things, that owners and operators of stationary sources with more than a threshold quantity of a regulated substance in a process submit a risk management plan (RMP) by June 21, 1999, to a central location specified by EPA. A RMP must include, in general, an offsite consequence analysis, a prevention program, and an emergency response program. The RMPs will be available to state and local governments and to the public. These regulations encourage sources to reduce the probability of accidentally releasing substances that have the potential to cause harm to public health and the environment. Further, the regulations stimulate dialog between industry and the public on ways to improve accident prevention and emergency response practices.

Section 112(l) of the CAA and 40 CFR 63.91 and 63.95, authorize EPA, in part, to delegate the authority to implement 112(r)(7) to any state or local agency which submits an approvable program to implement and enforce the section 112(r)(7) requirements, including the risk management program regulations set forth at 40 CFR part 68. An appropriate plan must contain, among other criteria, the following elements: a demonstration of the state's authority and resources to implement and enforce regulations that are at least as stringent as section 112(r) regulations; procedures for receiving, reviewing, and making publicly available RMPs; procedures to provide technical assistance to subject sources, including small businesses.

On September 28, 1998, the Ohio Accidental Release Prevention and Risk Management Planning Act (Chapter 3753–104 Ohio Revised Code) became effective. This law adopts the federal requirements found in CAA section 112(r) and the corresponding regulations for section 112(r)(7) set forth at 40 CFR part 68 for use with the Ohio section 112(r) program. Ohio's section 112(r) program has the authority and resources to educate the general public and subject sources through outreach programs; provide technical assistance;

review and make publicly available risk management plans; and adequately enforce its 112(r) program. Upon delegation, the State's program will be administered by the DAPC of OEPA. DAPC will work closely with OEPA's Division of Emergency Remedial Response (DERR) which is also responsible for implementation of the Federal Emergency Planning and Community Right-To-Know Act (EPCRA) program in the State. The DERR serves as Chair and staff to the State Emergency Response Commission (SERC) and has an established relationship with Ohio's eighty-seven Local Emergency Planning Committees (LEPCs).

Based on Ohio's delegation request and its pertinent laws and regulations, EPA has determined that such a delegation is appropriate in that Ohio has satisfied the criteria of 40 CFR 63.91 and 63.95. The Ohio program has adequate and effective authorities, resources, and procedures in place for implementation and enforcement of non-major and major sources subject to the section 112(r)(7) requirements. The State has the primary authority and responsibility to carry out all elements of the section 112(r)(7) program for all sources covered in the State, including on-site inspections, record keeping reviews, audits and enforcement. Although the State has primary authority and responsibility to implement and enforce the section 112(r)(7) requirements, nothing shall preclude, limit, or interfere with the authority of EPA to exercise its enforcement, investigatory, and information gathering authorities concerning this part of the Act.

Administrative Requirements

A. Executive Order 12866

Under E.O. 12866 (58 FR 51735; October 4, 1993), EPA must determine whether a regulatory action is ''significant'' and, therefore, subject to OMB review and the requirements of the Executive Order EPA has determined that the promulgation of risk management program regulations is a ''significant regulatory action'' under the terms of E.O. 12866 (61 FR 31668, June 20, 1996; 64 FR 963, January 6, 1999). However, the delegation of section 112(r)(7) unchanged from the Federal requirements does not create any new regulatory requirements. Therefore, this regulatory action is exempt from Executive Order 12866 review.

B. Executive Orders on Federalism

Under Executive Order 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a state, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected state, local, and tribal governments, the nature of their concerns, copies of written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of state, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.'' Today's rule does not create a mandate on state, local or tribal governments. The State of Ohio has voluntarily requested delegation of this program. The state will be implementing its own pre-existing Accidental Releases Prevention/Risk Management Planning program as described in the Supplemental Information Section of this notice. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

On August 4, 1999, President Clinton issued a new executive order on federalism, Executive Order 13132, (64 FR 43255 (August 10, 1999),) which will take effect on November 2, 1999. In the interim, the current Executive Order 12612, (52 FR 41685 (October 30, 1987),) on federalism still applies. This rule will not have a substantial direct effect on states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 12612. The rule affects only one State, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act.

C. Executive Order 13084

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly affects or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

D. Paperwork Reduction Act

Under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, the EPA must consider the paperwork burden imposed by any information collection request in a proposed or final rule. This rule will not impose any new information collection requirements.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA, Public Law 96–354, September 19, 1980) requires Federal agencies to give special consideration to the impact of regulation on small businesses. The RFA specifies that a regulatory flexibility analysis must be prepared if a screening analysis indicates a regulation will have significant impact on a substantial number of small entities. (5 U.S.C. 603 and 604.) Alternatively, EPA may certify that the regulatory action will not have a significant impact on a substantial number of small entities. Because the delegation of section 112(r)(7) unchanged from the Federal requirements does not create any new regulatory requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities.

F. Unfunded Mandates

Under section 202, 203 and 205 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act), EPA must undertake various actions in association with proposed or final rules that include a Federal mandate that may result in estimated costs of $100 million or more

to the private sector, or to state, local, or tribal governments in the aggregate.

EPA has determined that the approval action promulgated today does not constitute a Federal mandate that may result in estimated costs of $100 million or more to either state, local, or tribal governments in the aggregate, or to the private sector. The State voluntarily requested this delegation under section 112(l) for the purpose of implementing and enforcing the risk management program requirements of section 112(r)(7). The delegation imposes no new Federal requirements. Because the State was not required by law to seek delegation, this Federal action does not impose a mandate on the State.

G. Submission to Congress and the Comptroller General

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

H. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards (VCS) are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. Today's action does not require the public to perform activities conducive to the use of VCS. Therefore, EPA believes that voluntary consensus standards are inapplicable to this action.

I. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be '''economically significant''' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to Executive Order 13045 because it is not an economically significant rule as defined by Executive Order 12866, and because it does not involve decisions based on environmental health or safety risks.

List of Subjects

40 CFR Part 63

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous substances, Intergovernmental relations.

40 CFR Part 68

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous substances, Intergovernmental relations, Chemicals, Reporting and recordkeeping requirements.

Dated: October 21, 1999.

David A. Ullrich,

Acting Regional Administrator, Region 5.

[FR Doc. 99–28311 Filed 11–2–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300937; FRL–6387–4]

RIN 2070–AB70

Buprofezin; Extension of Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends a time-limited tolerance for residues of the insecticide buprofezin and its metabolites in or on curcubits at 0.5 part per million (ppm) for an additional 1–year period. This tolerance will expire and is revoked on December 31, 2000. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on cucurbits. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA.

DATES: This regulation is effective November 3, 1999. Objections and requests for hearings, identified by docket control number OPP–300937, must be received by EPA on or before January 3, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit III. of the ''SUPPLEMENTARY INFORMATION.'' To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300937 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Andrea Beard, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 308–9356; and e-mail address: beard.andrea@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American

Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**--Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–300937. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

EPA issued a final rule, published in the **Federal Register** of August 8, 1998 (63 FR 41720) (FRL–6018–5), which announced that on its own initiative under section 408 of FFDCA, 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) it established a time-limited tolerance for the residues of buprofezin and its metabolites in or on curcubits at 0.5 ppm, with an expiration date of December 31, 1999. EPA established the tolerance because section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

EPA received a request to extend the use of buprofezin on curcubits for this year's growing season due to the situation remaining an emergency. The silverleaf whitefly has been a major pest in Arizona since the late 1980s and has caused significant economic loss in a host of crops throughout the region. This new strain or species of whitefly has proven to be resistant to available alternative controls, and can cause extensive damage through reduced yields from feeding activities, excretion of a honeydew which leads to fungal diseases, and also has been found to transmit several viral diseases of curcubits. After having reviewed the submission, EPA concurs that emergency conditions exist. EPA has authorized under FIFRA section 18 the use of buprofezin on curcubits for control of the silverleaf whitefly in Arizona.

EPA assessed the potential risks presented by residues of buprofezin in or on curcubits. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. The data and other relevant material have been evaluated and discussed in the final rule of August 5, 1998 (63 FR 41720). Based on that data and information considered, the Agency reaffirms that extension of the time-limited tolerance will continue to meet the requirements of section 408(l)(6). Therefore, the time-limited tolerance is extended for an additional 1–year period. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations (CFR). Although this tolerance will expire and is revoked on December 31, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on curcubits after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA and the application occurred prior to the revocation of the tolerance. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

III. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–300937 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before January 3, 2000.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental

Protection Agency, 401 M St., SW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. M3708, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit III.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–300937, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

IV. Regulatory Assessment Requirements

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require prior consultation with State, local, and tribal government officials as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993) and Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19,1998), or special consideration of environmental justice related issues under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994) or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). The Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 12612, entitled *Federalism* (52 FR 41685, October 30, 1987). This action directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(b)(4). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

V. Submission to Congress and the Comptroller General

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

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 20, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

§ 180.511 [Amended]

2. In § 180.511, by amending paragraph (b) by changing the date for curcubits from ''12/31/99'' to read ''12/31/00''.

[FR Doc. 99–28637 Filed 11–2–99; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 94–150, 92–51, 87–154; FCC 99–207]

Attribution Ownership Rules

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: This rule announces the effective date of two of the rules published on September 17, 1999. Those rules amended the Commission's rules local public inspection file and filing requirements for broadcast licensees. The Commission amended the filing requirements for broadcasters to require filing of attributable TV LMAs. The Commission also amended the public inspection file rules to require that television time brokerage agreements and radio and television joint sales agreements be kept in commercial broadcast stations' public files.

DATES: Sections 73.3526(e)(14) and (16) and 73.3613(d) and (e) published at 64 FR 50621 (September 17, 1999) are effective on November 16, 1999.

FOR FURTHER INFORMATION CONTACT: Mania K. Baghdadi, Mass Media Bureau, (202) 418–2120.

SUPPLEMENTARY INFORMATION: On October 27, 1999 the Office of Management and Budget (''OMB'') approved the amendments to the public file rules pursuant to OMB Control No. 3060–0214, and on October 27, 1999, OMB approved the amendments to the filing requirements rules pursuant to OMB Control No. 3060–0185. Accordingly, the rules in Sections 73.3526(3)(14) and (16) and 73.3613(d) will be effective on November 16, 1999.

List of Subjects in 47 CFR Part 73

Radio broadcasting, Television broadcasting.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 99–28791 Filed 11–2–99; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 99–1444; MM Docket No. 96–249, RM–8926 and RM–9068; MM Docket No. 96–259, RM–8970, RM–9069, and RM–9070]

FM Broadcasting Services; St. Maries, Moscow, Post Falls, and Troy, Idaho

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In MM Docket No. 96–249, the Chief, Allocations Branch, granted the petition for rulemaking filed by Pentacle Investments, Inc. (RM–8926), set forth in *Notice of Proposed Rulemaking,* 61 FR 66,249, published December 17, 1996, to allot Channel 221A at St. Maries, Idaho. In MM Docket No. 96–259, the Chief denied the petition for rulemaking filed by Darin L. Siebert (RM–8970), set forth in the *Notice of Proposed Rulemaking,* 62 FR 372, published January 3, 1997, to allot Channel 277A at Moscow, Idaho. However, the Chief granted two counterproposals filed in response to this *Notice*: by Rook Broadcasting, Inc. (RM–9069), licensee of Station KCDA(FM), Coeur d'Alene, Idaho, to upgrade its station by substituting Channel 276C1 for Channel 276C2 and to change that station's community of license by modifying it for operation at Post Falls, Idaho, and by Radio Palouse, Inc. (RM–9070) to allot Channel 262A at Troy, Idaho. With this action, the proceeding is terminated.

DATES: Effective November 26, 1999. A filing window for Channel 221A at St. Maries, Idaho and for Channel 262A at Troy, Idaho, will not be opened at this time. Instead, the Commission will address the issue of opening a filing window for this channel in a subsequent order.

FOR FURTHER INFORMATION CONTACT: J. Bertron Withers, Jr., Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the *Report and Order,* MM Dockets 96–249 and 96–259, adopted September 29, 1999, and released October 12, 1999. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center, 445 12th Street, SW, Washington, DC 20554. The complete text of this decision also may be purchased from the Commission's copy contractor, International Transcription Service, 1231 20th Street, N.W., Washington, DC 20036, (202) 857–3800.

Channel 221A can be allotted at St. Maries, Idaho in compliance with the Commission's minimum distance separation requirements without a site restriction at reference coordinates North Latitude 47–18–54 and West Longitude 116–34–30. Channel 276C1 can be allotted at Post Falls, Idaho in compliance with the Commission's minimum distance separation requirements at a site restricted to 6.0 kilometers (3.7 miles) north of the community at coordinates North Latitude 47–39–35 and West Longitude 116–57–12. Channel 262A can be allotted at Troy, Idaho in compliance with the Commission's minimum distance separation requirements at a site restricted to 7.7 kilometers (4.8 miles) east of the community at coordinates North Latitude 46–44–49 and West Longitude 116–39–59. Because St. Maries, Troy, and Post Falls are located within 320 kilometers (199 miles) of the U.S.-Canadian border, concurrence of the Canadian government has been obtained.

The Chief referred back to the Audio Services Division for final disposition, the application filed by Spokane Public Radio, Inc. (BPED–961210MC), which had been treated as a counterproposal (RM–9068) in MM Docket No. 96–249. That application seeks to upgrade Station KSFC(FM) at Spokane by substituting Channel 220C2 for Channel 220A. The Chief also rejected an alternative proposal offered by Spokane Public Radio to allot Channel 278A to St. Maries in lieu of Channel 221A. Since this decision removes the conflict with the application filed by Wilson Creek Communications, L.L.C. (BPH–970227ID), to upgrade Station KVYF(FM) at Wilson Creek by substituting Channel 278C1 for Channel 277C3, processing of this application may be resumed upon finality in this proceeding.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 reads continues to read as follows:

Authority: Sections 47 U.S.C. 154, 303, 334, and 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments, under Idaho, is amended by adding St. Maries, Channel 221A and Troy, Channel 262A and by removing Channel 276C2 at Coeur d'Alene and adding Post Falls, Channel 276C1.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 99–28481 Filed 11–2–99; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 20, and 95

[FCC 99–239; WT Docket No. 98–169]

218–219 MHz Service

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document modifies the regulations governing the licensing of the 218–219 MHz Service to maximize the efficient and effective use of the 218–219 MHz band. The Commission amends the rules to redesignate the 218–219 MHz Service from a strictly private radio service to a service that can be used in common carrier and private operations, extend the license term to ten years, adopt a ''substantial service'' analysis to replace the three- and five-year construction benchmarks, and permit partitioning and disaggregation of spectrum. Additionally, the Commission addresses the constitutional issues raised by Graceba Total Communications, Inc. that are before the Commission on remand from the D.C. Circuit Court of Appeals, together with similar issues raised by other commenters in the proceeding.

DATES: Effective January 3, 2000.

ADDRESSES: Federal Communications Commission, 445 12th Street, S.W., Room 4–C207, Washington, D.C. 20554. A copy of any comments on the information collection contained herein should be submitted to Judy Boley, Federal Communications Commission, 445 12th Street, S.W., Room 1–C804, Washington, D.C. 20554 or via the Internet to jboley@fcc.gov; and to Timothy Fain, OMB Desk Officer, 10236 NEOB, 725 17th Street, N.W., Washington, D.C. 20503 or via the Internet to fain—t@al.eop.gov.

FOR FURTHER INFORMATION CONTACT: Jamison Prime, Shellie Blakeney or Nick Kolovos of the Policy and Rules Branch, Public Safety and Private Wireless Division, Wireless Telecommunications Bureau, (202) 418–0680. For further information concerning the information collection contained in the *Report and Order and Memorandum Opinion and Order,* contact Judy Boley at (202) 418–0215 or via the Internet to jboley@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Report and Order and Memorandum Opinion and Order* in WT Docket No. 98–169, FCC 99–239, adopted September 7, 1999, and released September 10, 1999. The full text of the *Report and Order and Memorandum Opinion and Order* is available for inspection and copying during normal business hours in the FCC Reference Center, 445 12th Street, S.W., Room CY-A257, Washington, D.C. 20554. The full text of the *Report and Order and Memorandum Opinion and Order* may also be purchased from the Commission's copy contractor, International Transcription Services, 1231 20th Street, N.W., Washington, D.C. 20036, telephone (202) 857–3800, facsimile (202) 857–3805. The full text of the *Report and Order and Memorandum Opinion and Order* may also be downloaded at: <http://www.fcc.gov/Bureaus/Wireless/Orders/1999/fcc99239.wp≥. Alternative formats (computer diskette, large print, audio cassette, and Braille) are available to persons with disabilities by contacting Martha Contee at (202) 418–0260, TTY (202) 418–2555, or at mcontee@fcc.gov.

Synopsis of the Report and Order and Memorandum Opinion and Order

The *Report and Order* gives maximum flexibility to 218–219 MHz Service providers, letting them choose their regulatory status. Mobile service providers may elect their regulatory status as either commercial (under the Commercial Mobile Radio Service [CMRS] rules) or private (under the Private Mobile Radio Service rules). Fixed service providers may elect their regulatory status as either common carrier or private, under the conditions set forth in Title III of the Communications Act of 1934, as amended. Regardless of regulatory status, the *Report and Order* further clarifies that both one-and two-way communications are permissible, as well as Response Transmitter Unit-to-Response Transmitter Unit (RTU-to-RTU) communications (in addition to RTU interconnection with the public switched network or any CMRS service). License terms are extended to ten years, regardless of whether the license was obtained by lottery or auction.

Regarding payment options, existing licensees that (a) were current in installment payments (*i.e.*, less than 90 days delinquent) as of March 16, 1998, or (b) had properly filed grace period requests under the former installment payment rules, are eligible for a new payment structure. These eligible licensees may choose between (a) reamortization of principal and interest installment payments over the new ten-year period; (b) amnesty wherein licensees surrender any licenses they choose to the Commission for subsequent auction and, in return, have all of the outstanding debt on those licenses forgiven (together with a refund of any installment payments already made, either in full or applied toward retained licenses, as applicable); or (c) prepayment whereupon licensees may retain or return as many licenses as they desire. Licensees electing the prepayment option, however, must prepay the outstanding principal of any license they wish to retain.

The *Report and Order* also resolves constitutional concerns raised by Graceba Total Communications, Inc. regarding a bidding preference for minorities and women that was used in the 1994 auction for what is now the 218–219 MHz Service. Now, every winning bidder that met the small business qualifications for that auction receives a 25 percent bidding credit, in order to achieve parity with the bidding credit formerly given to minorities and women. Minority-and women-owned winning bidders are not disadvantaged by this action because all such bidders also met the small business qualifications.

Regarding service and construction requirements, the three-and five-year construction benchmarks are replaced by a ''substantial service'' construction requirement, defined as a ''service that is sound, favorable, and substantially above a level of mediocre service which might minimally warrant renewal.'' In addition, the following ''safe harbor'' examples achieve compliance: (a) a demonstration of coverage to twenty percent of the population or land area of the licensed service area; (b) a demonstration of specialized or technologically sophisticated service that does not require a high level of coverage to be of benefit to customers; or (c) a demonstration of service to niche markets or a focus on serving populations outside of areas currently serviced by other licensees. These criteria are to be demonstrated at the time of license renewal.

License transfer restrictions on lotteried licenses are relaxed, though they remain subject to case-by-case,

public interest analysis. Spectrum aggregation restrictions are also relaxed, so that cross-ownership is allowed of both frequency segment A (218.0–218.5 MHz) and frequency segment B (218.5–219.0 MHz) in the same service area. Partitioning and disaggregation are now allowed, and any partitionee/disaggregatee is authorized to hold its license for the remainder of the original licensee's term.

The *Report and Order* revises several technical standards as well, responsive to changes in the original scope of use contemplated for the 218–219 MHz Service. The duty cycle limitation, of a maximum of five seconds per hour for each RTU, is eliminated. The 100 milliwatt power limitation on mobile RTUs is reduced to an average of 4 watts, while maintaining protection for TV Channel 13 reception. Automatic power control restrictions are eliminated. The cell transmitter station (CTS) antenna height/transmitter power ratios are removed, but CTS antennas may still not be taller than is necessary to assure adequate service. The 20 watt maximum effective radiated power for transmitters is retained. Section 95.861(e) of the Commission's Rules continues to provide the framework for resolving interference complaints, with the further requirement that licensees produce an interference control plan that includes, as part of the planning process, an analysis of the proposed system and the methods used to eliminate co- and adjacent channel interference, together with updates to reflect changes in system design or construction.

Finally, the Part 1, Subpart Q standardized auction rules are incorporated by reference, providing a uniform set of competitive bidding rules on issues concerning designated entities, application and payment, competitive bidding design, procedure and timing, and anti-collusion. Small businesses and very small businesses will receive bidding credits consistent with the Part 1 rules, but installment payments will no longer be available as a means of financing winning bids. Small businesses are defined as having average annual gross revenues not to exceed $15 million for the preceding three years, and very small businesses are defined as having average annual gross revenues not to exceed $3 million for the preceding three years.

The *Memorandum Opinion and Order* dismisses a Petition for Reconsideration filed by Interactive America Corporation (IAC). IAC challenged the Commission's failure, prior to the then-planned auction of IAC's defaulted licenses, to disclose IAC's pending appeal (Auction No. 13), but that argument is moot because the Commission subsequently postponed Auction No. 13, and the D.C. Circuit denied IAC's petition for review. IAC also argued that any 218–219 MHz Service auction should be delayed until final rules are adopted. However, this *Report and Order* adopts such rules, rendering that argument moot as well.

Regulatory Flexibility Act Final Analysis

As required by the Regulatory Flexibility Act (RFA),[1] an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the *Amendment of Part 95 of the Commission's Rules to Provide Regulatory Flexibility in the 218–219 MHz Service and Amendment of Part 95 of the Commission's Rules to Allow Interactive Video and Data Service Licensees to Provide Mobile Services, Order, Memorandum Opinion and Order, and Notice of Proposed Rulemaking.*[2] The Commission sought written public comment on the proposals in the *218–219 MHz Flex NPRM,* including comment on the IRFA. This present Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.[3]

I. Need for, and Objectives of, the Report and Order

This rulemaking proceeding was initiated to secure public comment on proposals to maximize the efficient and effective use of spectrum in the 218–219 MHz band, allocated in 1992 to the Interactive Video and Data Service (IVDS) in the Personal Radio Services, now redesignated as the 218–219 MHz Service. In attempting to maximize the use of the 218–219 MHz band, we continue our efforts to improve the efficiency of spectrum use, reduce the regulatory burden on spectrum users, facilitate technological innovation, and provide opportunities for development of competitive new service offerings. The rules adopted in this *Report and Order* are also designed to implement Congress' goal of giving small businesses the opportunity to participate in the provision of spectrum-based services in accordance with Section 309(j) of the Communications Act of 1934, as amended (the Communications Act).[4]

II. Summary of Significant Issues Raised by Public Comments in Response to the Initial Regulatory Flexibility Analysis

No petitions were filed in direct response to the IRFA. In general, commenters and reply commenters supported our proposals to provide additional flexibility in the 218–219 MHz Service. Moreover, many of the commenters and reply commenters were existing 218–219 MHz Service licensees many of whom, as discussed *infra,* qualify as small businesses. These commenters overwhelmingly supported proposals that would permit (1) acquisitions by partitioning or disaggregation; (2) 218–219 MHz Service licensees and applicants to choose regulatory status; and (3) non-defaulting 218–219 MHz Service licensees currently participating in the installment payment plan to elect one of three restructuring plans concerning their outstanding payments, despite the increased reporting requirements that these proposals may entail.

III. Description and Estimate of the Number of Small Entities to Which the Rules Apply

The Regulatory Flexibility Act directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted. The Regulatory Flexibility Act generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act, unless the Commission has developed one or more definitions that are appropriate for its activities.[5] 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

[1] *See* 5 U.S.C. 603. The RFA, *see* 5 U.S.C. 601 *et. seq.,* has been amended by the Contract With America Advancement Act of 1996, Public Law Number 104–121, 110 Stat. 847 (1996) (CWAAA). Title II of the CWAAA is the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).

[2] *Amendment of Part 95 of the Commission's Rules to Provide Regulatory Flexibility in the 218–219 MHz Service and Amendment of Part 95 of the Commission's Rules to Allow Interactive Video and Data Service Licensees to Provide Mobile Services (proceeding terminated), Order, Memorandum Opinion and Order, and Notice of Proposed Rulemaking,* 63 FR 52215 (Sept. 30, 1998), 13 FCC Rcd 19064, 19101 (1998) (*218–219 MHz Flex NPRM*).

[3] *See* 5 U.S.C. 604.

[4] 47 U.S.C. 257, 309(j).

[5] U.S.C. 601(3) (incorporating by reference the definition of ''small business concern'' in 15 U.S.C. 632). 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 Small Business Administration 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**.''

established by the SBA.[6] A small organization is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' [7] Below, we further describe and estimate the number of small entity licensees and regulatees that may be affected by the proposed rules, if adopted.

The rules adopted in this *Report and Order* affect a number of small entities who are either licensees, or who may choose to become applicants for licenses, in the 218–219 MHz Service. Such entities fall into two categories: (1) those using the 218–219 MHz Service for providing interactivity capabilities in conjunction with broadcast services; and (2) those using the 218–219 MHz Service to operate other types of wireless communications services with a wide variety of uses, such as commercial data applications and two-way telemetry services. Theoretically, an entity could fall into both categories. The spectrum uses in the two categories differ markedly.

With respect to the first category, the provision of interactivity capabilities in conjunction with broadcast services could be described as a wireless provider of subscription television service. The SBA's rules applicable to subscription television services define small entities as those with annual gross revenues of $11 million or less.[8] In the *Competitive Bidding Tenth Report and Order*, we extended special competitive bidding provisions to small businesses with annual gross revenues that are not more than $15 million, and additional benefits to very small businesses with annual gross revenues that are not more than $3 million.[9] On January 6, 1998, the SBA approved of the small business size standards established in the *Competitive Bidding Tenth Report and Order*.[10]

The Commission's estimate of the number of small business entities operating in the 218–219 MHz band for interactivity capabilities with television viewers begins with the 1992 Bureau of Census report on businesses listed under SIC Code 4841, subscription television services, which is the most recent information available. The total number of entities under this category is 1,788.[11] There are 1,463 companies in the 1992 Census Bureau report which are categorized as small businesses providing cable and pay TV services.[12] We know that many of these businesses are cable and television service businesses, rather than businesses operating in the 218–219 MHz band. We also know that, to date, we have issued 612 licenses in the 218–219 MHz Service. Therefore, the number of small entities currently providing interactivity capability to television viewers in the 218–219 MHz Service which will be subject to the rules will be less than 612.

With respect to the second category, neither the Commission nor the SBA has developed a specific definition of small entities applicable to 218–219 MHz band licensees that would provide wireless communications services other than that described above. Generally, the applicable definition of a small entity in this instance appears to be the definition under the SBA rules applicable to establishments primarily engaged in furnishing telegraph and other message communications, SIC Code 4822. This definition provides that a small entity is an entity with annual receipts of $5 million or less.[13] The 1992 Census data, which is the most recent information available, indicates that of the 286 firms under this category, 247 had annual receipts of $4.999 million or less.[14]

The first auction of 218–219 MHz spectrum resulted in 170 entities winning licenses for 594 Metropolitan Statistical Area (MSA) licenses. Of the 594 licenses, 557 were won by entities qualifying as a small business. For that auction, we defined a small business as an entity, together with its affiliates, that has no more than a $6 million net worth and, after federal income taxes (excluding any carry over losses), has no more than $2 million in annual profits each year for the previous two years.[15] We cannot estimate, however, the number of licenses that will be won by entities qualifying as small or very small businesses under our rules in future auctions of 218–219 MHz spectrum. Given the success of small businesses in the previous auction, and the above discussion regarding the prevalence of small businesses in the subscription television services and message communications industries, we assume for purposes of this FRFA that in future auctions, all of the licenses may be awarded to small businesses, which would be affected by the rule changes we propose.

IV. Description of Projected Reporting, Recordkeeping and Other Compliance Requirements

The final rules adopted in this *Report and Order* alter the reporting and recordkeeping requirements for a number of small business entities. Specifically, (1) 218–219 MHz Service licensees will not be required to file a license renewal application after five years from the date of grant of the license, but will be required to file a license renewal application after ten years after the date of grant of the license; (2) 218–219 MHz Service licensees will not be required to file construction reports at specified intervals after initial licensure, but will be obligated to demonstrate that they are providing ''substantial service'' as a condition for renewal of their license; and (3) acquisitions by partitioning or disaggregation will be treated as assignments of a license and parties will be required to comply with the 218–219 MHz Service licensing requirements. In addition small business may make elections under the final rules that will alter their reporting and recordkeeping requirements. Specifically, (1) 218–219 MHz Service licensees and applicants may choose to elect regulatory status (common carrier, private, commercial mobile radio service, private mobile radio service) and file appropriate documentation coincident with the regulatory status elected; (2) non-defaulting 218–219 MHz Service licensees currently participating in the installment payment plan may elect one of three restructuring plans concerning their outstanding payments; and (3) 218–219 MHz Service licensees electing to continue making installment payments may be required to execute loan documents as a condition of the

[6] Small Business Act, 15 U.S.C. 632 (1996).

[7] 5 U.S.C. 601(4).

[8] 13 CFR 121.201, SIC Code 4841.

[9] Implementation of Section 309(j) of the Communications Act, Competitive Bidding, PP Docket No. 93–253, *Tenth Report and Order*, 61 FR 60198 (Nov. 27, 1996), 11 FCC Rcd 19974, 19981–85 (1996) (*Competitive Bidding Tenth Report and Order*), *recon. pending.*

[10] *See* Letter to Daniel B. Phythyon, Chief, WTB, from Aida Alverez, Administrator, SBA, Dated Jan. 6, 1998.

[11] U.S. Small Business Administration 1992 Economic Census Industry and Enterprise Report, Table 2D, SIC Code 4841 (Bureau of the Census data adapted by the Office of Advocacy of the U.S. Small Business Administration).

[12] The Census table divides those companies by the amount of annual receipts. There is a dividing point at companies with annual receipts of $10 million. The next increment is annual receipts of $17 million, a category that greatly exceeds the SBA definition of small businesses that provide subscription television services. However, there are 17 firms in this category, with revenues between $10–$17 million. Approximately 1,480 SIC Code 4841 category firms have annual gross receipts of $15 million or less. Only a small fraction of those 1,480 firms provide IVDS.

[13] 13 CFR 121.201, SIC Code 4822.

[14] 1992 Economic Census Industry and Enterprise Receipts Size Report, U.S. Bureau of the Census, U.S. Department of Commerce, Table 2D, SIC Code 4822 (industry data prepared by the Census Bureau under contract to the U.S. SBA Office of Advocacy).

[15] Implementation of Section 309(j) of the Communications Act, Competitive Bidding, PP Docket No. 93–253, *Fourth Report and Order*, 59 FR 24947 (May 13, 1994), 9 FCC Rcd 2330, 2336 (1994).

reamortization of its installment payment plan under the revised ten-year term.

V. Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

In response to general comments filed in this proceeding we have adopted final rules designed to maximize opportunities for participation by, and growth of, small businesses in providing wireless services. Specifically, we expect that the extension of license terms from five to ten years and allowing partitioning and disaggregation of licenses, will specifically assist small businesses. We adopted a plan that provided for a reamortization of installment payment debt in conjunction with the extension of license term that differed from our original proposal in specific response to concerns raised in comments and reply comments. Commenters noted that our original proposal would have required licensees to pay two years worth of principal payments, as well as the accrued interest, in a lump sum, within ninety days of the *Report and Order* to retain their licenses, and claimed that such a plan would not allow licensees in particular, small businesses sufficient time to make new capital arrangements. Commenters proposed a variety of means of providing relief beyond that which we proposed in the *218–219 MHz Flex NPRM*. We note that some of these proposals such as a ten-year payout schedule that would be entirely interest-free [16] may have resulted in greater relief than that provided by the reamortization procedures adopted in the *Report and Order*.

We also believe that our proposals regarding permissible uses of 218–219 MHz Service, liberalization of construction requirements and technical restrictions, and elimination of the cross-ownership restriction, will make expansion of 218–219 MHz Service operations easier, and this flexibility assists all licensees, including small business licensees. We considered proposals by small business interests to eliminate (instead of liberalize) technical restrictions for the service,[17] but concluded that limited technical restrictions are still necessary in order to protect other licensees offering services (such as TV Channel 13 broadcasting) operating in or in close proximity of the 218–219 MHz band. We further believe that by retroactively applying a bidding credit for small businesses to the IVDS auction and by adopting our general auction rules that provide for small business bidding credits, we will maximize opportunities for participation by, and growth of, small businesses in the 218–219 MHz Service. For these reasons, we did not consider any significant alternatives to our proposals to minimize significant economic impact on small entities, nor were any significant alternatives of this nature proposed by commenters and reply commenters.

[16] *See* CRSPI Reply Comments at 2.

[17] *See, e.g.,* Petty Comments at 1.

Report to Congress

The Commission will send a copy of the *Report and Order,* including this FRFA, in a report to be sent to Congress pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996, *see* 5 U.S.C. 801(a)(1)(A). In addition, the Commission will send a copy of the *Report and Order,* including FRFA, to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the *Report and Order* and FRFA (or summaries thereof) will also be published in the **Federal Register**. *See* 5 U.S.C. 604(b).

List of Subjects in 47 CFR Parts 1, 20 and 95

Communications equipment, Radio, Reporting and recordkeeping requirements.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

Rule Changes

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR parts 1, 20 and 95 as follows:

PART 1—PRACTICE AND PROCEDURE

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

Authority: 15 U.S.C. 79 *et seq.*; 47 U.S.C. 151, 154(i), 154(j), 155, 225, and 303(r).

2. Section 1.2105 is amended by revising paragraph (a)(2)(xi) is to read as follows:

§ 1.2105 Bidding application and certification procedures; prohibition of collusion.

(a) * * *

(2) * * *

(xi) For C block and 218–219 MHz Service applicants, an attached statement made under penalty of perjury indicating whether or not the applicant has ever been in default on any Commission licenses or has ever been delinquent on any non-tax debt owed to any Federal agency.

* * * * *

PART 20—COMMERCIAL MOBILE RADIO SERVICES

3. The authority citation for Part 20 continues read as follows:

Authority: 47 U.S.C. 154, 160, 251–254, 303, and 332 unless otherwise noted.

4. Section 20.9 is amended by redesignating paragraph (a)(13) as (a)(14), redesignating paragraph (a)(12) as (a)(13) and by adding a new paragraph (a)(12) to read as follows:

§ 20.9 Commercial mobile radio services.

(a) * * *

(12) Mobile operations in the 218–219 MHz Service (part 95, subpart F of this chapter) that provide for-profit interconnected service to the public;

* * * * *

PART 95—PERSONAL RADIO SERVICES

5. The authority citation for Part 95 continues to read as follows:

Authority: Secs. 4, 303, 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 303.

6. Section 95.1 is amended be revising paragraph (b) to read as follows:

§ 95.1 The General Mobile Radio Service (GMRS).

* * * * *

(b) The 218–219 MHz Service is a two-way radio service authorized for system licensees to provide communication service to subscribers in a specific service area. The rules for this service are contained in subpart F of this part.

Subpart F Heading—[Revised]

7. The heading for subpart F is revised to read, ''218–219 MHz Service.''

8. Section 95.801 is revised to read as follows:

§ 95.801 Scope.

This subpart sets out the regulations governing the licensing and operation of a 218–219 MHz system. This subpart supplements Part 1, Subpart F of this chapter, which establishes the requirements and conditions under which commercial and private radio stations may be licensed and used in the Wireless Telecommunications Services. The provisions of this subpart contain additional pertinent information for current and prospective licensees specific to the services governed by this part 95.

9. Sections 95.803 (a) and (b) and the section heading are revised to read as follows:

§ 95.803 218–219 MHz Service description.

(a) The 218–219 MHz Service is a two-way radio service authorized for system licensees to provide communication service to subscribers in a specific service area.

(b) The components of each 218–219 MHz Service system are its administrative apparatus, its response transmitter units (RTUs), and one or more cell transmitter stations (CTSs). RTUs may be used in any location within the service area.

* * * * *

10. Section 95.805 is revised to read as follows:

§ 95.805 Permissible communications.

A 218–219 MHz Service system may provide any fixed or mobile communications service to subscribers within its service area on its assigned spectrum, consistent with the Commission's rules and the regulatory status of the system to provide services on a common carrier or private basis.

11. Section 95.807 is added to read as follows:

§ 95.807 Requesting regulatory status.

(a) Authorizations for systems in the 218–219 MHz Service will be granted to provide services on a common carrier basis or a private basis, or on both a common carrier and private basis in a single authorization.

(1) *Initial applications.* An applicant will specify on FCC Form 601 if it is requesting authorization to provide services on a common carrier basis, a private basis, or on both a common carrier and private basis.

(2) *Amendment of pending applications.* Any pending application may be amended to:

(i) Change the carrier status requested; or

(ii) Add to the pending request in order to obtain both common carrier and private status in a single license.

(3) *Modification of license.* A licensee may modify a license to:

(i) change the carrier status authorized; or

(ii) add to the status authorized in order to obtain both common carrier and private status in a single license. Applications to change, or add to, carrier status in a license must be submitted on FCC Form 601 in accordance with § 1.1102 of this chapter.

(4) *Pre-existing licenses.* Licenses issued before [effective date of rules] are authorized to provide services on a private basis. Licensees may modify this initial status pursuant to paragraph (a)(3) of this section.

(b) An applicant or licensee may submit a petition at any time requesting clarification of the regulatory status required to provide a specific communications service.

12. Section 95.811 is amended by revise paragraphs (b), (c), and (d) to read as follows:

§ 95.811 License requirements.

* * * * *

(b) A CTS must be individually licensed to the 218–219 MHz Service licensee for the service area in which the CTS is located in accordance with part 1, subpart F of this chapter if it:

(1) Is in the vicinity of certain receiving locations (see § 1.924 of this chapter);

(2) May have significant environmental effect (see part 1, subpart I of this chapter);

(3) Is part of an antenna structure that requires notification to the Federal Aviation Administration (see part 17, subpart B of this chapter); or

(4) Has an antenna the tip of which exceeds:

(i) 6.1 meters (20 feet) above ground level; or

(ii) 6.1 meters (20 feet) above the top of an existing man-made structure (other than an antenna structure) on which it is mounted.

(c) All CTSs not meeting the licensing criteria under paragraph (b) of this section are authorized under the 218–219 MHz Service system license.

(d) Each component RTU in a 218–219 MHz Service system is authorized under the system license or if associated with an individually licensed CTS, under that CTS license.

13. Section 95.812 is added to read as follows:

§ 95.812 License term.

(a) The term of each 218–219 MHz Service system license is ten years from the date of original issuance or renewal.

(b) Licenses for individually licensed CTSs will be issued for a period running concurrently with the license of the associated 218–219 MHz Service system with which it is licensed.

14. Section 95.813 is amended by removing paragraph (c) and by revising paragraph (b) to read as follows:

§ 95.813 License eligibility.

* * * * *

(b) An entity that loses its 218–219 MHz Service authorization due to failure to meet the construction requirements specified in § 95.833 of this part may not apply for a 218–219 MHz Service system license for three years from the date the Commission takes final action affirming that the 218–219 MHz Service license has been canceled.

15. Section 95.815 is amended by revising paragraphs (a) and (b) to read as follows:

§ 95.815 License application.

(a) In addition to the requirements of part 1, subpart F of this chapter, each application for a 218–219 MHz Service system license must include a plan analyzing the co- and adjacent channel interference potential of the proposed system, identifying methods being used to minimize this interference, and showing how the proposed system will meet the service requirements set forth in § 95.831 of this part. This plan must be updated to reflect changes to the 218–219 MHz Service system design or construction.

(b) In addition to the requirements of part 1, subpart F of this chapter, each request by a 218–219 MHz Service system licensee to add, delete, or modify technical information of an individually licensed CTS (*see* § 95.811(b) of this part) must include a description of the system after the proposed addition, deletion, or modifications, including the population in the service area, the number of component CTSs, and an explanation of how the system will satisfy the service requirements specified in § 95.831 of this part.

* * * * *

16. Section 95.816 is revised to read as follows:

§ 95.816 Competitive bidding proceedings.

(a) Mutually exclusive initial applications for 218–219 MHz Service system licenses are subject to competitive bidding procedures. The procedures set forth in part 1, Subpart Q of this chapter will apply unless otherwise provided in this part.

(b) *Installment payments.* Eligible Licensees that elect resumption pursuant to Amendment of part 95 of the Commission's Rules to Provide Regulatory Flexibility in the 218–219 MHz Service, *Report and Order and Memorandum Opinion and Order,* FCC 99–239 (released September 10, 1999) may continue to participate in the installment payment program. Eligible Licensees are those that were current in installment payments (*i.e.* less than ninety days delinquent) as of March 16, 1998, or those that had properly filed grace period requests under the former installment payment rules. All unpaid interest from grant date through election date will be capitalized into the principal as of Election Day creating a new principal amount. Installment payments must be made on a quarterly basis. Installment payments will be calculated based on new principal

amount as of Election Day and will fully amortize over the remaining term of the license. The interest rate will equal the rate for five-year U.S. Treasury obligations at the time of licensing.

(c) *Eligibility for small business provisions.*

(1) A small business is an entity that, together with its affiliates and controlling interests, has average gross revenues not to exceed $15 million for the preceding three years.

(2) A very small business is an entity that, together with its affiliates and controlling interests, has average gross revenues not to exceed $3 million for the preceding three years.

(3) For purposes of determining whether an entity meets either of the definitions set forth in paragraph (b)(1) or (b)(2) of this section, the gross revenues of the entity, its affiliates, and controlling interests shall be considered on a cumulative basis and aggregated.

(4) Where an applicant (or licensee) cannot identify controlling interests under the standards set forth in this section, the gross revenues of all interest holders in the applicant, and their affiliates, will be attributable.

(5) A consortium of small businesses (or a consortium of very small businesses) is a conglomerate organization formed as a joint venture between or among mutually independent business firms, each of which individually satisfies the definition in paragraph (b)(1) of this section (or each of which individually satisfies the definition in paragraph (b)(2) of this section). Where an applicant or licensee is a consortium of small businesses (or very small businesses), the gross revenues of each small business (or very small business) shall not be aggregated.

(d) *Controlling interest.*

(1) For purposes of this section, controlling interests includes individuals or entities with *de jure* and *de facto* control of the applicant. *De jure* control is greater than 50 percent of the voting stock of a corporation, or in the case of a partnership, the general partner. *De facto* control is determined on a case-by-case basis. An entity must disclose its equity interest and demonstrate at least the following indicia of control to establish that it retains *de facto* control of the applicant:

(i) The entity constitutes or appoints more than 50 percent of the board of directors or management committee;

(ii) The entity has authority to appoint, promote, demote, and fire senior executives that control the day-to-day activities of the licensee; and

(iii) the entity plays an integral role in management decisions.

(2) *Calculation of certain interests.*

(i) Ownership interests shall be calculated on a fully diluted basis; all agreements such as warrants, stock options and convertible debentures will generally be treated as if the rights thereunder already have been fully exercised.

(ii) Partnership and other ownership interests and any stock interest equity, or outstanding stock, or outstanding voting stock shall be attributed as specified below.

(iii) Stock interests held in trust shall be attributed to any person who holds or shares the power to vote such stock, to any person who has the sole power to sell such stock, and, to any person who has the right to revoke the trust at will or to replace the trustee at will. If the trustee has a familial, personal, or extra-trust business relationship to the grantor or the beneficiary, the grantor or beneficiary, as appropriate, will be attributed with the stock interests held in trust.

(iv) Non-voting stock shall be attributed as an interest in the issuing entity.

(v) Limited partnership interests shall be attributed to limited partners and shall be calculated according to both the percentage of equity paid in and the percentage of distribution of profits and losses.

(vi) Officers and directors of an entity shall be considered to have an attributable interest in the entity. The officers and directors of an entity that controls a licensee or applicant shall be considered to have an attributable interest in the licensee or applicant.

(vii) Ownership interests that are held indirectly by any party through one or more intervening corporations will be determined by successive multiplication of the ownership percentages for each link in the vertical ownership chain and application of the relevant attribution benchmark to the resulting product, except that if the ownership percentage for an interest in any link in the chain exceeds 50 percent or represents actual control, it shall be treated as if it were a 100 percent interest.

(viii) Any person who manages the operations of an applicant or licensee pursuant to a management agreement shall be considered to have an attributable interest in such applicant or licensee if such person, or its affiliate pursuant to § 1.2110(b)(4) of this chapter, has authority to make decisions or otherwise engage in practices or activities that determine, or significantly influence:

(A) The nature or types of services offered by such an applicant or licensee;

(B) The terms upon which such services are offered; or

(C) The prices charged for such services.

(ix) Any licensee or its affiliate who enters into a joint marketing arrangement with an applicant or licensee, or its affiliate, shall be considered to have an attributable interest, if such applicant or licensee, or its affiliate, has authority to make decisions or otherwise engage in practices or activities that determine, or significantly influence:

(A) The nature or types of services offered by such an applicant or licensee;

(B) The terms upon which such services are offered; or

(C) The prices charged for such services.

(e) *Bidding credits.* A winning bidder that qualifies as a small business or a consortium of small businesses as defined in this subsection may use the bidding credit specified in § 1.2110(e)(2)(ii) of this chapter. A winning bidder that qualifies as a very small business or a consortium of very small businesses as defined in this subsection may use the bidding credit specified in accordance to § 1.2110(e)(2)(i) of this chapter.

(f) Winning bidders in Auction No. 1, which took place on July 28–29, 1994, that, at the time of that auction, met the qualifications under the Commission's rules then in effect, for small business status will receive a twenty-five percent bidding credit pursuant to Amendment of Part 95 of the Commission's Rules to Provide Regulatory Flexibility in the 218–219 MHz Service, *Report and Order and Memorandum Opinion and Order,* FCC 99–239 (released September 10, 1999).

17. Section 95.819 is revised to read as follows:

§ 95.819 License transferability.

(a) A 218–219 MHz Service system license acquired through competitive bidding procedures (including licenses obtained in cases of no mutual exclusivity), together with all of its component CTS licenses, may be transferred, assigned, sold, or given away only in accordance with the provisions and procedures set forth in 47 CFR 1.2111.

(b) A 218–219 MHz Service system license obtained through random selection procedures, together with all of its component CTS licenses, may be transferred, assigned, sold, or given away, to any other entity in accordance with the provisions and procedures set forth in § 1.948 of this chapter.

(c) If the transfer, assignment, sale, or gift of a license is approved, the new

licensee is held to the construction requirements set forth in § 95.833 of this part.

18. Section 95.823 is added to read as follows:

§ 95.823 Geographic partitioning and spectrum disaggregation.

(a) *Eligibility*. Parties seeking Commission approval of geographic partitioning or spectrum disaggregation of 218–219 MHz Service system licenses shall request an authorization for partial assignment of license pursuant to § 1.948 of this chapter.

(b) *Technical standards.*

(1) *Partitioning.* In the case of partitioning, requests for authorization of partial assignment of a license must include, as attachments, a description of the partitioned service area and a calculation of the population of the partitioned service area and the licensed geographic service area. The partitioned service area shall be defined by coordinate points at every 3 seconds along the partitioned service area unless an FCC-recognized service area (*i.e.* Economic Areas) is utilized or county lines are followed. The geographic coordinates must be specified in degrees, minutes, and seconds, to the nearest second of latitude and longitude, and must be based upon the 1983 North American Datum (NAD83). In the case where an FCC-recognized service area or county lines are utilized, applicants need only list the specific area(s) (through use of FCC designations or county names) that constitute the partitioned area.

(2) *Disaggregation*. Spectrum maybe disaggregated in any amount.

(3) *Combined partitioning and disaggregation*. The Commission will consider requests for partial assignments of licenses that propose combinations of partitioning and disaggregation.

(c) *Provisions applicable to designated entities.*

(1) *Unjust enrichment.* See § 1.2111(e) of this chapter.

(2) *Parties not qualified for installment payment plans.*

(i) When a winning bidder (partitionor or disaggregator) that elected to pay for its license through an installment payment plan partitions its license or disaggregates spectrum to another party (partitionee or disaggregatee) that would not qualify for an installment payment plan, or elects not to pay for its share of the license through installment payments, the outstanding principal balance owed by the partitionor or disaggregator shall be apportioned according to § 1.2111(e)(3) of this chapter. The partitionor or disaggregator is responsible for accrued and unpaid interest through and including the consummation date.

(ii) The partitionee or disaggregatee shall, as a condition of the approval of the partial assignment application, pay its entire *pro rata* amount of the outstanding principal balance on or before the consummation date. Failure to meet this condition will result in cancellation of the grant of the partial assignment application.

(iii) The partitionor or disaggregator shall be permitted to continue to pay its *pro rata* share of the outstanding balance and, if applicable, shall receive loan documents evidencing the partitioning and disaggregation. The original interest rate, established pursuant to § 1.2110(f)(3)(i) of this chapter at the time of the grant of the initial license in the market, shall continue to be applied to the partitionor's or disaggregator's portion of the remaining government obligation.

(iv) A default on the partitionor's or disaggregator's payment obligation will affect only the partitionor's or disaggregator's portion of the market.

(3) Parties qualified for installment payment plans.

(i) Where both parties to a partitioning or disaggregation agreement qualify for installment payments, the partitionee or disaggregatee will be permitted to make installment payments on its portion of the remaining government obligation.

(ii) Each party may be required, as a condition to approval of the partial assignment application, to execute loan documents agreeing to pay its *pro rata* portion of the outstanding principal balance due, as apportioned according to § 1.2111(e)(3) of this chapter, based upon the installment payment terms for which it qualifies under the rules. Failure by either party to meet this condition will result in the automatic cancellation of the grant of the partial assignment application. The interest rate, established pursuant to § 1.2110(f)(3)(i) of this chapter at the time of the grant of the initial license in the market, shall continue to be applied to both parties' portion of the balance due. Each party will receive a license for its portion of the partitioned market.

(iii) A default on an obligation will affect only that portion of the market area held by the defaulting party.

(d) *Construction requirements.*

(1) *Partitioning.* Partial assignors and assignees for license partitioning have two options to meet construction requirements. Under the first option, the partitionor and partitionee would each certify that they will independently satisfy the applicable construction requirements set forth in § 95.833 of this part for their respective partitioned areas. If either licensee failed to meet its requirement in § 95.833 of this part, only the non-performing licensee's renewal application would be subject to dismissal. Under the second option, the partitionor certifies that it has met or will meet the requirement in § 95.833 of this part for the entire market. If the partitionor fails to meet the requirement in § 95.833 of this part, however, only its renewal application would be subject to forfeiture at renewal.

(2) *Disaggregation*. Partial assignors and assignees for license disaggregation have two options to meet construction requirements. Under the first option, the disaggregator and disaggregatee would certify that they each will share responsibility for meeting the applicable construction requirements set forth in § 95.833 of this part for the geographic service area. If parties choose this option and either party fails to do so, both licenses would be subject to forfeiture at renewal. The second option would allow the parties to agree that either the disaggregator or the disaggregatee would be responsible for meeting the requirement in § 95.833 of this part for the geographic service area. If parties choose this option, and the party responsible for meeting the construction requirement fails to do so, only the license of the non-performing party would be subject to forfeiture at renewal.

(3) All applications requesting partial assignments of license for partitioning or disaggregation must include the above-referenced certification as to which of the construction options is selected.

(4) Responsible parties must submit supporting documents showing compliance with the respective construction requirements within the appropriate construction benchmarks set forth in § 95.833 of this part.

19. Section 95.831 is revised to read as follows:

§ 95.831 Service requirements.

Subject to the initial construction requirements of § 95.833 of this subpart, each 218–219 MHz Service system license must demonstrate that it provides substantial service within the service area. Substantial service is defined as a service that is sound, favorable, and substantially above a level of service which might minimally warrant renewal.

20. Section 95.833 is revised to read as follows:

§ 95.833 Construction requirements.

(a) Each 218–219 MHz Service licensee must make a showing of

''substantial service'' within ten years of the license grant. A ''substantial service'' assessment will be made at renewal pursuant to the provisions and procedures contained in § 1.949 of this chapter.

(b) Each 218–219 MHz Service licensee must file a report to be submitted to inform the Commission of the service status of its system. The report must be labeled as an exhibit to the renewal application. At minimum, the report must include:

(1) A description of its current service in terms of geographic coverage and population served;

(2) An explanation of its record of expansion, including a timetable of new construction to meet changes in demand for service;

(3) A description of its investments in its 218–219 MHz Service systems;

(4) A list, including addresses, of all component CTSs constructed; and

(5) Copies of all FCC orders finding the licensee to have violated the Communications Act or any FCC rule or policy; and a list of any pending proceedings that relate to any matter described in this paragraph.

(c) Failure to demonstrate that substantial service is being provided in the service area will result in forfeiture of the license, and will result in the licensee's ineligibility to apply for 218–219 MHz Service licenses for three years from the date the Commission takes final action affirming that the 218–219 MHz Service license has been canceled pursuant to § 95.813 of this part.

21. Section 95.853 is revised to read as follows:

§ 95.853 Frequency segments.

There are two frequency segments available for assignment to the 218–219 MHz Service in each service area. Frequency segment A is 218.000–218.500 MHz. Frequency segment B is 218.501–219.000 MHz.

22. Section 95.855 is revised to read as follows:

§ 95.855 Transmitter effective radiated power limitation.

The effective radiated power (ERP) of each CTS and RTU shall be limited to the minimum necessary for successful communications. No CTS or fixed RTU may transmit with an ERP exceeding 20 watts. No mobile RTU may transmit with an ERP exceeding 4 watts.

23. Section 95.859 is amended by revising paragraph (a) and by removing and reserving paragraph (b) to read as follows:

§ 95.859 Antennas.

(a) The overall height from ground to topmost tip of the CTS antenna shall not exceed the height necessary to assure adequate service. Certain CTS antennas must be individually licensed to the 218–219 MHz System licensee (see § 95.811(b) of this part) and the antenna structures of which they are a part must be registered with the Commission (*see* part 17 of this chapter).

24. Section 95.861 is revised to read as follows:

§ 95.861 Interference.

(a) When a 218–219 MHz Service system suffers harmful interference within its service area or causes harmful interference to another 218–219 MHz Service system, the licensees of both systems must cooperate and resolve the problem by mutually satisfactory arrangements. If the licensees are unable to do so, the Commission may impose restrictions including, but not limited to, specifying the transmitter power, antenna height or area, duty cycle, or hours of operation for the stations concerned.

(b) The use of any frequency segment (or portion thereof) at a given geographical location may be denied when, in the judgment of the Commission, its use in that location is not in the public interest; the use of a frequency segment (or portion thereof) specified for the 218–219 MHz Service system may be restricted as to specified geographical areas, maximum power, or other operating conditions.

(c) A 218–219 MHz Service licensee must provide a copy of the plan required by § 95.815(b) of this part to every TV Channel 13 station whose Grade B predicted contour overlaps the licensed service area for the 218–219 MHz Service system. The 218–219 MHz Service licensee must send the plan to the TV Channel 13 licensee(s) within 10 days from the date the 218–219 MHz Service licensee submits the plan to the Commission, and the 218–219 MHz Service licensee must send updates to this plan to the TV Channel 13 licensee(s) within 10 days from the date that such updates are filed with the Commission pursuant to § 95.815(b) of this part.

(d) Each 218–219 MHz Service system licensee must provide upon request, and install free of charge, an interference reduction device to any household within a TV Channel 13 station Grade B predicted contour that experiences interference due to a component CTS or RTU.

(e) Each 218–219 MHz Service system licensee must investigate and eliminate harmful interference to television broadcasting and reception, from its component CTSs and RTSs, within 30 days of the time it is notified in writing, by either an affected television station, an affected viewer, or the Commission, of an interference complaint. Should the licensee fail to eliminate the interference within the 30-day period, the CTS(s) or RTU(s) causing the problem(s) must discontinue operation.

(f) The boundary of the 218–219 MHz Service system, as defined in its authorization, is the limit of interference protection for that 218–219 MHz Service system.

§ 95.863 [Removed]

25. Section 95.863 is removed.

[FR Doc. 99–27874 Filed 11–2–99; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 101

[FCC 99–179–ET Docket No. 95–183]

37.0–38.6 GHz and 38.6–40.0 GHz Bands

AGENCY: Federal Communications Commission.

ACTION: Final rule; correction.

SUMMARY: The Federal Communications Commission published rules in the **Federal Register** concerning the service rules for the 37.0–38.6 GHz and 38.6–40.0 GHz bands. This document makes corrections to those rules.

DATES: Effective October 22, 1999.

FOR FURTHER INFORMATION CONTACT: Jennifer Burton, Wireless Telecommunications Bureau, Public Safety and Private Wireless Division, Policy and Rules Branch, (202) 418–0680. *TTY:* (202) 418–7233.

SUPPLEMENTARY INFORMATION:

Background

The Commission inadvertently included typographical errors in certain final rules published in the **Federal Register** dated August 23, 1999, (64 FR 45891). This correction amends those typographical errors. This correction also amends § 101.56(i) to comport with the Commission's decision in the *Memorandum Opinion and Order* to allow 39 GHz licensees that obtain a bidding credit at auction to subsequently partition or disaggregate subject to the Commission's unjust enrichment rules, the substance of which was not reflected in the final regulations.

List of Subjects in 47 CFR Part 101

Radio, Communications equipment.

Federal Communications Commission.

Magalie Roman Sales,

Secretary.

Rule Changes

For the reasons set forth in the preamble, amend part 101 of title 47 of the Code of Federal Regulations as follows:

PART 101—FIXED MICROWAVE SERVICES

1. The authority citation for Part 101 continues to read as follows:

Authority: Sec. 4 and 303 of the Communications Act of 1934, as amended, 47 U.S.C. Sections 154 and 303, unless otherwise noted.

2. In § 101.56, paragraphs (d)(1) and (d)(2) are redesignated as paragraphs (d) and (e) and paragraph (i) is revised to read as follows:

§ 101.56 Partitioned Services Areas (PSAs) and Disaggregate Spectrum.

* * * * *

(i) Licensees, including those using bidding credits in a competitive bidding procedure, shall have the authority to partition service areas or disaggregate spectrum. Licensees who utilize bidding credits must comply with the requirements set forth in § 1.2111 (d) and (e).

* * * * *

§ 101.147 Frequency assignments.

3. In § 101.147, paragraph (u)(2) is redesignated as (v)(2).

[FR Doc. 99–28482 Filed 11–2–99; 8:45 am]

BILLING CODE 6712–01–M

Proposed Rules

Federal Register
Vol. 64, No. 212
Wednesday, November 3, 1999

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

Food and Nutrition Service

7 CFR Part 278

[Amendment No. 380]

RIN 0584–AC05

Food Stamp Program: Retailer Application Processing

AGENCY: Food and Nutrition Service, USDA.

ACTION: Proposed rule.

SUMMARY: This action proposes to revise the initial application processing timeframe for retail food stores and wholesale food concerns that apply for authorization to accept and redeem food stamp benefits and clarify verification requirements. In addition to lengthening the time allowed for processing applications, this rule would clarify Food and Nutrition Service (FNS) regulatory authority to require specific documentation from an applicant to verify a firm's eligibility. This rule will also incorporate two provisions of the Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA) of 1996, related to the collection of tax information from applicant firms or from firms being reauthorized in the program, and the provision of written permission for FNS to verify such information with appropriate agencies. These changes are being proposed as a means to ensure that only legitimate food stores are allowed to participate in the Food Stamp Program.

DATES: Comments must be received on or before January 3, 2000 to be assured of consideration.

ADDRESSES: Comments should be submitted to Karen J. Walker, Chief, Redemption Management Branch, Benefit Redemption Division, Food and Consumer Service, USDA, 3101 Park Center Drive, Alexandria, Virginia 22302. Comments may also be data faxed to the attention of Ms. Walker at (703) 605–0232. All written comments will be open for public inspection during regular business hours (8:30 a.m. to 5 p.m., Monday through Friday) at 3101 Park Center Drive, Alexandria, Virginia, Room 706.

FOR FURTHER INFORMATION CONTACT: Questions regarding the proposed rulemaking should be addressed to Ms. Walker at the above address or by telephone at (703) 305–2418.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This proposed rule has been determined to be significant for purpose of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

Executive Order 12372

The Food Stamp Program is listed in the Catalog of Federal Domestic Assistance under 10.551. For the reasons set forth in the final rule in 7 CFR 3015, Subpart V and related Notice (48 FR 29115), this Program is excluded from the scope of Executive Order 12372 which requires intergovernmental consultation with State and local officials.

Regulatory Flexibility Act

This rule has been reviewed with regard to the requirements of the Regulatory Flexibility Act of 1980 (5 U.S.C. 601–602). The Under Secretary for Food, Nutrition, and Consumer Services, has certified that this proposed rule does not have a significant economic impact on a substantial number of small entities. The rule would have almost no impact on the majority of applicant firms, most of which are legitimate food stores.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995, this notice announces our intent to collect additional information associated with the application completed by retail food stores and meal services to request approval to participate in the Food Stamp Program (FSP) and to obtain approval for 3 years on the revised burden estimates.

Comments on this notice must be submitted by January 3, 2000.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the performance of the functions of the agency, including whether the information will have practical utility; (b) The accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) Ways to enhance the quality, utility and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to Lori Shack, Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20502 (a copy may also be sent to Karen J. Walker, Chief, Redemption Management Branch, Benefit Redemption Division, Food and Nutrition Service, Department of Agriculture, 3101 Park Center Drive, Alexandria, Virginia 22302. For further information, or for copies of the information collection, please contact Ms. Walker at the above address.)

All responses to this notice will be summarized and included in the request for OMB approval, and will become a matter of public record.

Title: Food Stamp Program Store Applications.

OMB Number: 0584–0008.

Expiration Date: October 31, 2002.

Type of Request: Revision of a currently approved collection.

Abstract: The Food and Nutrition Service (FNS) of the Department of Agriculture is the Federal agency responsible for the FSP. The Food Stamp Act of 1977, as amended (the Act) (7 U.S.C. 2011–2036), requires that the Agency determine the eligibility of firms and certain food service organizations to accept and redeem food stamp benefits and to monitor them for compliance and continued eligibility.

Part of FNS' responsibility is to accept applications from retail food establishments and meal service programs that wish to participate in the FSP, review the applications in order to determine whether or not applicants meet eligibility requirements, and make determinations whether to grant or deny authorization to accept and redeem food stamp benefits. FNS is also responsible for requiring updates to application

information and reviewing that information to determine whether or not the firms or services continue to meet eligibility requirements.

There are currently 3 application forms approved under OMB No. 0584–0008. Together these forms are used by retailers, wholesalers, meal service providers, certain types of group homes, shelters, and State-contracted restaurants, to apply to FNS for authorization to participate in the FSP. Form FNS–252, Food Stamp Application For Stores is generally used by stores, excluding facilities which provide meal services such as communal dining, shelters and other meal service programs, which are newly applying for authorization; Form FNS–252R, Food Stamp Program Application For Stores—Reauthorization is used by the majority of currently authorized stores to apply for reauthorization, excluding facilities which provide meal services such as communal dining, shelters and other meal service programs; and Form FNS–252–2, Application to Participate in the Food Stamp Program for Communal Dining Facility/Others generally used by communal dining and restaurant facilities and other food service programs which are newly applying or applying for reauthorization. In a few cases, at the discretion of the FNS field offices, some stores would be required to complete Form FNS–252 to apply for reauthorization. Section 9(c) of the Act provides the necessary authorization(s) to collect the information contained in these forms.

We do not collect information on the number of FSP applications received annually. Current burden estimates associated with these 3 application forms are determined from information maintained in STARS (Store Tracking and Redemption System) based on the total number of currently authorized stores or the number of newly authorized stores. The number of expected applications is divided between initial applications from new applicants and applications for reauthorization from currently authorized stores.

For burden estimates associated with new applicants (initial authorizations), we used the number of stores (all types) newly authorized/approved currently estimated at 20,696 (rounded to 20,700) based on FY 1997 year-end data from STARS and inflated this number by 10% (2,070) to account for denied applications received for a total of 22,770 applications expected to be received and processed from stores annually. It is estimated that 98% (22,315) of the 22,770 applications expected to be received would be on Form FNS–252 and 2% (423) would be on Form FNS–252–2. In addition, an estimated 32 private restaurants applying for FSP participation in the State-administered special restaurant program annually will use Form FNS–252 versus Form FNS–252–2 to apply for participation reducing the number of expected applications for Form FNS–252–2 by 32 and increasing the number of expected applications using Form FNS–252 by the same amount.

For burden estimates associated with firms applying for reauthorization, we used the total number of stores (all types) authorized (184,300) as of December 1997. Generally, authorized stores are subject to reauthorization at least once every 4 years. Thus, it is estimated that 25% (46,000) of all authorized stores would be subject to reauthorization in any given year. Using the number of authorized stores as of December 1997, it is estimated that 46,000 reauthorization applications would be expected to be received annually. Of the 46,000 reauthorization applications expected, it is estimated that 96% (44,160) will be on Form FNS–252R, 3% (1,380) will be on Form FNS–252–2, and 1% (460) will be on Form FNS–252.

The number of respondents completing at least 1 of the 3 applications in question annually, as currently approved by OMB, is as follows:

FNS–252		
New authorizations	22,347	(22,770 × .98 + 32)
Reauthorizations	460	(184,000 × .25 × .01)
	22,807	
FNS–252–2		
New authorizations	423	(22,770 × .02 − 32)
Reauthorizations	1,380	(184,000 × .25 × .03)
	1,803	
FNS–252R		
Reauthorizations	44,160	(184,000 × .25 × .01 −1,380 − 460)
Total responses	68,770	

It should be noted that the number of applicant and authorized stores has been declining over the past few years due to several program changes, such as changes in eligibility requirements, stronger sanctions against violators, and implementation of Electronic Benefit Transfer systems. These declines have resulted in a reduction in the overall number of applications expected to be received annually.

Hourly burden time per response varies by type of application and includes the time to review instructions, search existing data resources, gather and copy the data needed, complete and review the application, and submit the form and documentation to FNS.

As currently approved by OMB, the hourly burden rate per response for: (1) Form FNS–252 is 20 to 68 minutes, with the average being 27.5 minutes; (2) 10 to 20 minutes for Form FNS 252–2, with the average being 12 minutes; and, (3) 7 to 8 minutes, with the average being 7.5 minutes for Form FNS–252R.

Information Collection—Proposed Rule

This proposed rule at § 278.1(b) requires that applicant firms submit copies of income and sales tax filing documents to the FNS if requested during the application or reauthorization process. The proposed rule further provides that FNS can deny a firm's application if they do not supply requested documentation. Lastly, the proposed rule would require firms to sign a release form which will authorize FNS to verify all relevant business related tax filings with appropriate agencies, and to obtain corroborating documentation from other sources as deemed necessary. These new requirements will not result in changes to current burden estimates or

methodologies used to arrive at current burden estimates as approved by OMB, because: (1) Currently approved burden estimates already include time associated with collecting, copying and submitting this type of documentation, or other sufficient documentation, to FNS. The new proposal simply allows FNS to mandate the submission of a particular type of document, such as sales and tax filing documents and to deny applications which do not provide the specific documentation; and (2) FNS would design a standard release form for the purpose of the new requirement to sign a release form. This would be a one-time burden for new applicants, including applicants for reauthorization. It is estimated that burden associated with a one-time requirement to affix a single signature to a standard form would be minimal and is not being assessed separately.

The burden estimates, as approved by OMB through October 31, 2002, are shown below:

Affected Public: Food retail and wholesale firms, meal service programs, certain types of group homes, shelters, and State-contracted restaurants.

Estimated Number of Respondents: 68,770.

Estimated Number of Responses per respondent: 1.

Estimated Time per Response: 0.229413.

Estimated Total Annual Burden: 15,777.

SUMMARY OF BURDEN ESTIMATES FOR FORMS FNS–252, 252–2 AND 252R

Title	Number of respondents	Responses per respondent	Total annual responses	Burden hours per response	Total annual burden hours
Form FNS–252	22,807	1	22,807	.4500	10,263
Form FNS–252–2	1,803	1	1,803	.2000	361
Form FNS–252R	44,160	1	44,160	.1167	5,153
Totals	68,770	1	68,770	.....	15,777

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is intended to have a preemptive effect with respect to any State or local laws, regulations or policies which conflict with its provisions or which would otherwise impede its full implementation. This rule is not intended to have retroactive effect unless so specified in the ''Effective Date'' paragraph of this preamble. Prior to any judicial challenge to the provisions of this rule or the application of its provisions, all applicable administrative procedures are as follows: (1) For Program benefit recipients—State administrative procedures issued pursuant to 7 U.S.C. 2020(e)(10) and 7 CFR 273.15; (2) For State Agencies—administrative procedures issued pursuant to 7 U.S.C. 2023 set out as 7 CFR 276.7 (for rules related to non-quality control liabilities) or part 284 (for rules related to quality control liabilities: (3) For Program retailers and wholesalers—administrative procedures issued pursuant to 7 U.S.C. 2023 set out at 7 CFR 278.8.

Unfunded Mandate Analysis

Title II of the Unfunded Mandate Reform Act of 1995 (UMRA) Public Law 104–04, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, the Department generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, or tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. When such a statement is needed for a rule, section 205 of the UMRA generally requires the Department to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, more cost-effective or least burdensome alternative that achieves the objectives of the rule.

This rule contains no Federal mandates (under the regulatory provisions of title II of the UMRA) which impose costs on State, local, or tribal governments or to the private sector of $100 million or more in any one year. Thus, this rule is not subject to the requirements of sections 202 and 205 of the URMA.

Background

The authorization of retail food stores and wholesale food concerns to accept and redeem food stamp benefits is the responsibility of the Department's FNS Field Offices. This rule makes four changes, two discretionary and two reflecting additional authorities provided by the Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA). The discretionary changes alter the timeframe within which FNS must approve or reject a firm's application, and specify types of documents firms might be asked to provide. The PRWORA changes authorize the Department to require that applicant firms sign a release form allowing FNS to verify the accuracy of information submitted by firms, and that FNS may request the submission of tax records.

Application Processing Timeframes

Current rules at 7 CFR 278.1(a) provide that an FNS officer in charge shall deny or approve authorization, or request more information, within 30 days of receipt of the firm's application. If FNS returns an incomplete application and/or requests more documentation from the applicant, the 30-day time clock then stops until a fully completed application and/or the additional information is received from the applicant, at which point FNS has a full 30 days to approve or deny authorization.

Current rules do not define a completed application. This proposed rule would clarify what is meant by a completed application. It is proposed that a completed application means that all information (other than an on-site visit) that FNS deems necessary in order to make a determination on the firm's application has been received. This information includes, but is not limited to a completed application form, all required information and documentation from the applicant, as well as all needed third-party verification and documentation. In most instances, the current rule is adequate to ensure the eligibility of a firm. Current rules become problematic, however, when the field office is not familiar with the store, or needs more information about the firm's qualifications to determine whether it is a legitimate retail food store. Experience has shown that, in such cases, a visit is necessary to verify the nature and scope of a firm's

business in questionable circumstances. FNS is proposing in this rule that Field Offices have a 45-day time period in order to process completed applications and to make any needed store visits.

On site-visits may be conducted during the 45-day period by employees of FNS or by a designee of the Secretary of Agriculture (such as a firm under contract to USDA) or by an official of a State or local government. In the interest of efficiency and the responsible use of resources, on-site visits must be carefully planned and clustered in geographic areas. Thus, the 45-day period following the receipt of a completed application is necessary to allow additional time to effectively plan and carry out these on-site visits, and to allow the field office to make a determination as to whether the firm qualifies for authorization.

In order to address this need, FNS is proposing in this rule that the field office shall have 45 days from the receipt of a completed application to approve or deny the application. FNS is confident this will allow sufficient time to conduct an on-site visit if necessary and to make a final determination as to whether a store qualifies for authorization to participate in the FSP.

Information for Verifying Eligibility for Authorization

Current rules do not specify the types of documentation which firms may be required to provide when applying for authorization. In the interest of program integrity, however, it is necessary that FNS stipulate its specific authority to require firms to provide verification and documentation to determine a store's eligibility. This proposed rule (7 CFR 278.1(b)) identifies the type of documentation that may be required by FNS by stipulating that such information may include, but not be limited to, State and local business licenses, Social Security cards, drivers' licenses, photographic identification cards, bills of sale, deeds, leases, sales contracts, State certificates of incorporation, sales records and invoice records.

Tax Records

Section 833 of the PRWORA amends section 9 of the Food Stamp Act and provides the Secretary with the authority to require applicant firms to submit copies of relevant income and sales tax filing documents when applying for participation or continued authorization in the program. Firms that are applying for initial authorization or reauthorization in the FSP may now be required to submit copies of relevant business related income and sales tax filing documents to FNS as a condition of eligibility for program participation. Failure of a firm to provide such documentation if requested by FNS would serve as a basis for the denial of such a firm's application for authorization or of a firm's reauthorization in the program. This program change is reflected in 278.1(b). Since this is a statutory provision over which the Secretary has no authority to amend, implementation of this provision cannot be affected by public comment.

Authorization To Verify Tax Filings and Other Documentation

Section 833 of PRWORA also permits the Secretary to implement, through regulations, a requirement that firms provide, upon request, written authorization to allow FNS to verify all relevant tax filings and to obtain corroborating documentation from other sources so that the accuracy of information provided on the application by stores and concerns may be verified. Section 278.1(b) of the regulation proposes to require that all firms provide written authorization for FNS to verify all relevant business tax filings with appropriate agencies and for FNS to obtain corroborating documentation from other sources so as to ensure that the accuracy of information provided by stores and concerns may be verified. Examples of the types of agencies that could be contacted for the purpose of verifying applicant information include, but are not limited to wholesale suppliers, State or local licensing agencies, State or local liquor and lottery control boards, financial institutions, Federal and State income and sales tax agencies, and Federal, State or local law enforcement agencies. Retailers will be requested to complete a general release form that would provide permission for FNS to access information maintained by any agency or entity that has information directly related to the information requested by FNS on FSP application materials.

This authority will greatly enhance the ability of FNS to ensure that only legitimate stores are authorized to participate in the program and that no false information is filed on the FSP application. This is applicable to all firms, whether new or currently participating firms seeking reauthorization in the program.

List of Subjects in 7 CFR Part 278

Administrative practice and procedure, Banks, Banking, Claims, Food stamps, Groceries—retail, Groceries, General line—wholesalers, Penalties.

Accordingly, 7 CFR part 278 is proposed to be amended as follows:

PART 278—PARTICIPATION OF RETAIL FOOD STORES, WHOLESALE FOOD CONCERNS AND INSURED FINANCIAL INSTITUTIONS

1. The authority citation for part 278 continues to read as follows:

Authority: 7 U.S.C. 2011–2036.

2. In § 278.1:

a. Paragraph (a) is amended by removing the last sentence and adding three new sentences in its place; and

b. The introductory text of paragraph (b) is revised.

The revisions read as follows:

§ 278.1 Approval of retail food stores and wholesale food concerns.

(a) *Application.* * * * FNS shall approve or deny the application within 45 days of receipt of a completed application. A completed application means that all information (other than an on-site visit) that FNS deems necessary in order to make a determination on the firm's application has been received. This information includes, but is not limited to, a completed application form, all information and documentation from the applicant, as well as any needed third-party verification and documentation.

(b) *Determination of authorization.* An applicant shall provide sufficient data and information on the nature and scope of the firm's business for FNS to determine whether the applicant's participation will further the purposes of the program. Upon request, an applicant shall provide documentation to FNS to verify information provided on the application form. Such documentation may include, but is not limited to, State and local business licenses, Social Security cards, drivers' licenses, photographic identification cards, bills of sale, deeds, leases, sales contracts, State certificates of incorporation, sales records, invoice records and business-related tax records. Retail food stores and wholesale food concerns and other entities eligible for authorization also shall be required to sign a release form which will authorize FNS to verify all relevant business related tax filings with appropriate agencies, and to obtain corroborating documentation from other sources as deemed necessary to ensure the legitimacy and eligibility of applicant firms, as well as the accuracy of information provided by the stores and concerns. Failure to comply with any request for information or failure to sign a written release form shall result

in denial of the application for authorization or withdrawal of a firm or concern from the program. In determining whether a firm qualifies for authorization, FNS shall consider all of the following:

* * * * *

Dated: October 25, 1999.

Shirley R. Watkins,

Under Secretary, Food, Nutrition and Consumer Services.

[FR Doc. 99–28547 Filed 11–2–99; 8:45 am]

BILLING CODE 3410–30–U

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1217

[Docket No. FV–99–703–PR1]

Proposed Olive Oil Promotion, Research, and Information Order; Reopening of Comment Period

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Reopening of the comment period.

SUMMARY: Notice is hereby given that the comment period on the proposed Olive Oil Promotion, Research, and Information Order is reopened until December 3, 1999.

DATES: Comments must be received by December 3, 1999.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposed rule to the Docket Clerk, Research and Promotion Branch, Fruit and Vegetable Programs, Agricultural Marketing Service, USDA, Stop 0244, Room 2535 South Building, 1400 Independence Avenue, SW., Washington, D.C. 20250–0244. Comments should be submitted in triplicate and will be made available for public inspection at the above address during regular business hours. Comments may also be submitted electronically to: malinda.farmer@usda.gov. All comments should reference the docket number and the date and page number of this issue of the **Federal Register**. A copy of this rule may be found at: www.ams.usda.gov/fv/rpdocketlist.htm. Pursuant to the Paperwork Reduction Act (PRA), send comments regarding the accuracy of the burden estimate, ways to minimize the burden, including the use of automated collection techniques or other forms of information technology, or any other aspect of this collection of information to the above address. Comments concerning the information collection under the PRA should also be sent to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Oliver L. Flake, Research and Promotion Branch, Fruit and Vegetable Programs, AMS, USDA, Stop 0244, 1400 Independence Avenue, SW., Room 2535 South Building, Washington, DC 20250–0244; telephone (202) 720–9915 or fax (202) 205–2800.

SUPPLEMENTARY INFORMATION: A proposed rule was published in the **Federal Register** (64 FR 46754; August 26, 1999). The proposed rule contains the proposal submitted by the North American Olive Oil Association (NAOOA). Prior to submitting its proposal, the NAOOA had coordinated a task force consisting of the NAOOA, the California Olive Oil Council, the Texas Olive Oil Council, and other companies involved in the olive oil business.

Under the proposed Order, first handlers and importers would pay an assessment to the proposed Olive Oil Council (Council). Assessments collected under the program, at the rate of $0.01 per pound, are expected to generate between $3 million and $4 million annually. The Council would use the assessments collected to conduct a promotion, research, and information program to maintain, develop, and expand markets for olive oil. The comment period ended October 25, 1999.

On October 22, the Task Force Coordinator requested that additional time be provided for interested persons to comment on the proposed rule. The task force coordinator stated that discussions are still taking place among industry participants and that allowing additional discussion will help to ensure that the process allows all parties to participate.

After reviewing the situation, and in accordance with the task force request, the Department is reopening the comment period for 30 additional days. This will provide interested persons a total of 90 days to review the proposed rule, perform a more complete analysis, and submit any written comments.

This delay should not substantially add to the time required to complete this rulemaking action. Accordingly, the period in which to file written comments is reopened until December 3, 1999. This notice is issued pursuant to the Commodity Promotion, Research, and Information Act of 1996, 7 U.S.C. 7401–7425; Public Law 104–127, enacted April 4, 1996.

Dated: October 27, 1999.

Eric M. Forman,

Acting Deputy Administrator, Fruit and Vegetgable Programs.

[FR Doc. 99–28832 Filed 11–1–99; 8:51 am]

BILLING CODE 3410–02–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 2

[Docket No. PRM–2–12]

Michael Stein; Receipt of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; Notice of receipt.

SUMMARY: The Nuclear Regulatory Commission (NRC) has received and requests public comment on a petition for rulemaking dated July 26, 1999, filed by Michael Stein (petitioner). The petition has been docketed by the Commission and has been assigned Docket No. PRM–2–12. The petitioner believes that the NRC regulations pertaining to deliberate misconduct and employee protection do not contain certain needed safeguards. The petitioner is requesting that the NRC regulations pertaining to employee protection and deliberate misconduct be amended to ensure that all individuals are afforded the right to respond to an NRC determination that the individual has violated these regulations.

DATES: Submit comments by January 18, 2000. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Submit comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Attention: Rulemakings and Adjudications staff.

Deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:30 am and 4:15 pm on Federal workdays.

For a copy of the petition, write: David L. Meyer, Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

You may also provide comments via the NRC's interactive rulemaking website (http://www.ruleforum.llnl.gov). This site provides the capability to upload comments as files (any format), if your web browser supports that function. For

information about the interactive rulemaking website, contact Ms. Carol Gallagher, (301) 415–5905 (e-mail: CAG@nrc.gov).

FOR FURTHER INFORMATION CONTACT: David L. Meyer, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: 301–415–7162 or Toll Free: 1–800–368–5642 or E-mail: DLM1@NRC.GOV.

SUPPLEMENTARY INFORMATION:

Background

On July 28, 1999, the Nuclear Regulatory Commission (NRC) received a petition for rulemaking submitted by Michael Stein (petitioner). Although Mr. Stein is an employee of the NRC, he submitted the petition as an individual member of the public. The NRC recently initiated an enforcement action involving a notice of violation against an individual without conducting a prior pre-decisional enforcement conference. As a result, the petitioner states that the NRC regulations pertaining to deliberate misconduct and employee protection do not contain certain important safeguards. The petitioner requests that the NRC regulations governing deliberate misconduct and employee protection be amended to ensure that all individuals are afforded the right to respond to an NRC determination that the individual has violated these regulations before the NRC issues the action.

The NRC has determined that the petition meets the threshold sufficiency requirements for a petition for rulemaking under 10 CFR 2.802. The petition has been docketed as PRM–2–12. The NRC is soliciting public comment on the petition for rulemaking.

Discussion of the Petition

The petitioner requests that the title of the NRC regulations codified at 10 CFR Part 2, Subpart B be amended to be the ''Procedure for Imposing Requirements by Order, or for Modification, Suspension, or Revocation of a License, or for Issuance of a Notice of Violation to an Individual, or for Imposing Civil Penalties.'' The petitioner also suggests amending 10 CFR 2.201 entitled, ''Notice of Violation,'' by adding a new paragraph (b). In a meeting between the petitioner and the NRC staff on October 14, 1999, the language of suggested paragraph was modified by changing the word ''order'' to ''Notice of Violation'' each time it appears in the second sentence of paragraph (b)(2) and to include Part 76 in the list of 10 CFR parts presented in the introductory text of paragraph. The NRC notes that a paragraph (b) currently appears in the codified text of § 2.201. Therefore, the NRC is presenting the paragraph suggested by the petitioner as a new paragraph (c). The new paragraph suggested by the petitioner would read as follows:

§ 2.201 Notice of violation.

* * * *

(c) In response to an alleged violation of the employee protection or deliberate misconduct regulations contained in 10 CFR Parts 19, 30, 40, 50, 60, 61, 70, 72, and 76 the Commission may serve on the individual a Notice of Violation as described in 10 CFR 2.201(a). This Notice of Violation to the individual shall state that:

(1) The answer to the Notice of Violation shall state any facts, explanations, and arguments denying the charges of violation;

(2) If the individual charged with the violation files an answer denying the violation, the Executive Director for Operations, or the Executive Director's designee, upon consideration of the answer, will issue an Order imposing, mitigating, or withdrawing the Notice of Violation to the individual. The individual charged with a violation of the employee protection or deliberate misconduct regulations may, within twenty (20) days of the date of the Notice of Violation or other time specified in the Notice of Violation, request a hearing;

(3) If the individual charged with an employee protection or deliberate misconduct violation requests a hearing, the Commission will issue an order designating the time and place of the hearing;

(4) If a hearing is held, an order will be issued after the hearing by the presiding officer or the Commission dismissing the proceeding, or imposing, mitigating or withdrawing the Notice of Violation. This shall be considered the final NRC action with regard to the Notice of Violation at issue in the proceeding.

The petitioner suggests that the current NRC regulations pertaining to employee protection be amended. Although the petitioner did not specifically identify the employee protection regulations to be amended, the NRC believes that these regulations are 10 CFR 30.7, 40.7, 50.7, 60.9, 61.9, 70.7, 72.10, and 76.7. The Commission specifically requests comments on whether this is a complete list of employee protection regulations that should be amended under the petition. The petitioner's suggested language reads as follows:

An individual charged with a violation of the employee protection regulations in Part X, has the right to a hearing pursuant to 10 CFR 2.201(b). In addition, prior to the issuance of a Notice of Violation pursuant to 10 CFR Part 2.201 or an Order pursuant to 10 CFR 2.202, the individual charged with such a violation shall have the right to inform the agency either by written correspondence or by a predecisional enforcement conference, regarding their involvement in the alleged violation of this section.

The petitioner also proposes that the current NRC regulations pertaining to deliberate misconduct be amended. Although the petitioner did not specifically identify the deliberate misconduct regulations to be amended, the NRC believes that these regulations are 10 CFR 30.10, 40.10, 50.5, 52.9, 60.11, 61.9b, 70.10, 71.11, 72.12, 76.10, and 110.7b. The Commission specifically requests comments on whether this is a complete list of deliberate misconduct regulations that should be amended under the petition. The petitioner's suggested language reads as follows:

An individual charged with a violation of the deliberate misconduct regulations in Part X, has the right to a hearing pursuant to 10 CFR 2.201(b). In addition, prior to the issuance of a Notice of Violation pursuant to 10 CFR 2.201 or an Order pursuant to 10 CFR 2.202, the individual charged with such a violation shall have the right to inform the agency either by written correspondence or by a predecisional enforcement conference, regarding their involvement in the alleged violation of this section.

The petitioner contends that his proposed amendment would ensure that all individuals have the opportunity to address an NRC determination that the individual has violated either the deliberate misconduct or employee protection regulations before the NRC issues the action.

The Petitioner's Conclusions

The petitioner concludes that the NRC regulations governing deliberate misconduct and employee protection are missing certain safeguards he believes are important. The petitioner requests that the NRC regulations pertaining to deliberate misconduct and employee protection be amended as discussed above to ensure that each individual has an opportunity to address an NRC determination that he or she has violated these regulations.

Dated at Rockville, Maryland, this 28th day of October, 1999.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 99–28757 Filed 11–2–99; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 2 and 50

RIN 3150–AG38

Antitrust Review Authority: Clarification

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is proposing to clarify its regulations to reflect more clearly its limited antitrust review authority by explicitly limiting the types of applications that must include antitrust information. Specifically, because the Commission is not authorized to conduct antitrust reviews of post-operating license transfer applications, or at least is not required to conduct this type of review and has decided that it no longer will conduct them, no antitrust information is required as part of a post-operating license transfer application. Because the current regulations do not clearly specify which types of applications are not subject to antitrust review, these proposed clarifying amendments would bring the regulations into conformance with the Commission's limited statutory authority to conduct antitrust reviews.

DATES: The comment period expires January 3, 2000. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date. Comments may be submitted either electronically or in written form.

ADDRESSES: Written comments should be sent to: Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff.

You may also provide comments via the NRC's interactive rulemaking web site (*http://ruleforum.llnl.gov*). This site provides the ability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking web site, contact Ms. Carol Gallagher, 301–415–5905; e-mail *CAG@nrc.gov*.

Comments received on this rulemaking may be examined at the NRC Public Document Room, 2120 L Street NW (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Jack R. Goldberg, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone 301–415–1681; e-mail JRG1@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction and Purpose

In a license transfer application filed on October 27, 1998, by Kansas Gas and Electric Company (KGE) and Kansas City Power and Light Company (KCP&L) (Applicants), Commission approval pursuant to 10 CFR 50.80 was sought of a transfer of the Applicants' possession-only interests in the operating license for the Wolf Creek Generating Station, Unit 1, to a new company, Westar Energy, Inc. Wolf Creek is jointly owned by the Applicants, each of which owns an undivided 47 percent interest. The remaining 6 percent interest is owned by Kansas Electric Power Cooperative, Inc. (KEPCo). The Applicants requested that the Commission amend the operating license for Wolf Creek pursuant to 10 CFR 50.90 by deleting KGE and KCPL as licensees and adding Westar Energy in their place. KEPCo opposed the transfer on antitrust grounds, claiming that the transfer would have anticompetitive affects and would result in ''significant changes'' in the competitive market. KEPCo petitioned the Commission to intervene in the transfer proceeding and requested a hearing, arguing that the Commission should conduct an antitrust review of the proposed transfer under Section 105c of the Atomic Energy Act, 42, U.S.C. 2135(c). Applicants opposed the petition and request for a hearing.

By Memorandum and Order dated March 2, 1999, CLI–99–05, 49 NRC 199 (1999), the Commission indicated that although its staff historically has performed a ''significant changes'' review in connection with certain kinds of license transfers, it intended to consider in the Wolf Creek case whether to depart from that practice and ''direct the NRC staff no longer to conduct significant changes reviews in license transfer cases, including the current case.'' In deciding this matter, the Commission stated that it expected to consider a number of factors, including its statutory mandate, its expertise, and its resources. Accordingly, the Commission directed the Applicants and KEPCo to file briefs on the single question: ''whether as a matter of law or policy the Commission may and should eliminate all antitrust reviews in connection with license transfers and therefore terminate this adjudicatory proceeding forthwith.'' *Id.* at 200.

Because the issue of the Commission's authority to conduct antitrust reviews of license transfers is of interest to, and affects, more than only the parties directly involved in, or affected by, the proposed Wolf Creek transfer, the Commission in that case invited *amicus curiae* briefs from ''any interested person or entity.'' CLI–99–05, 49 NRC at 200, n.1. (Briefs on the issue subsequently were received from a number of nonparties.) In addition, widespread notice of the Commission's intent to decide this matter in the Wolf Creek proceeding was provided by publishing that order on the NRC's web site and in the **Federal Register**, and also by sending copies to organizations known to be active in or interested in the Commission's antitrust activities. *Id.*

After considering the arguments presented in the briefs, and based on a thorough de novo review of the scope of the Commission's antitrust authority, the Commission concluded that the structure, language, and history of the Atomic Energy Act do not support its prior practice of conducting antitrust reviews of post-operating license transfers. The Commission stated:

> It now seems clear to us that Congress never contemplated such reviews. On the contrary, Congress carefully set out exactly when and how the Commission should exercise its antitrust authority, and limited the Commission's review responsibilities to the anticipatory, prelicensing stage, prior to the commitment of substantial licensee resources and at a time when the Commission's opportunity to fashion effective antitrust relief was at its maximum. The Act's antitrust provisions nowhere even mention post-operating license transfers.
>
> The statutory scheme is best understood, in our view, as an implied prohibition against additional Commission antitrust reviews beyond those Congress specified. At the least, the statute cannot be viewed as a requirement of such reviews. In these circumstances, and given what we view as strong policy reasons against a continued expansive view of our antitrust authority, we have decided to abandon our prior practice of conducting antitrust reviews of post-operating license transfers * * *.

Kansas Gas and Electric Co. (Wolf Creek Generating Station, Unit 1), CLI–99–19, 49 NRC 441, 446 (1999).

II. Discussion

The Commission's decision in Wolf Creek was based on a thorough consideration of the documented purpose of Congress's grant of limited antitrust authority to the NRC's predecessor, the Atomic Energy Commission, the statutory framework of that authority, the carefully-crafted statutory language, and the legislative history of the antitrust amendments to the Atomic Energy Act. The Commission's Wolf Creek decision explained that, in eliminating the theretofore government monopoly over atomic energy, Congress wished to

provide incentives for its further development for peaceful purposes but was concerned that the high costs of nuclear power plants could enable the large electric utilities to monopolize nuclear generating facilities to the anticompetitive harm of smaller utilities. Therefore, Congress amended the Atomic Energy Act to provide for an antitrust review in the prelicensing stages of the regulatory licensing process. Congress focused its grant of antitrust review authority on the two steps of the Commission's licensing process: the application for the facility's construction permit and the application for the facility's initial operating license. It is at these early stages of the facility's licensing that the Commission historically was believed by Congress to be in a unique position to remedy a situation inconsistent with the antitrust laws by providing ownership access and related bulk power services to smaller electric systems competitively disadvantaged by the planned operation of the nuclear facility. Congress emphasized that the Commission's review responsibilities were to be exercised at the anticipatory, prelicensing stages prior to the commitment of substantial licensee resources and at a time when the Commission's opportunity to fashion effective relief was at its maximum. See Wolf Creek at 446–448.

The Commission next focused on the structure and language of its antitrust review authority found exclusively in Section 105 of the Atomic Energy Act, 42 U.S.C. 2135. Section 105c provides for a mandatory and complete antitrust review at the construction permit phase of the licensing process when all entities who might wish ownership access to the nuclear facility and who are in a position to raise antitrust concerns are able to seek an appropriate licensing remedy from the Commission prior to actual operation of the facility. The construction permit antitrust review contrasts markedly from the only other review authorized by the statute. Specifically, Section 105c explicitly provides that the antitrust review provisions ''shall not apply'' to an application for an operating license unless ''significant changes in the licensee's activities or proposed activities have occurred subsequent to the previous review * * * in connection with the construction permit for the facility.'' Section 105c.(2). Following this more limited and conditional review prior to initial operation of the facility, Section 105 makes clear that traditional antitrust forums are available to consider asserted anticompetitive conduct of Commission licensees, which are not relieved of operation of the antitrust laws. Section 105a, b. Further, if any Commission licensee is found to have violated any antitrust law, the Commission has the authority to take any licensing action it deems necessary. Section 105a. See *id.* at 447–452.

After describing this statutory framework and structure, the Commission then closely examined the language of its statutory antitrust review authority. The Commission found that it focused on only two types of applications, namely those for a construction permit and those for an initial operating license, but not for other types of applications explicitly mentioned in Section 103 of the Atomic Energy Act, such as applications to ''acquire'' or ''transfer'' a license. Even if an application to transfer an operating license were considered an application for an operating license for the transferee, the Commission found that the specific ''significant changes'' review process mandated by Section 105 does not lend itself to an antitrust review of post-operating license transfer applications. The Commission noted that its past practice of conducting ''significant changes'' reviews of post-operating license transfer applications did not use the construction permit review as the benchmark for comparison as mandated by Section 105, but instead examined whether there were significant changes compared with the previous *operating license review*. Like the statutory framework, the statutory language was found to be inconsistent with authorization to conduct post-operating license antitrust reviews and certainly could not be found to support a required review at that time. *See id.* at 452–456.

Finally, the Commission reviewed the legislative history of the antitrust amendments. It found that the Joint Committee on Atomic Energy, in its authoritative report on the Commission's prelicensing antitrust authority, explicitly clarified the scope of the terms ''license application'' and ''application for a license'' in the language which was enacted as Section 105. The Commission stated:

> In its Report, the Joint Committee [11] made clear that the term ''license application'' referred only to applications for construction permits or operating licenses filed as part of the ''initial'' licensing process for a new facility not yet constructed, or for modifications which would result in a substantially different facility:
>
> The committee recognizes that applications may be amended from time to time, that there may be applications to extend or review [sic-renew] a license, and also that the form of an application for construction permit may be such that, from the applicant's standpoint, it ultimately ripens into the application for an operating license. The phrases ''any license application'', ''an application for a license'', and ''any application'' as used in the clarified and revised subsection 105c. refer to the initial application for a construction permit, the initial application for an operating license, or the initial application for a modification which would constitute a new or substantially different facility, as the case may be, as determined by the Commission. The phrases do not include, for purposes of triggering subsection 105 c., other applications which may be filed during the licensing process.

See *id.* at 458, quoting Report By The Joint Committee On Atomic Energy: Amending The Atomic Energy Act of 1954, As Amended, To Eliminate The Requirement For A Finding Of Practical Value, To Provide For Prelicensing Antitrust Review Of Production And Utilization Facilities, And To Effectuate Certain Other Purposes Pertaining To Nuclear Facilities, H.R. Rep. No. 91–1470 (also Rep. No. 91–1247), 91st Cong., 2nd Sess., at 29 (1970), 3 U.S. Code and Adm. News 4981 (1970) (''Joint Committee Report'') (*quoting* from legislative history of 1954 Act).

In summary, the Commission concluded that neither the language of the Commission's statutory authority to conduct antitrust reviews nor its legislative history support any authority to perform antitrust reviews of post-operating license transfer applications and certainly cannot be interpreted to require such reviews.

The Commission's Wolf Creek decision is published in its entirety at 64 FR 33916; June 24, 1999. Interested persons are encouraged to read the Wolf Creek decision in its entirety for a complete understanding of the Commission's interpretation of its statutory antitrust authority.

Because of the Commission's past practice of conducting antitrust reviews of license transfer applications, including those at the post-operating license stage of the regulatory process, the Commission in the Wolf Creek case also closely examined its rules of practice to determine whether they required or warranted revision to

[11] The Joint Committee Report is the best source of legislative history of the 1970 amendments. *See Alabama Power Co.* v. *NRC*, 692 F.2d, 1362, 1368 (11th Cir. 1982). The Report was considered by both houses in their respective floor deliberations on the antitrust legislation and is entitled to special weight because of the Joint Committee's ''peculiar responsibility and place * * * in the statutory scheme.'' *See Power Reactor Development Co.* v. *International Union*, 367 U.S. 396, 409 (1961).

conform to its decision in the Wolf Creek decision. The Commission concluded that, notwithstanding its past interpretation of its rules as being consistent with an antitrust review of all transfer applications, including those involving post-operating license transfers, the rules themselves do not explicitly mandate such reviews. *Id.* at 462, 467.

The Commission's practice has been to perform a ''significant changes'' review of applications to directly transfer Section 103 construction permit and operating licenses to a new entity, including those applications for post-operating license transfers. While the historical basis for such reviews in the case of post-operating license transfer applications remains cloudy—it does not appear that the Commission ever explicitly focused on the issue of whether such reviews were authorized or required by law, but instead apparently assumed that they were [14]—the reasons, even if known, would have to yield to a determination that such reviews are not authorized by the Act. *See American Telephone & Telegraph Co.* v. *FCC,* 978 F.2d 727, 733 (D.C. Cir. 1992). We now in fact have concluded, upon a close analysis of the Act, that Commission antitrust reviews of post-operating license transfer applications cannot be squared with the terms or intent of the Act and that we therefore lack authority to conduct them. But even if we are wrong about that, and we possess some general residual authority to continue to undertake such antitrust reviews, it is certainly true that the Act nowhere requires them, and we think it sensible from a legal and policy perspective to no longer conduct them.

It is well established in administrative law that, when a statute is susceptible to more than one permissible interpretation, an agency is free to choose among those interpretations. *Chevron,* 467 U.S. at 842–43. This is so even when a new interpretation at issue represents a sharp departure from prior agency views. Id. at 862. As the Supreme Court explained in *Chevron,* agency interpretations and policies are not ''carved in stone'' but rather must be subject to re-evaluations of their wisdom on a continuing basis. *Id.* at 863–64. Agencies ''must be given ample latitude to ''adapt its rules and policies to the demands of changing circumstances.'' *Motor Vehicle Mfrs. Assn. of United States, Inc.* v. *State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 42 (1983), *quoting Permian Basin Area Rate Cases,* 390 U.S. 747, 784 (1968). An agency may change its interpretation of a statute so long as it justifies its new approach with a ''reasoned analysis'' supporting a permissible construction. *Rust* v. *Sullivan, 500 U.S. 173, 186–87 (1991); Public Lands Council* v. *Babbit,* 154 F.3d 1160, 1175 (10th Cir. 1998); *First City Bank* v. *National Credit Union Admin Bd.*, 111 F.3d 433, 442 (6th Cir. 1997); *see also Atchison, T. & S. F. Ry. Co.* v. *Wichita Bd. of Trade,* 412 U.S. 800, 808 (1973); *Hatch* v. *FERC,* 654 F.2d 825, 834 (D.C. Cir. 1981); *Greater Boston Television Corp.* v. *FCC,* 444 F.2d 841, 852 (D.C. Cir. 1971).

We therefore give due consideration to the Commission's established practice of conducting antitrust reviews of post-operating license transfer applications but appropriately accord little weight to it in evaluating anew the issue of Section 105's scope and whether, even if such reviews are authorized by an interpretation of Section 105, they should continue as a matter of policy. Moreover, as we noted above, the Commission's actual practice of reviewing license transfer applications for significant changes is on its face inconsistent with the statutory requirement regarding how significant changes must be determined. The fact that the statutory method does not lend itself to post-operating license transfer applications, while the different one actually used does logically apply, also must be considered and suggests that such a review is not required by the plain language of the statute and was never intended by Congress.

In support of the arguments advanced in KEPCo's briefs and some of the amicus briefs that the Commission must conduct antitrust reviews of transfer applications, various NRC regulations and guidance are cited. Just as the Commission's past practices cannot justify continuation of reviews unauthorized by statute, neither can regulations or guidance to the contrary. Before accepting the argument that our regulations require antitrust reviews of post-operating license transfer applications, however, they warrant close consideration.

Section 50.80 of the Commission's regulations, 10 CFR 50.80, ''Transfer of licenses,'' provides, in relevant part:

(b) An application for transfer of a license shall include [certain technical and financial information described in sections 50.33 and 50.34 about the proposed transferee] as would be required by those sections if the application were for an initial license, and, if the license to be issued is a class 103 license, the information required by § 50.33a.

Section 50.33a, ''Information requested by the Attorney General for antitrust review,'' which by its terms applies only to applicants for construction permits, requires the submittal of antitrust information in accordance with 10 CFR Part 50, Appendix L. Appendix L, in turn, identifies the information ''requested by the Attorney General in connection with his review, pursuant to section 105c of the Atomic Energy Act of 1954, as amended, of certain license applications for nuclear power plants.'' ''Applicant'' is defined in Appendix L as ''the entity applying for authority to construct or operate subject unit and each corporate parent, subsidiary and affiliate.'' ''Subject unit'' is defined as ''the nuclear generating unit or units for which application for construction or operation is being made.'' Appendix L does not explicitly apply to applications to transfer an operating license.

KEPCo argues that the section 50.80(b) requirement, in conjunction with the procedural requirements governing the filing of applications discussed below, requires the submittal of antitrust information in support of post-operating license transfer applications and that the Wolf Creek case cannot lawfully be dismissed without a ''significant changes'' determination. *See* KEPCo Brief at 11. While we agree that section 50.80 may imply that antitrust information is required for purposes of a ''significant changes'' review, linguistically it need not be read that way. The Applicants plausibly suggest that the phrase ''the license *to be* issued'' could be interpreted to apply only to entities that have not yet been issued an initial license. *See* App. Brief at 11.[15] Moreover, neither this regulation nor any other states the purpose of the submittal of antitrust information. For applications to construct or operate a proposed facility, it is clear that section 50.80(b), in conjunction with section 50.33a and Appendix L, requires the information specified in Appendix L for purposes of the Section 105c antitrust review, for construction permits, and for the ''significant changes'' review for operating licenses. But for applications to transfer an existing operating license, there are other Section 105 purposes which could be served by the information. Such information could be useful, for example, in determining the fate of any existing antitrust license conditions relative to the transferred license, as well as for purposes of the Commission's Section 105b responsibility to report to the Attorney General any information which appears to or tends to indicate a violation of the antitrust laws.

While we acknowledge that information submitted under section 50.80(b) has not been used for these purposes in the past, and has instead been used to develop ''significant changes'' findings, the important point is that section 50.80(b) is simply an information submission rule. It does not, in and of itself, mandate a ''significant changes'' review of license transfer applications. No Commission rule imposes such a legal requirement.

[14] Until recently, the Commission's staff applied the ''significant changes'' review process to both ''direct'' and ''indirect'' transfers. Indirect transfers involve corporate restructuring or reorganizations which leave the licensee itself intact as a corporate entity and therefore involve no application for a new operating license. The vast majority of indirect transfers involve the purchase or acquisition of securities of the licensee (*e.g.*, the acquisition of a licensee by a new parent holding company). In this type of transfer, existing antitrust license conditions continue to apply to the same licensee. The Commission recently did focus on antitrust reviews of indirect license transfer applications and approved the staff's proposal to no longer conduct ''significant changes'' reviews for such applications because there is no effective application for an operating license in such cases. See Staff Requirements Memorandum (November 18, 1997) on SECY–97–227, Status Of Staff Actions On Standard Review Plans For Antitrust Reviews And Financial Qualifications And Decommissioning-Funding Assurance Reviews.

[15] This reading is consistent with the history of section 50.80(b). Its primary purpose appears to have been to address transfers which were to occur before issuance of the initial (original) operating license, transfers which unquestionably fall within the scope of Section 105c. *See Detroit Edison Company* (Enrico Fermi Atomic Power Plant, Unit No. 2), LBP–78–13, 7 NRC 583, 587–88 (1978). When section 50.80(b) was revised in 1973 to require submission of the antitrust information specified in section 50.33a, the stated purpose was to obtain the ''*prelicensing* antitrust advice by the Attorney General.'' 38 FR 3955, 3956 (February 9, 1973) (emphasis added).

Nonetheless, in conjunction with this decision, we are directing the NRC staff to initiate a rulemaking to clarify the terms and purpose of section 50.80 (b).[16]

KEPCo also argues that the Commission's procedural requirements governing the filing of license applications supports its position that antitrust review is required in this case. *See* KEPCo Brief at 11–13. The Applicants disagree, arguing that nothing in those regulations states that transfer applications will be subject to antitrust reviews. *See* App. Reply Brief at 3. For the same reasons we believe that the specific language in Section 105c does not support antitrust review of post-operating license transfer applications, we do not read our procedural requirements to indicate that there will be an antitrust review of transfer applications. Indeed, the language in 10 CFR 2.101(e)(1) regarding operating license applications under Section 103 tracks closely the process described in Section 105c. As stated in 10 CFR 2.101(e)(1), the purpose of the antitrust information is to enable the staff to determine ''whether significant changes in the licensee's activities or proposed activities have occurred since the completion of the *previous antitrust review in connection with the construction permit*.'' (Emphasis added.) As explained above, this description of the process for determining ''significant changes'' is consistent with an antitrust review of the initial operating license application for a facility but wholly inconsistent with an antitrust review of post-operating license transfer applications.

Id. at 459–463 (footnotes in original).

Indeed, after considering the various interpretations of the rules advanced by the parties and *amici curiae* in the Wolf Creek proceeding, the Commission concluded: ''Not one comma of the Commission's current regulations need be changed in the wake of a cessation of such reviews, although because of the NRC's past practice of conducting such reviews, we have decided that clarification of our rules is warranted.'' *Id*. at 467. Therefore, the Commission directed that the rules be clarified ''by explicitly limiting which types of applications must include antitrust information,'' *Id*. at 463, and that Regulatory Guide 9.3, ''Information Needed by the AEC Regulatory Staff in Connection with Its Antitrust Review of Operating License Applications for Nuclear Power Plants,'' and NUREG–1574, ''Standard Review Plan on Antitrust Reviews,'' also be clarified.

The proposed clarifications make clear that, consistent with the decision in the Wolf Creek case, no antitrust information is required to be submitted as part of any application for Commission approval of a post-operating license transfer. Because the current regulations do not clearly specify which types of applications are not subject to antitrust review, these proposed clarifying amendments will bring the regulations into conformance with the Commission's limited statutory authority to conduct antitrust reviews and its decision that such reviews of post-operating license transfer applications are not authorized or, if authorized, are not required and not warranted.[1]

Direct transfers of facility licenses which are proposed *prior* to the issuance of the initial operating license for the facility, however, are and continue to be subject to the Commission's antitrust review.[2] In order to make clear that the Commission's regulations do not require antitrust information as part of applications for post-operating license transfers, the Commission is proposing to amend its regulations by specifying that antitrust information must be submitted only with applications for construction permits and ''initial'' operating licenses for the facility and applications for transfers of licenses prior to the issuance of the ''initial'' operating license. Thus, the word ''initial'' would be inserted to modify ''operating license'' in appropriate locations and the word ''application'' would be modified where necessary to make clear that the application must be for a construction permit or initial operating license. Appendix L to 10 CFR Part 50, ''Information Requested by the Attorney General for Antitrust Review [of] Facility License Applications,'' would be similarly amended and clarified and a new definition would be added there to define ''initial operation'' to mean operation pursuant to the first operating license issued by the Commission for the facility.

III. Plain Language

The Presidential Memorandum dated June 1, 1998, entitled, ''Plain Language in Government Writing,'' directed that the government's writing be in plain language. This memorandum was published June 10, 1998 (63 FR 31883). In complying with this directive, editorial changes have been made in the proposed revisions to improve the organization and readability of the existing language of paragraphs being revised. These types of changes are not discussed further in this notice. The NRC requests comment on this proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed under the **ADDRESSES** heading.

IV. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Public Law 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this proposed rule, the NRC proposes to eliminate the submission of antitrust information in connection with post-operating license applications for transfers of facility operating licenses. This rule would not constitute the establishment of a standard that establishes generally-applicable requirements.

V. Finding of No Significant Environmental Impact and Categorical Exclusion

The Commission has determined under the National Environmental Policy Act (NEPA) of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule, if adopted, falls within the categorical exclusions appearing at 10 CFR 51.22 (c)(1), (2), and (3)(i) and (iii) for which neither an Environmental Assessment nor an Environmental Impact Statement is required.

VI. Paperwork Reduction Act Statement

The proposed rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*.). Existing requirements were approved by the Office of Management and Budget, approval number 3150–0011.

[16] In one important respect the language of section 50.80(b), quoted above, in fact supports the Commission's analysis of Section 105 and its legislative history. The phrase ''if the application were for an *initial license*'' certainly demonstrates that, consistent with the clearly intended focus of Section 105c on antitrust reviews of applications for initial licenses, the Commission has long distinguished initial operating license applications from license transfer applications. Be that as it may, clarification of section 50.80(b) will be appropriate in the wake of our decision that our antitrust authority does not extend to antitrust reviews of post-operating license transfer applications.

[1] The same principle holds in the context of Part 52 of the Commission's regulations. Under that Part, the operating license is issued simultaneously with the construction permit in a combined license. The application for the combined license is subject to the agency's antitrust review, but antitrust reviews of post-combined license transfer applications are not authorized or, if authorized, are not required and not warranted.

[2] The paragraph speaks only to the historically typical case in which a construction permit (CP) is issued first, and then years later an operating license (OL). Under Part 52, the CP and OL are issued simultaneously, and the antitrust review is done before issuance. Thus, there could be no direct transfer of the facility CP before issuance of the initial OL.

VII. Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

VIII. Regulatory Analysis

The proposed revisions to the regulations clarify that antitrust information is required to be submitted only in connection with applications for construction permits and initial operating licenses and not in connection with applications for post-operating license transfers. Therefore, to the extent that, in the past, antitrust information was submitted with applications for post-operating license transfers, these proposed revisions will reduce the burden on such applicants by eliminating the submission of antitrust information and the costs associated with preparing and submitting that information. In short, the proposed revisions will result in no additional burdens or costs on any applicants or licensees and will reduce burdens and costs on others. Clearly, because the proposed revisions only affect when antitrust information need be submitted to the Commission, there will be no effect on the public health and safety or the common defense and security, and they will continue to be adequately protected. The cost savings to applicants resulting from these revisions justify taking this action.

To determine whether the amendments contained in this proposed rule were appropriate, the Commission considered the following options:

1. The No-Action Alternative

This alternative was considered because the current rules are not explicitly inconsistent with the Commission's decision that antitrust reviews of post-operating license transfers are not authorized, or at least are not required and should be discontinued. Because the current rules have been interpreted to be consistent with the Commission's practice of conducting such reviews, however, in that they have been interpreted to require the submission of antitrust information with post-operating license transfer applications, the Commission concluded that clarification of the rules are appropriate. Therefore, the Commission determined that this alternative is not acceptable.

2. Clarification of 10 CFR Parts 2 and 50

For the reasons explained above and in the Commission's Wolf Creek decision, the Commission decided that its rules could and should be made clearer that no antitrust information should be submitted with applications for post-operating license transfers because antitrust reviews of such applications are not authorized or, if authorized, should be discontinued as a matter of policy. Therefore, to make clear that there is no need to submit antitrust information in connection with post-operating license transfers, and because the proposed revisions would result in cost savings to certain applicants, with no additional costs or burdens on anyone, this option was chosen.

IX. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this rule, if adopted, will not have a significant economic impact on a substantial number of small entities that are subject to the requirements of the rule. This proposed rule affects only the licensing and operation of nuclear power plants. The entities that own these plants do not fall within the scope of the definition of ''small entities'' set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810). Furthermore, this proposed rule does not subject any entities to any additional requirements, nor does it require any additional information from any entity. Instead, the proposed rule, if adopted, will clarify that certain information is not required to be submitted in connection with applications for post-operating license transfers.

X. Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this proposed rule and a backfit analysis is not required because these amendments do not involve any provisions that would impose backfits as defined in 10 CFR 50.109. The rule does not constitute a backfit because it does not propose a change to or additions to requirements for existing structures, systems, components, procedures, organizations or designs associated with the construction or operation of a facility. Rather, this proposed rule eliminates the need for certain applicants to submit antitrust information with their applications.

XI. Proposed Amendments

List of Subjects

10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalties, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 50

Antitrust, Classified Information, Criminal penalties, Fire protection, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy reorganization Act of 1974, as amended; and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Parts 2 and 50.

PART 2—RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

1. The authority section for part 2 continues to read as follows:

Authority: Secs.161, 181, 68 Stat. 948, 953, as amended (42 U.S.C. 2201, 2231); sec. 191, as amended, Pub. L. 87–615, 76 Stat. 409 (42 U.S.C. 2241); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); 5 U.S.C. 552.

Section 2.101 also issued under secs. 53, 62, 63, 81, 103, 104, 105, 68 Stat. 930, 932, 933, 935, 936, 937, 938, as amended (42 U.S.C. 2073, 2092, 2093, 2111, 2133, 2134, 2135); sec. 114(f), Pub. L. 97–425, 96 Stat. 2213, as amended (42 U.S.C. 10134(f)); sec. 102, Pub. L. 91–190, 83 Stat. 853, as amended (42 U.S.C. 4332); sec. 301, 88 Stat. 1248 (42 U.S.C. 5871). Sections 2.102, 2.103, 2.104, 2.105, 2.721 also issued under secs. 102, 103, 104, 105, 183, 189, 68 Stat. 936, 937, 938, 954, 955, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2233, 2239). Section 2.105 also issued under Pub. L. 97–415, 96 Stat. 2073 (42 U.S.C. 2239). Sections 2.200–2.206 also issued under secs. 161 b, i, o, 182, 186, 234, 68 Stat. 948–951, 955, 83 Stat. 444, as amended (42 U.S.C. 2201 (b), (i), (o), 2236, 2282); sec. 206, 88 Stat 1246 (42 U.S.C. 5846). Sections 2.205(j) also issued under Pub. L. 101–410, 104 Stat. 890, as amended by section 31001(s), Pub. L. 104–134, 110 Stat. 1321–373 (28 U.S.C. 2461 note). Sections 2.600–2.606 also issued under sec. 102, Pub. L. 91–190, 83 Stat. 853, as amended (42 U.S.C. 4332). Sections 2.700a, 2.719 also issued under 5 U.S.C. 554. Sections 2.754, 2.760, 2.770, 2.780 also issued under 5 U.S.C. 557. Section 2.764 also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 2.790 also issued under sec. 103, 68 Stat. 936, as amended (42 U.S.C. 2133) and 5 U.S.C. 552. Sections 2.800 and 2.808 also issued under 5 U.S.C. 553. Section 2.809 also issued under 5 U.S.C. 553 and sec. 29, Pub. L. 85–256, 71 Stat. 579, as amended (42 U.S.C. 2039). Subpart K also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97–425, 96 Stat. 2230 (42 U.S.C. 10154). Subpart L also issued under sec. 189, 68 Stat. 955 (42

U.S.C. 2239). Appendix A also issued under sec. 6, Pub. L. 91–560, 84 Stat. 1473 (42 U.S.C. 2135).

2. In § 2.101 paragraphs (e)(1) and (e)(2) are revised to read as follows:

§ 2.101 Filing of application.

* * * * *

(e)(1) Upon receipt of the antitrust information responsive to Regulatory Guide 9.3 submitted in connection with an application for a facility's initial operating license under section 103 of the Act, the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, shall publish in the **Federal Register** and in appropriate trade journals a ''Notice of Receipt of Initial Operating License Antitrust Information.'' The notice shall invite persons to submit, within thirty (30) days after publication of the notice, comments or information concerning the antitrust aspects of the application to assist the Director in determining, pursuant to section 105c of the Act, whether significant changes in the licensee's activities or proposed activities have occurred since the completion of the previous antitrust review in connection with the construction permit. The notice shall also state that persons who wish to have their views on the antitrust aspects of the application considered by the NRC and presented to the Attorney General for consideration should submit such views within thirty (30) days after publication of the notice to: U.S. Nuclear Regulatory Commission, Washington, DC 20555. Attention: Chief, Policy Development and Technical Support Branch.

(2) If the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate, after reviewing any comments or information received in response to the published notice and any comments or information regarding the applicant received from the Attorney General, concludes that there have been no significant changes since the completion of the previous antitrust review in connection with the construction permit, a finding of no significant changes shall be published in the **Federal Register**, together with a notice stating that any request for reevaluation of such finding should be submitted within thirty (30) days of publication of the notice. If no requests for reevaluation are received within that time, the finding shall become the NRC's final determination. Requests for a reevaluation of the no significant changes determination may be accepted after the date when the Director's finding becomes final but before the issuance of the initial operating license only if they contain new information, such as information about facts or events of antitrust significance that have occurred since that date, or information that could not reasonably have been submitted prior to that date.

* * * * *

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

3. The authority section for part 50 continues to read as follows:

Authority: Secs. 102, 103, 104, 105, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 1244, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 50.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 50.10 also issued under secs. 101, 185, 68 Stat. 955 as amended (42 U.S.C. 2131, 2235), sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.13, 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138). Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a and Appendix Q also issued under sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under sec. 204, 88 Stat. 1245 (42 U.S.C. 5844). Section 50.37 also issued under E.O. 12829, 3 CFR 1993 Comp., p. 570; E.O. 12958, as amended, 3 CFR, 1995 Comp., p. 333; E.O. 12968, 3 CFR 1995 Comp., p. 391. Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97–415, 96 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80–50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C 2237).

4. In § 50.42 paragraph (b) is revised to read as follows:

§ 50.42 Additional standards for class 103 licenses

* * * * *

(b) Due account will be taken of the advice provided by the Attorney General, under subsection 105c of the Act, and to any evidence that may be provided during any proceedings in connection with the antitrust aspects of the application for a construction permit or the facility's initial operating license.

(1) For this purpose, the Commission will promptly transmit to the Attorney General a copy of the construction permit application or initial operating license application. The Commission will request any advice as the Attorney General considers appropriate in regard to the finding to be made by the Commission as to whether the proposed license would create or maintain a situation inconsistent with the antitrust laws, as specified in subsection 105a of the Act. This requirement will not apply—

(i) With respect to the types of class 103 licenses which the Commission, with the approval of the Attorney general, may determine would not significantly affect the applicant's activities under the antitrust laws; and

(ii) To an application for an initial license to operate a production or utilization facility for which a class 103 construction permit was issued unless the Commission, after consultation with the Attorney General, determines such review is advisable on the ground that significant changes have occurred subsequent to the previous review by the Attorney General and the Commission.

(2) The Commission will publish any advice it receives from the Attorney General in the **Federal Register**. After considering the antitrust aspects of the application for a construction permit or initial operating license, the Commission, if it finds that the construction permit or initial operating license to be issued or continued, would create or maintain a situation inconsistent with the antitrust laws specified in subsection 105a of the Act, will consider, in determining whether a construction permit or initial operating license should be issued or continued, other factors the Commission considers necessary to protect the public interest, including the need for power in the affected area.[1]

5. In § 50.80 paragraph (b) is revised to read as follows:

§ 50.80 Transfer of licenses.

* * * * *

(b) An application for transfer of a license shall include as much of the information described in §§ 50.33 and

[1] As permitted by subsection 105c(8) of the Act, with respect to proceedings in which an application for a construction permit was filed prior to Dec. 19, 1970, and proceedings in which a written request for antitrust review of an application for an operating license to be issued under section 104b has been made by a person who intervened or sought by timely written notice to the Atomic Energy Commission to intervene in the construction permit proceeding for the facility to obtain a determination of antitrust considerations or to advance a jurisdictional basis for such determination within 25 days after the date of publication in the **Federal Register** of notice of filing of the application for an operating license or Dec. 19, 1970, whichever is later, the Commission may issue a construction permit or operating license in advance of consideration of, and findings with respect to the antitrust aspects of the application, provided that the permit or license so issued contains the condition specified in § 50.55b.

50.34 of this part with respect to the identity and technical and financial qualifications of the proposed transferee as would be required by those sections if the application were for an initial license, and, if the license to be issued is a class 103 construction permit or initial operating license, the information required by § 50.33a. The Commission may require additional information such as data respecting proposed safeguards against hazards from radioactive materials and the applicant's qualifications to protect against such hazards. The application shall include also a statement of the purposes for which the transfer of the license is requested, the nature of the transaction necessitating or making desirable the transfer of the license, and an agreement to limit access to Restricted Data pursuant to § 50.37. The Commission may require any person who submits an application for license pursuant to the provisions of this section to file a written consent from the existing licensee or a certified copy of an order or judgment of a court of competent jurisdiction attesting to the person's right (subject to the licensing requirements of the Act and these regulations) to possession of the facility involved.

* * * * *

6. In Appendix L to Part 50, the heading of Appendix L and Definition 1 are revised, Definitions 3 through 6 are redesignated as Definitions 4 through 7, and a new Definition 3 is added, to read:

Appendix L to Part 50—Information Requested by the Attorney General for Antitrust Review of Facility Construction Permits and Initial Operating Licenses

* * * * *

I. Definitions

1. *Applicant* means the entity applying for authority to construct or initially operate subject unit and each corporate parent, subsidiary and affiliate. Where application is made by two or more electric utilities not under common ownership or control, each utility, subject to the applicable exclusions contained in § 50.33a, should set forth separate responses to each item herein.

* * * * *

3. *Initially operate* a unit means to operate the unit pursuant to the first operating license issued by the Commission for the unit.

* * * * *

Dated at Rockville, Maryland, this 27th day of October 1999.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,

Secretary of the Commission.

[FR Doc. 99–28593 Filed 11–2–99; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

RIN 3150–AG15

Clarification and Addition of Flexibility

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations on spent fuel storage to specify those sections of 10 CFR Part 72 that apply to general licensees, specific licensees, applicants for a specific license, certificate holders, and applicants for a certificate. The proposed amendment is consistent with past NRC staff licensing practice and would eliminate any ambiguity for these persons by clarifying which portions of Part 72 apply to their activities. This proposed rule would eliminate the necessity for repetitious Part 72 specific license hearing reviews of cask design issues that the Commission previously considered and resolved during approval of the cask design. This proposed rule would also allow an applicant for a Certificate of Compliance (CoC) to begin cask fabrication under an NRC-approved quality assurance (QA) program before the CoC is issued.

DATES: Submit comments by January 18, 2000. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Comments may be sent by mail to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 am and 4:15 pm on Federal workdays.

You may also provide comments via the NRC's interactive rulemaking web site through the NRC home page (http://www.nrc.gov). This site provides the availability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking site, contact Ms. Carol Gallagher (301) 415–5905; e-mail CAG@nrc.gov.

Certain documents related to this rulemaking, including comments received, the regulatory analysis, and a Table of Applicability, may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. These same documents also may be viewed and downloaded electronically via the interactive rulemaking website established by NRC for this rulemaking.

FOR FURTHER INFORMATION CONTACT: Anthony DiPalo, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6191, or e-mail at AJD@nrc.gov.

SUPPLEMENTARY INFORMATION:

Background

The Commission's regulations at 10 CFR Part 72 were originally designed to provide specific licenses for the storage of spent nuclear fuel in an independent spent fuel storage installation (ISFSI) (45 FR 74693; November 12, 1980). In 1990, the Commission amended Part 72 to include a process for approving the design of spent fuel storage casks and issuing a CoC (Subpart L) and for granting a general license to reactor licensees (Subpart K) to use NRC-approved casks for the storage of spent nuclear fuel (55 FR 29181; August 17, 1990). Although the Commission intended that the requirements imposed in Subpart K for general licensees be used in addition to, rather than in lieu of, appropriate existing requirements, ambiguity exists as to which Part 72 requirements, other than those in Subpart K, are applicable to general licensees.

In addition, the Commission has identified two aspects of Part 72 where it would be desirable to reduce the regulatory burden and provide additional flexibility to applicants for a specific license or for a CoC.

First, the staff anticipates that the Commission may receive several applications for specific licenses for ISFSI's that will propose using storage cask designs previously approved by NRC under the provisions of Subpart L of Part 72 (i.e., cask designs that have been issued a CoC and are listed in § 72.214). Section 72.18, ''Elimination of repetition,'' permits an applicant to incorporate by reference information contained in previous applications, statements, or reports filed with the NRC, including cask designs approved under Subpart L. Section 72.46 requires that in an application for a license under Part 72, the Commission shall issue or cause to be issued a notice of proposed action and opportunity for a license hearing in accordance with 10 CFR Part 2. Under current Part 72 regulations, the adequacy of the design of these previously approved casks could be at issue during a § 72.46 license hearing for a specific license

application (i.e., issues on the cask design which have been previously addressed by the Commission, including resolution of public comments, that could be the subject of license hearings).

Second, § 72.234(c), which was part of the 1990 amendments to Part 72, prohibits an applicant for a CoC from beginning fabrication of a spent fuel cask before the NRC issues a CoC for the cask design. However, an applicant for a specific license is currently allowed to begin fabrication of spent fuel storage casks before the license is issued. At the time the 1990 rule was proposed, a commenter suggested that a fabricator (i.e. applicant for a CoC) be allowed to take the risk of beginning fabrication before the receipt of the CoC. However, the Commission took the position, ''[i]f a vendor has not received the certificate, then the vendor does not have the necessary approved specifications and may design and fabricate casks to meet incorrect criteria,'' (55 FR 29185; August 17, 1990).

Since 1990, the Commission has reviewed and approved several cask designs. These reviews and follow-up requests for additional information have established the NRC's expectation as to how its criteria for cask design and fabrication should be met. In January 1997, the NRC published NUREG–1536, ''Standard Review Plan for Dry Cask Storage Systems,'' informing CoC applicants of its expectations in reviewing cask designs. Since then, the Commission has granted six exemptions from § 72.234(c) allowing applicants to begin fabrication prior to issuance of the CoC. One exemption request is currently under review by NRC. Additional exemption requests from § 72.234(c) requirements are anticipated.

Discussion

Clarification

This proposed rulemaking would eliminate the regulatory uncertainty that now exists in Part 72 by adding a new section § 72.13 which specifies which Part 72 regulations apply to general licensees, specific licensees, applicants for a specific license, certificate holders, and applicants for a CoC.

Flexibility

First, this proposed rule would eliminate the necessity for repetitious § 72.46 specific license hearing board reviews of cask design issues that the Commission has previously considered during approval of the cask design. The Commission anticipates receipt of several applications, for specific ISFSI licenses, that will propose using storage cask designs previously approved by the NRC. Applicants for a specific license presently have the authority under § 72.18 to incorporate by reference into their application, information contained in previous applications, statements, or reports filed with the Commission, including information from the Safety Analysis Report on a cask design previously approved by the NRC under the provisions of Subpart L. The Commission believes previously reviewed cask design issues should be excluded from the scope of a license hearing. This is because the public had the right during the Subpart L approval process to comment on the adequacy of the cask design. The right of the public to comment on cask designs would not be affected by this rulemaking. For new cask design issues, this rulemaking would not limit the scope of staff's review of the application or of license hearings. For example, a cask's previously reviewed and approved thermal, criticality, and structural designs could not be raised as issues in a licensing hearing. However, design interface issues between the approved cask design and specific site characteristics (*e.g.,* meteorological, seismological, radiological, and hydrological) or changes to the cask's approved design may be raised as issues at a potential hearing. Furthermore, the rights of the public to petition the Commission under § 2.206 to raise new safety issues on the adequacy of the cask design would not be affected by this rulemaking.

Second, the proposed rule would permit an applicant for approval of a spent fuel storage cask design under Subpart L to begin fabrication of casks before the NRC has approved the cask design and issued the CoC. Currently, an applicant for a CoC is not permitted under § 72.234(c) to begin cask fabrication until after the CoC is issued. Applicants for a specific license, and their contractors, are currently allowed to begin fabrication of casks before the Commission issues their license. However, general licensees and their contractors (*i.e,* the certificate holder) are not allowed to begin fabrication before the CoC is issued. Consequently, this proposed rule would eliminate NRC's disparate treatment between general and specific licensees. In addition to allowing an applicant for a CoC to begin fabrication of a cask, comments would be requested on the need for a general licensee to also begin fabrication of a cask before issuance of the CoC. The Commission and the staff have previously determined that exemptions from the fabrication prohibition are authorized by law and do not endanger life or property, the common defense, or security and are otherwise in the public interest. The Commission anticipates that additional cask designs will be submitted to the NRC for approval and expects that these designs will be similar in nature to those cask designs that have already been approved. The Commission also expects that exemption requests to permit fabrication would also be received. This rulemaking would eliminate the need for such exemption requests.

This proposed rule would revise the quality assurance regulations in Subpart G of Part 72 to require that an applicant for a CoC, who voluntarily wishes to begin cask fabrication, must conduct cask fabrication under an NRC-approved QA program. Currently, applicants for a CoC are required by § 72.234(b) to conduct design, fabrication, testing, and maintenance activities under a QA program that meet the requirements of Subpart G. Prior NRC approval of the applicant's QA program is not required by § 72.234(b). However, § 72.234(c) precludes cask fabrication until after the CoC is issued. The Commission believes this proposed rule is a conditional relaxation to permit fabrication before the CoC is issued. Since NRC staff would approve the applicant's QA program as part of issuance of a CoC, staff approval of the QA program prior to fabrication is a question of timing (*e.g.,* when the program is approved, as opposed to imposing a new requirement for approval of a program). The Commission expects that any financial or scheduler risks associated with fabrication of casks prior to issuance of the CoC would be borne by the applicant. The Commission believes that the proposed rule is not a backfit because § 72.62 applies to licensees after the license is issued and does not apply to applicants prior to issuance of the license or CoC. This rule would require that a cask for which fabrication was initiated before issuance of the CoC must conform to the issued CoC before it may be used.

This proposed rule would also require an applicant for a specific license, who voluntarily wishes to begin fabrication of casks before the license is issued, to conduct fabrication under an NRC-approved QA program. Currently, an applicant for a specific license is required by § 72.140(c) to obtain NRC approval of its QA program before spent fuel is loaded into the ISFSI. The Commission does not believe this proposed rule would impose a separate requirement, rather it would require

different timing on when the QA program is approved.

This proposed rule would also revise § 72.140(d) to allow a licensee, applicant for a license, certificate holder, and applicant for a CoC to use an existing Part 50, 71, or 72 QA program that was previously approved by the NRC.

As a result of this proposed rule, both licensees and certificate holders will be required to accomplish any fabrication activities under an NRC-approved QA program. The Commission believes this proposed rule's increase in flexibility and change in timing of approval of a QA program is not a backfit.

In addition to an applicant's fabrication of a cask design prior to issuance of the CoC, the Commission is requesting comments on the need for a general licensee to also begin fabrication of a cask design, before the cask design is approved and the CoC is issued.

Section-by-Section Discussion of Proposed Amendments

This proposed rule would make several amendment changes to Part 72 which are characterized as follows. This proposed rule would eliminate the regulatory uncertainty that now exists in Part 72 and explicitly specifies which regulations apply to general licensees, specific licensees, and certificate holders. The proposed rule would eliminate the necessity for repetitious reviews in a specific license hearing of cask design issues that the Commission previously considered during approval of the cask design. The proposed rule would permit an applicant for approval of a spent fuel storage cask design to begin cask fabrication, at its own risk, before the NRC has issued the CoC. The proposed rule would require that NRC approval of the quality assurance program be obtained before cask fabrication can commence.

Section 72.13 Applicability

This new section identifies those sections of Part 72 that apply to specific licenses, general licenses, and Certificates of Compliance. No changes to the underlying regulations would result from this amendment, it is intended for clarification only.

Section 72.46 Public Hearings

A new paragraph (e) would be added to this section to indicate that the scope of any license hearing, for an application for an ISFSI license, shall not include any issues that were previously resolved by the Commission during the approval process of the design of a spent fuel storage cask, when the application incorporates by reference, information on the design of an NRC-approved spent fuel storage cask. The Commission considers rereview of cask design issues, which have been previously resolved as an unnecessary regulatory burden on applicants causing unnecessary expenditure of staff and hearing board resources. For example, the cask's previously reviewed and approved thermal, criticality, and structural designs could not be raised as issues in a hearing. However, design interface issues between the approved cask design and specific site characteristics (*e.g.*, meteorological, seismological, radiological, and hydrological) or changes to the cask's approved design may be raised as issues at a potential hearing.

This proposed rulemaking would not limit the scope of staff's review of the application or of license hearings, for new cask design issues that were not considered by the Commission during previous approval of the cask design. In addition, the rights of the public to petition the Commission under § 2.206 to raise new safety issues on the adequacy of the cask design would not be affected by this rulemaking.

Section 72.86 Criminal Penalties

Paragraph (b) of this section lists those Part 72 regulations for which criminal sanctions may not be issued, because the Commission considers these sections to be non-substantive regulations issued under the provisions of § 161(b), (i), or (o) of the Atomic Energy Act of 1954 (AEA).

Substantive regulations are those regulations that create duties, obligations, conditions, restrictions, limitations, and prohibitions (see final rule on ''Clarification of Statutory Authority for Purposes of Criminal Enforcement'' (57 FR 55062; November 24, 1992)). The Commission considers that the new § 72.13 would not be a substantive regulation, issued under the provisions of § 161(b), (i), or (o) of the AEA. Therefore, paragraph (b) of this section would be revised to add § 72.13 to indicate that willful violations of this new section would not be subject to criminal penalties.

Section 72.140 Quality Assurance Requirements

Paragraph (c)(1) would be revised to add applicants for a specific license and applicants for a CoC. Paragraph (c)(2) would be revised to add the requirement that an applicant for a specific license shall obtain NRC-approval of its QA program before beginning fabrication or testing of a spent fuel storage cask. Paragraph (c)(3) would be revised to indicate that an applicant for a CoC shall obtain NRC-approval of its QA program requirement before beginning fabrication or testing of a spent fuel storage cask. These revisions would result in consistent treatment of general licensees, specific licensees, applicants for a specific license, certificate holders, and applicants for a CoC. These revisions would also ensure that the NRC has reviewed and approved a QA program before commencement of any fabrication or testing activities.

Paragraph (d) would be revised to clarify the use of previously approved QA programs by a licensee, applicant for a license, certificate holder, and applicant for a CoC. The Commission expects these persons to notify the NRC of their intent to use a QA program previously approved by the NRC under the provisions of Parts 50, 71, or 72.

Section 72.234 Conditions of approval

Paragraph (c) of this section would be revised to permit an applicant for a CoC to begin fabrication of spent fuel storage casks (under an NRC-approved QA program), at the applicant's own risk, before the NRC issues the CoC. The Commission expects that any risks associated with fabrication (*e.g.*, rewelding, reinspection, or even abandonment of the cask) would be borne by the applicant. The NRC would also require that a cask fabricated before the CoC was issued conform to the issued CoC before spent fuel is loaded. Requiring an applicant to conform a fabricated cask to the issued CoC would not be subject to the backfit review provisions of § 72.62.

Section 72.236 Specific Requirements For Spent Fuel Storage Cask Approval

The introductory text in this section before paragraph (a) would be revised as a conforming change to § 72.234(c) to indicate that all of the requirements in this section apply to both certificate holders and applicants for a CoC.

Criminal Penalties

For the purposes of Section 223 of the Atomic Energy Act (AEA), the Commission is issuing the proposed rule to amend 10 CFR 72.140, 72.234, and 72.236 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement.

Agreement State Compatibility

Under the ''Policy Statement on Adequacy and Compatibility of Agreement State Programs'' approved by the Commission on June 30, 1997, and published in the **Federal Register** on September 3, 1997 (62 FR 46517), this

proposed rule is classified as Category NRC. Compatibility is not required for Category NRC regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the AEA or the provisions of Title 10 of the Code of Federal Regulations.

Plain Language

The Presidential Memorandum dated June 1, 1998, entitled, ''Plain Language in Government Writing,'' directed that the government's writing be in plain language. The NRC requests comments on this proposed rule specifically with respect to the clarity and effectiveness of the language used. Comments should be sent to the address listed under the heading **ADDRESSES** above.

Voluntary Consensus Standards

The National Technology Transfer Act of 1995, (Pub. L. 104–113), requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. The NRC is proposing to amend its regulations on spent fuel storage in those sections of 10 CFR Part 72 that apply to general licensees, specific licensees, applicants for a specific license, certificate holders, and applicants for a certificate. This proposed rule would eliminate the necessity for repetitious Part 72 specific license hearing reviews of cask design issues that the Commission previously considered and resolved during approval of the cask design. This proposed rule would also allow an applicant for a Certificate of Compliance (CoC) to begin cask fabrication before the CoC is issued. This action does not constitute the establishment of a standard that establishes generally applicable requirements.

Environmental Impact: Categorical Exclusion

The NRC has determined that this proposed rule is the type of action described in the categorical exclusion in 10 CFR 51.22(c)(2) and (3). This action represents amendments to the regulations which are corrective or of a minor or nonpolicy nature and do not substantially modify the existing regulations. Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed rule.

Paperwork Reduction Act Statement

This proposed rule would decrease the burden on licensees by eliminating the requirement to request an exemption to begin cask design before a license is issued, and by allowing all licensees and CoC holders to reference previously approved QA programs. The public burden reduction for this information collection would average 200 hours per exemption request. However, because no burden has previously been approved for exemption requests and no licensees are expected to reference previously approved QA programs in the foreseeable future, no burden reduction can be taken for this rulemaking. Existing requirements were approved by the Office of Management and Budget, approval number 3150–0132.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

Regulatory Analysis

Statement of the Problem and Objective

The Commission's regulations at 10 CFR Part 72 were originally designed to provide specific licenses for the storage of spent nuclear fuel in independent spent fuel storage installations (ISFSIs) (45 FR 74693; November 12, 1980). In 1990, the Commission amended Part 72 to include a process for approving the design of spent fuel storage casks and issuance of a CoC (Subpart L); and for granting a general license to reactor licensees (Subpart K) to use NRC-approved casks for storage of spent nuclear fuel (55 FR 29181; August 17, 1990). Although the Commission intended that the requirements imposed in Subpart K for general licensees be used in addition to, rather than in lieu of, appropriate existing requirements, ambiguity exists as to which of the Part 72 requirements, other than those in Subpart K, are applicable to general licensees. This rulemaking would resolve that ambiguity.

In addition, the Commission has identified two aspects of Part 72 where it would be desirable to reduce the regulatory burden for applicants, NRC staff, and hearing boards and to afford additional flexibility to applicants for a CoC:

First, this proposed rule would eliminate the necessity for repetitious reviews, during a Part 72 specific license hearing (§ 72.46), of cask design issues that the Commission has previously considered during approval of the cask design. The Commission anticipates receipt of several applications, for specific ISFSI licenses, that will propose using storage cask designs previously approved by the NRC. Applicants for a specific license presently have the authority under § 72.18 to incorporate by reference into their application, information contained in previous applications, statements, or reports filed with the Commission, including information from the Safety Analysis Report for a cask design previously approved by the NRC under the provisions of Subpart L. The Commission believes previously reviewed cask design issues should be excluded from the scope of a license hearing. This is because the public had the right to question the adequacy of the cask design, during the approval process under Subpart L. The right of the public to comment on cask designs would not be affected by this rulemaking. For new cask design issues, this rulemaking would not limit the scope of staff's review of the application or of license hearings. For example, a cask's previously reviewed and approved thermal, criticality, and structural designs could not be raised as issues in a hearing. However, design interface issues between the approved cask design and specific site characteristics (e.g., meteorological, seismological, radiological, and hydrological) or changes to the cask's approved design may be raised as issues at a potential hearing. In addition, the rights of the public to petition the Commission under § 2.206 to raise new safety issues on the adequacy of the cask design would not be affected by this rulemaking.

Second, the proposed rule would permit an applicant for approval of a spent fuel storage cask design under Subpart L to begin fabrication of casks before the NRC has approved the cask design and issued the CoC. Currently, an applicant for a CoC is not permitted under § 72.234(c) to begin cask fabrication until after the CoC is issued. Applicants for a specific license, and their contractors, are currently allowed to begin fabrication of casks before the Commission issues their license. However, general licensees and their contractors (i.e, the certificate holder) are not allowed to begin fabrication before the CoC is issued. Consequently, this proposed rule would eliminate NRC's disparate treatment between general and specific licensees. In addition to allowing an applicant for a CoC to begin fabrication of a cask prior to issuance of the CoC, comments would be requested on the need for a general licensee to also begin fabrication of a cask before the CoC is issued. The Commission and the staff have

previously determined that exemptions from the fabrication prohibition are authorized by law and do not endanger life or property, the common defense, or security and are otherwise in the public interest. The Commission anticipates that additional cask designs will be submitted to the NRC for approval and expects that these designs will be similar in nature to those cask designs that have already been approved. The Commission also expects that exemption requests to permit fabrication would also be received. Therefore, this rulemaking would eliminate the need for such exemption requests.

This proposed rule would revise the quality assurance regulations in Subpart G of Part 72 to require that an applicant for a CoC, who voluntarily wishes to begin cask fabrication, must conduct cask fabrication under an NRC-approved QA program. Currently, applicants for a CoC are required by § 72.234(b) to conduct design, fabrication, testing, and maintenance activities under a QA program that meets the requirements of Subpart G. Prior NRC approval of the applicant's QA program is not required by § 72.234(b). However, § 72.234(c) precludes cask fabrication until after the CoC is issued. The Commission believes this proposed rule is a conditional relaxation to permit fabrication before the CoC is issued. Since NRC staff would approve the applicant's QA program as part of issuance of a CoC, staff approval of the QA program prior to fabrication is a question of timing (e.g., when the program is approved, as opposed to imposing a new requirement for approval of a program). The Commission expects that any financial or scheduler risks associated with fabrication of casks prior to issuance of the CoC would be borne by the applicant. The Commission believes that the proposed rule is not a backfit because § 72.62 applies to licensees after the license is issued and does not apply to applicants prior to issuance of the license or CoC. This rule would require that a cask for which fabrication was initiated before issuance of the CoC must conform to the issued CoC before it may be used.

This proposed rule would also require an applicant for a specific license, who voluntarily wishes to begin fabrication of casks before the license is issued, to conduct fabrication under an NRC-approved QA program. Currently, an applicant for a specific license is required by § 72.140(c) to obtain NRC approval of its QA program before spent fuel is loaded into the ISFSI. The Commission does not believe this proposed rule would impose a separate requirement, rather it would require different timing on when the QA program is approved.

This proposed rule would also revise § 72.140(d) to allow a licensee, applicant for a license, certificate holder, and applicant for a CoC to use an existing Part 50, 71, or 72 QA program that was previously approved by the NRC.

As a result of this proposed rule both licensees and certificate holders will be required to accomplish any fabrication activities under an NRC-approved QA program. The Commission believes this proposed rule's increase in flexibility and change in timing of approval of a QA program is not a backfit.

The Commission expects that any risks associated with fabrication (e.g., rewelding, reinspection, or even abandonment of the cask) would be borne by the applicant. In particular, the staff would require that a cask, which was fabricated before the CoC was issued, must conform with the issued CoC. Requiring an applicant to conform a fabricated cask to the issued CoC would not be subject to the backfit review provisions of § 72.62.

Identification and Preliminary Analysis of Alternative Approaches to the Problem

- Option 1—Conduct a rulemaking that would address the regulatory problems as described above.

First, this proposed rulemaking would specify the sections in Part 72 that apply to general licensees, specific licensees, and certificate holders. This would eliminate the need to resolve on a case-by-case basis questions on which Part 72 sections are applicable to those activities. The proposed rule is administrative in nature and other than the cost of rulemaking, would have no impact.

Second, this rulemaking would reduce the regulatory burden on applicants, staff, and hearing board resources relating to any § 72.46 license hearings involving cask design issues associated with an application for a specific license, where the cask design has been previously approved by the NRC. Elimination of the need for repetitious reviews of cask design issues and licensing hearings on these same cask design issues together would save 1.0 FTE of applicant effort and 1.0 FTE of staff effort for each license application received. NRC expects to receive three applications in 1999 and six applications each year in 2000 and 2001. While applicants for a license are currently allowed to incorporate by reference information on cask design information, this rulemaking would reduce applicant burden associated with providing additional information on the cask design and responding to hearing board contentions on issues which have been previously reviewed.

Third, this rulemaking would also provide increased flexibility to applicants for a CoC by allowing them to begin cask fabrication, before the CoC is issued. This rulemaking would reduce the burden on applicants for a CoC associated with submission of requests for exemption from § 72.234(c). Certificate holders have requested these exemptions to take advantage of favorable business conditions (*i.e.*, they want to begin fabrication of casks a soon as possible to meet their contract obligations). Elimination of the need for submission and review of exemption requests from the cask fabrication requirement of § 72.234(c) would save 0.1 FTE of applicant effort and 0.1 FTE of staff effort, for each exemption request not received. Without this action, NRC expects that two requests for exemption from § 72.234(c) would be received each year in 1999 and beyond. This rulemaking would also eliminate the disparate treatment of general and specific licensees under Part 72, with respect to fabrication of spent fuel storage casks. This rulemaking would also reduce staff burden associated with review of such exemption requests. Because a certificate holder is currently required by § 72.140(c)(3) to obtain NRC approval of its QA program before commencing fabrication, and the staff is currently required to review and approve such programs, no increase in applicant burden or staff resources would occur with respect to the proposed change to § 72.140(c)(3). However, the timing of the staff review and approval of the QA program would change.

The impact of this option consists primarily of a reduction in regulatory burden on an applicant for a specific license, a reduction in regulatory burden and increase in regulatory flexibility for an applicant for a cask design, and a reduction in the expenditure of NRC resources involved in reviewing applications for a specific license, supporting license hearings, and reviewing requests for exemption from § 72.234(c). This option would result in the expenditure of NRC resources to conduct this rulemaking.

- Option 2—No action.

The benefit of the no action alternative is that NRC resources will be conserved because no rulemaking would be conducted. The impact of this alternative would be that the regulatory problems described above would not be addressed. Instead, applicant and staff resources will continue to be expended

on repetitious reviews of previously approved cask designs, conducting licensing hearings on previously approved cask design issues, and processing requests for exemption from § 72.234(c), to allow fabrication of casks.

Estimation and Evaluation of Values and Impacts

The clarification of which Part 72 sections apply to specific licensees, applicants for a specific license, general licensees, certificate holders, and applicants for a CoC alone would have no impacts other than the cost of rulemaking, because this action is administrative in nature.

The elimination of the need for repetitious reviews of cask design issues, that were previously reviewed by the NRC, and elimination of licensing hearings on these same cask design issues together would save 1.0 FTE of applicant effort and 1.0 FTE of staff effort for each license application received. NRC expects to receive three applications in 1999 and six applications each year in 2000 and 2001.

The elimination of the need for submission and review of exemption requests from the cask fabrication requirement of § 72.234(c) would save 0.1 FTE of applicant effort and 0.1 FTE of staff effort, for each exemption request not received. Without this action, NRC expects that two requests for exemption from § 72.234(c) would be received each year in 1999 and beyond.

Presentation of Results

The recommended action is to adopt the first option because it will set forth a clear regulatory base for Part 72 general licensees, specific licensees, applicants for a specific license, certificate holders, and applicants for a CoC.

The recommended action would eliminate the need for repetitious license hearing adjudication of cask design issues that the Commission has previously reviewed in approving the cask design, when an applicant for a specific license has incorporated by reference a cask design that has been approved by the Commission under the provisions of Subpart L. This is because the public had the right to question the adequacy of the cask design during the approval process under Subpart L. The right of the public to comment on cask designs would not be affected by this rulemaking. This rulemaking would not limit the scope of staff's review of the application or license hearings for issues which were not considered by the Commission during previous approval of the cask design. In addition, the rights of the public to petition the Commission under § 2.206 to raise new safety issues on the adequacy of the cask design would not be affected by this rulemaking. The Commission considers rereview of cask design issues which have been previously evaluated and dispositioned as an unnecessary regulatory burden on applicants and an unnecessary expenditure of staff and hearing board resources. For example, the cask's previously reviewed and approved thermal, criticality, and structural designs could not be raised as issues in a hearing. However, design interface issues between the approved cask design and specific site characteristics (*e.g.*, meteorological, seismological, radiological, and hydrological) or changes to the cask's approved design may be raised as issues at a potential hearing. Therefore, this action has no safety impact.

The recommended action would permit an applicant for approval of a spent fuel storage cask design under Subpart L to begin fabrication of casks before the NRC has approved the cask design and issued the CoC. Currently, an applicant for a CoC is not permitted under § 72.234(c) to begin cask fabrication until after the CoC is issued. Applicants for a specific license, and their contractors, are currently allowed to begin fabrication of casks before the Commission issues their license. However, general licensees and their contractors (*i.e*, the certificate holder) are not allowed to begin fabrication before the CoC is issued. Consequently, this proposed rule would eliminate NRC's disparate treatment between general and specific licensees. In addition to allowing an applicant for a CoC to begin fabrication of a cask prior to issuance of the CoC, comments would be requested on the need for a general licensee to also begin fabrication of a cask before the CoC is issued. The Commission and the staff have previously determined that exemptions from the fabrication prohibition are authorized by law and do not endanger life or property, the common defense, or security and are otherwise in the public interest. The Commission anticipates that additional cask designs will be submitted to the NRC for approval and expects that these designs will be similar in nature to those cask designs that have already been approved. The Commission also expects that exemption requests to permit fabrication would also be received. Therefore, this rulemaking would eliminate the need for such exemption requests.

This proposed rule would revise the quality assurance regulations in Subpart G of Part 72 to require that an applicant for a CoC, who voluntarily wishes to begin cask fabrication, must conduct cask fabrication under an NRC-approved QA program. Currently, applicants for a CoC are required by § 72.234(b) to conduct design, fabrication, testing, and maintenance activities under a QA program that meet the requirements of Subpart G. Prior NRC approval of the applicant's QA program is not required by § 72.234(b). However, § 72.234(c) precludes cask fabrication until after the CoC is issued. The Commission believes this proposed rule is a conditional relaxation to permit fabrication before the CoC is issued. Since NRC staff would approve the applicant's QA program as part of issuance of a CoC, staff approval of the QA program prior to fabrication is a question of timing (*e.g.*, when the program is approved, as opposed to imposing a new requirement for approval of a program). The Commission expects that any financial or scheduler risks associated with fabrication of casks prior to issuance of the CoC would be borne by the applicant. The Commission believes that the proposed rule is not a backfit because § 72.62 applies to licensees after the license is issued and does not apply to applicants prior to issuance of the license or CoC. This rule would require that a cask for which fabrication was initiated before issuance of the CoC must conform to the issued CoC before it may be used.

This proposed rule would also require an applicant for a specific license, who voluntarily wishes to begin fabrication of casks before the license is issued, to conduct fabrication under an NRC-approved QA program. Currently, an applicant for a specific license is required by § 72.140(c) to obtain NRC approval of its QA program before spent fuel is loaded into the ISFSI. The Commission does not believe this proposed rule would impose a separate requirement, rather it would require different timing on when the QA program is approved.

This proposed rule would also revise § 72.140(d) to allow a licensee, applicant for a license, certificate holder, and applicant for a CoC to use an existing Part 50, 71, or 72 QA program that was previously approved by the NRC.

As a result of this proposed rule, both licensees and certificate holders will be required to conduct any fabrication activities under an NRC-approved QA program. The Commission believes this proposed rule's increase in flexibility and change in timing of approval of a QA program is not a backfit. Therefore, these actions have no safety impact.

The Commission expects that any risks associated with fabrication (*e.g.*, rewelding, reinspection, or even abandonment of the cask) would be borne by the applicant. In particular, the staff would require that a cask, which was fabricated before the CoC was issued, must conform with the issued CoC. Requiring an applicant to conform a fabricated cask to the issued CoC would not be subject to the backfit review provisions of § 72.62.

The total cost of this rulemaking to the NRC is estimated at 1.9 FTE. The total savings to the NRC for this rulemaking is estimated at 16.5 FTE over a 3-year period (1999 through 2001). The total savings to applicants is estimated at 15.0 FTE over the same 3-year period. Therefore, this action would be considered cost beneficial to both NRC and applicants, would reduce the burden on applicants, and would improve the efficiency and effectiveness of the NRC. Consequently, the Commission believes public confidence in the safe storage of spent fuel at independent spent fuel storage installations would not be adversely affected by this rulemaking.

Decision Rationale

The rationale is to proceed with this proposed rulemaking implementing the Commission approved rulemaking plan. This rulemaking would save both staff and applicant resources as discussed above.

The clarification of the provisions of Part 72 and their application to general licensees, specific licensees, applicants for a specific license, certificate holders, and applicants for a CoC is administrative in nature and would have no safety impacts.

The elimination of the need for repetitious license hearings on cask design issues, that the NRC has previously reviewed and approved, in an application for a specific license would have no safety impacts. The public's right to comment on cask design issues, through the Subpart L cask approval process, will remain unchanged.

The flexibility to begin fabrication cask fabrication before the NRC issues the CoC, when combined with the requirement that cask fabrication must be performed under an NRC-approved QA program, would have no safety impacts.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. This proposed rule would clearly specify which sections of Part 72 apply to general licensees, specific licensees, applicants for a specific license, certificate holders, and applicants for a certificate and allow these persons to determine which Part 72 regulations apply to their activity. This clarification will eliminate the ambiguity that now exists. This proposed rule would also eliminate the need for repetitious license-hearing reviews of cask design issues, that were previously reviewed and approved by the NRC, when the applicant for a specific license incorporates by reference information on a cask design that was previously approved by the NRC. Finally, this proposed rule would allow applicants for a CoC to begin fabrication of a cask design before the NRC has issued a CoC. Applicants desiring to begin fabrication shall use an NRC-approval QA program. The requirement to obtain NRC-approval of the applicant's QA program is not considered an additional burden. An applicant who has been issued a CoC, and is then considered a certificate holder, is currently required by § 72.140(c)(2) to obtain NRC-approval before fabrication or testing is commenced; consequently, no actual increase in burden occurs. Similarly, an applicant for a license is currently required to obtain NRC-approval prior to receipt of spent fuel or high-level waste; consequently, no actual increase in burden occurs. This proposed rule does not impose any additional obligations on entities that may fall within the definition of ''small entities'' as set forth in Section 601(6) of the Regulatory Flexibility Act; or within the definition of ''small business'' as found in Section 3 of the Small Business Act, 15 U.S.C. 632; or within the size standards adopted by the NRC on April 11, 1985 (60 FR 18344).

Backfit Analysis

The NRC has determined that the backfit rule, § 72.62, does not apply to this proposed rule. Because these amendments would not involve any provisions that would impose backfits as defined in § 72.62(a), a backfit analysis is not required.

List of Subjects in 10 CFR Part 72

Criminal penalties, Manpower training programs, Nuclear materials, Occupational safety and health, Reporting and recordkeeping requirements, Security measures, Spent fuel.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Part 72.

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL AND HIGH-LEVEL RADIOACTIVE WASTE

1. The authority citation for Part 72 continues to read as follows:

Authority: Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 68 Stat. 929, 930, 932, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2238, 2282); sec. 274, Pub. L. 86–373, 73 Stat. 688, as amended (42 U.S.C. 2021); sec. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); Pub. L. 95–601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102–486, sec. 7902, 106 Stat. 3123 (42 U.S.C. 5851); sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332); Secs. 131, 132, 133, 135, 137, 141, Pub. L. 97–425, 96 Stat. 2229, 2230, 2232, 2241, sec. 148, Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168).

Section 72.44(g) also issued under secs. 142(b) and 148(c), (d), Pub. L. 100–203, 101 Stat. 1330–232, 1330–236 (42 U.S.C. 10162(b), 10168(c), (d)). Section 72.46 also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97–425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10165(g)). Subpart J also issued under secs. 2(2), 2(15), 2(19), 117(a), 141(h), Pub. L. 97–425, 96 Stat. 2202, 2203, 2204, 2222, 2224 (42 U.S.C. 10101, 10137(a), 10161(h)). Subparts K and L are also issued under sec. 133, 98 Stat. 2230 (42 U.S.C. 10153) and sec. 218(a), 96 Stat. 2252 (42 U.S.C. 10198).

2. Section 72.13 is added to Subpart A to read as follows:

§ 72.13 Applicability.

(a) This section identifies those sections, under this part, that apply to the activities associated with a specific license, a general license, or a certificate of compliance.

(b) The following sections apply to activities associated with a specific license: §§ 72.1; 72.2(a) through (e); 72.3 through 72.13(b); 72.16 through 72.34; 72.40 through 72.62; 72.70 through 72.86; 72.90 through 72.108; 72.120 through 72.130; 72.140 through 72.176; 72.180 through 72.186; 72.190 through 72.194; and 72.200 through 72.206.

(c) The following sections apply to activities associated with a general license: §§ 72.1; 72.2(a)(1), (b), (c), and (e); 72.3 through 72.6(c)(1); 72.7 through 72.13(a) and (c); 72.30(c) and (d); 72.32(c) and 72.32(d); 72.44(b), (d), (e),

and (f); 72.48; 72.50(a); 72.52; 72.54(d) through (m); 72.60; 72.62; 72.72 through 72.80(f); 72.82 through 72.86; 72.104; 72.106; 72.122; 72.124; 72.126; 72.140 through 72.176; 72.190 through 72.194; 72.210; 72.212; and 72.216 through 72.220.

(d) The following sections apply to activities associated with a certificate of compliance: §§ 72.1; 72.2(e) and (f); 72.3; 72.4; 72.5; 72.7; 72.9 through 72.13(a) and (d); 72.48; 72.84(a); 72.86; 72.124; 72.140 through 72.176; 72.214; and 72.230 through 72.248.

3. In § 72.46, paragraph (e) is added to read as follows:

§ 72.46 Public hearings.

* * * * *

(e) If an application for (or an amendment to) a specific license issued under this part incorporates by reference information on the design of an NRC-approved spent fuel storage cask, the scope of any public hearing held to consider the application will not include any cask design issues previously addressed by the Commission when it issued a Certificate of Compliance under subpart L of this part.

4. In § 72.86, paragraph (b) is revised to read as follows:

§ 72.86 Criminal penalties.

* * * * *

(b) The regulations in part 72 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 72.1, 72.2, 72.3, 72.4, 72.5, 72.7, 72.8, 72.9, 72.13, 72.16, 72.18, 72.20, 72.22, 72.24, 72.26, 72.28, 72.32, 72.34, 72.40, 72.46, 72.56, 72.58, 72.60, 72.62, 72.84, 72.86, 72.90, 72.96, 72.108, 72.120, 72.122, 72.124, 72.126, 72.128, 72.130, 72.182, 72.194, 72.200, 72.202, 72.204, 72.206, 72.210, 72.214, 72.220, 72.230, 72.238, and 72.240.

5. In § 72.140, paragraphs (c) and (d) are revised to read as follows:

§ 72.140 Quality assurance requirements.

* * * * *

(c) *Approval of program:*

(1) Each licensee, applicant for a license, certificate holder, or applicant for a CoC shall file a description of its quality assurance program, including a discussion of which requirements of this subpart are applicable and how they will be satisfied, in accordance with § 72.4.

(2) Each licensee shall obtain Commission approval of its quality assurance program prior to receipt of spent fuel at the ISFSI or spent fuel and high-level radioactive waste at the MRS. Each licensee or applicant for a specific license shall obtain Commission approval of its quality assurance program prior to commencing fabrication or testing of a spent fuel storage cask.

(3) Each certificate holder or applicant for a CoC shall obtain Commission approval of its quality assurance program prior to commencing fabrication or testing of a spent fuel storage cask.

(d) *Previously approved programs.* A quality assurance program previously approved by the Commission as satisfying the requirements of appendix B to part 50 of this chapter, subpart H to part 71 of this chapter, or subpart G to this part will be accepted as satisfying the requirements of paragraph (b) of this section, except that a licensee, applicant for a license, certificate holder, and applicant for a CoC who is using an appendix B or subpart H quality assurance program shall also meet the recordkeeping requirements of § 72.174. In filing the description of the quality assurance program required by paragraph (c) of this section, each licensee, applicant for a license, certificate holder, and applicant for a CoC shall notify the NRC, in accordance with § 72.4, of its intent to apply its previously approved quality assurance program to ISFSI activities or spent fuel storage cask activities. The notification shall identify the previously approved quality assurance program by date of submittal to the Commission, docket number, and date of Commission approval.

6. In § 72.234, paragraph (c) is revised to read as follows:

§ 72.234 Conditions of approval.

* * * * *

(c) An applicant for a CoC may begin fabrication of spent fuel storage casks before the Commission issues a CoC for the cask; however, applicants who begin fabrication of casks without a CoC do so at their own risk. A cask fabricated before the CoC is issued shall be made to conform to the issued CoC prior to being placed in service or prior to spent fuel being loaded.

* * * * *

7. Section 72.236 is amended by revising the introductory text to read as follows:

§ 72.236 Specific requirements for spent fuel storage cask approval and fabrication.

The certificate holder and applicant for a CoC shall ensure that the requirements of this section are met.

* * * * *

Dated at Rockville, Maryland, this 26th day of October, 1999.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 99–28594 Filed 11–2–99; 8:45 am]

BILLING CODE 7590–01–p

NUCLEAR REGULATORY COMMISSION

10 CFR Part 73

[Docket No. PRM–73–10]

Petition From the State of Nevada; Extension of Comment Period

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking: Extension of comment period.

SUMMARY: On September 13, 1999, the Nuclear Regulatory Commission (NRC) published for public comment a petition for rulemaking filed by the State of Nevada. The petitioner requested that the Commission amend its regulations governing safeguards for shipments of spent nuclear fuel against sabotage and terrorism. The petitioner requested that the NRC conduct a comprehensive assessment of the consequences of terrorist attacks that have the capability of radiological sabotage, including attacks against transportation infrastructure used during nuclear waste shipments, attacks involving capture of nuclear waste shipments and use of high energy explosives against a cask or casks, and direct attacks upon a nuclear waste shipping cask or casks using antitank missiles or other military weapons. The comment period was to have expired on November 29, 1999. John Allen, Chairman of the Hazardous Materials Transportation Committee of the Transportation Research Board, submitted a comment on October 11, 1999, and requested that the comment period be extended due to the tight filing date for the petition. In view of this request, the NRC believes it is appropriate to extend the comment period; therefore, the comment period is extended to January 28, 2000.

DATES: The comment period has been extended and now closes on January 28, 2000. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Send comments by mail addressed to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Attention: Rulemakings and Adjudications Staff.

Hand-deliver comments to: 11555 Rockville Pike, Rockville, Maryland,

between 7:30 a.m. and 4:15 p.m. on Federal workdays.

You may also provide comments via the NRC's interactive rulemaking website (http://ruleform.llnl.gov). This site provides the capability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking website, contact Ms. Carol Gallagher, 301–415–5905 (e-mail: cag@nrc.gov).

FOR FURTHER INFORMATION CONTACT: James Smith, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Telephone: 301–415–6459, or toll-free: 800–368–5642.

Dated at Rockville, Maryland, this 27th day of October, 1999.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 99–28596 Filed 11–2–99; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–NM–262–AD]

RIN 2120–AA64

Airworthiness Directives; Dassault Model Mystere-Falcon 50 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the supersedure of an existing airworthiness directive (AD), applicable to certain Dassault Model Mystere-Falcon 50 series airplanes, that currently requires a revision to the Limitations section of the FAA-approved Airplane Flight Manual (AFM) to include procedures to use certain values to correctly gauge the minimum allowable N1 speed of the operative engines during operation in icing conditions. This proposed AD would add a new requirement for operators to adjust the thrust reverser handle stop, install new wiring, and modify the Digital Electronic Engine Control (DEEC) software, which would terminate the AFM revision. This proposal is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by the proposed AD are intended to prevent flightcrew use of erroneous N1 thrust setting information displayed on the Engine Indication Electronic Display (EIED), which could result in in-flight shutdown of engine(s).

DATES: Comments must be received by December 3, 1999.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 98–NM–262–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Dassault Falcon Jet, P.O. Box 2000, South Hackensack, New Jersey 07606. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Norman B. Martenson, Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 98–NM–262–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 98–NM–262–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

On November 5, 1997, the FAA issued AD 97–21–16, amendment 39–10202 (62 FR 60773, November 13, 1997), applicable to certain Dassault Model Mystere-Falcon 50 series airplanes, to require a revision to the Limitations section of the FAA-approved Airplane Flight Manual (AFM) to include procedures to use certain values to correctly gauge the minimum allowable N1 speed of the operative engines during operation in icing conditions. That action was prompted by a report indicating that erroneous minimum anti-icing N1 thrust setting indications were displayed on the Engine Indication Electronic Display (EIED). The erroneous minimum N1 indications do not correspond with minimums specified in the Normal Procedures Section of the AFM for operations in icing conditions. The requirements of that AD are intended to prevent flightcrew use of erroneous N1 thrust setting information displayed on the EIED and consequent in-flight shutdown of engine(s).

Actions Since Issuance of Previous Rule

In the preamble to AD 97–21–16, the FAA indicated that the actions required by that AD were considered ''interim action'' and that further rulemaking action was being considered. The FAA now has determined that further rulemaking action is indeed necessary, and this proposed AD follows from that determination.

Explanation of Relevant Service Information

Dassault Aviation has issued Service Bulletin F50–276, dated June 24, 1998, which describes procedures for adjustment of the thrust reverser handle stop, installation of new wiring, and modification of the Digital Electronic Engine Control (DEEC) software whereby push-lights are installed and wired to the DEEC. The software changes affect the N1 synch, Mach hold logic, thrust reverser logic, and wing anti-ice and takeoff schedules. Accomplishment of the actions specified in the service bulletin is intended to adequately address the

identified unsafe condition. The Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, classified this service bulletin as mandatory and issued French airworthiness directive 98–228–021(B), dated June 17, 1998, in order to assure the continued airworthiness of these airplanes in France.

Dassault Service Bulletin F50–276 refers to Allied Signal Service Bulletin TFE731–76–5107, dated December 24, 1997, as an additional source of service information for accomplishment of the modification.

FAA's Conclusions

This airplane model is manufactured in France and is type certificated for operation in the United States under the provisions of §§ 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DGAC, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would supersede AD 97–21–16 to retain the requirement to revise the Limitations section of the FAA-approved Airplane Flight Manual (AFM) to include procedures to use certain values to correctly gauge the minimum allowable N1 speed of the operative engines during operation in icing conditions, and add a new requirement for adjustment of the thrust reverser handle stop, installation of new wiring, and modification of the Digital Electronic Engine Control (DEEC) software, which would terminate the need for the AFM revision.

Cost Impact

There are approximately 7 airplanes of U.S. registry that would be affected by this proposed AD.

The action that is currently required by AD 97–21–16, and retained in this AD, takes approximately 1 work hour per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the currently required actions on U.S. operators is estimated to be $60 per airplane.

The new actions that are proposed in this AD action would take approximately 2 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Required parts would cost approximately $1,026 per airplane. Based on these figures, the cost impact of the proposed requirements of this AD on U.S. operators is estimated to be $8,022, or $1,146 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the current or proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (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) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (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. Section 39.13 is amended by removing amendment 39–10202 (62 FR 60773, November 13, 1997), and by adding a new airworthiness directive (AD), to read as follows:

Dassault Aviation: Docket 98–NM–262–AD. Supersedes AD 97–21–16, Amendment 39–10202.

Applicability: Model Mystere-Falcon 50 series airplanes, serial numbers 251, 253, and subsequent; equipped with Allied-Signal TFE731–40 engines; certificated in any category; except those that have been modified in accordance with Dassault Service Bulletin F50–276, dated June 24, 1998.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent in-flight shutdown of the engine(s) due to the flight crew using erroneous N1 speed values displayed on the engine Indication Electronic Display (EIED), accomplish the following:

Restatement of the Requirements of AD 97–21–16, Amendment 39–10202

AFM Revision

(a) Within 1 day after November 18, 1997 (the effective date of AD 97–21–16, amendment 39–10202), revise the Limitations Section of the FAA-approved Airplane Flight Manual (AFM) to add the following. This may be accomplished by inserting a copy of this AD in the AFM. ''Operation in Icing Conditions:

The N1 speed of the operating engines must not be less than the minimum values specified in Normal Section 4, Sub-section 140, Page 2, of the AFM.''

New Requirements for This AD

Modification

(b) Within 6 months after the effective date of this AD, adjust the thrust reverser handle stop, install new ''push-light'' wiring on the instrument panel, and modify the Digital Electronic Engine Control (DEEC) software; in accordance with Dassault Service Bulletin F50–276, dated June 24, 1998. Accomplishment of such actions constitutes terminating action for the AFM revision required by paragraph (a) of this AD. Following accomplishment of the terminating action, the AFM revision

required by paragraph (a) of this AD may be removed from the AFM.

Note 2: Dassault Service Bulletin F50–276 refers to Allied Signal Service Bulletin TFE731–76–5107, dated December 24, 1997, as an additional source of service information for accomplishment of the modification.

Spares

(c) As of the effective date of this AD, no person shall install DEEC software, part number 2118882–4002, on any airplane.

Alternative Methods of Compliance

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(e) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 4: The subject of this AD is addressed in French airworthiness directive 98–228–021(B), dated June 17, 1998.

Issued in Renton, Washington, on October 27, 1999.

Vi L. Lipski,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–28656 Filed 11–2–99; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 99–AGL–53]

Proposed Modification of Class E Airspace; Bemidji, MN.

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This action proposes to modify Class E airspace at Bemidji, MN. A Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) to Runway (Rwy) 31 has been developed for Bemidji-Beltrami County Airport. Controlled airspace extending upward from 700 to 1,200 feet above ground level (AGL) is needed to contain aircraft executing the approach. This action proposes to increase the radius of the existing controlled airspace for this airport.

DATES: Comments must be received on or before December 17, 1999.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Office of the Assistant Chief Counsel, AGL–7, rules Docket No. 99–AGL–53, 2300 East Devon Avenue, Des Plaines, Illinois 60018.

The official docket may be examined in the Office of the Assistant Chief Counsel, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois. An informal docket may also be examined during normal business hours at the Air Traffic Division, Airspace Branch, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois.

FOR FURTHER INFORMATION CONTACT: Denis C. Burke, Air Traffic Division, Airspace Branch, AGL–520, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (847) 294–7568.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 99–AGL–53.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the rules Docket, FAA, Great Lakes Region, Office of the Assistant Chief Counsel, 2300 East Devon Avenue, Des Plaines, Illinois, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA–230, 800 Independence Avenue, SW, Washington, DC 20591, or by calling (202) 267–3484. Communications must identify the docket number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to 14 CFR part 71 to modify Class E airspace at Bemidiji, MN, to accommodate aircraft executing the proposed GPS Rwy 31 SIAP at Bemidji-Beltrami County Airport by modifying the existing controlled airspace. Controlled airspace extending upward from the surface is needed to contain aircraft executing the approach. The area would be depicted on appropriate aeronautical charts. Class E airspace areas designated as a surface area for an airport are published in paragraph 6002 and Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9G dated September 1, 1999, and effective September 16, 1999, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, Therefore this, proposed regulation—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule will

not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9G, Airspace Designations and Reporting Points, dated September 1, 1999, and effective September 16, 1999, is amended as follows:

Paragraph 6002 Class E airspace areas designated as a surface area for an airport.

* * * * *

AGL MN E2 Bemidiji, MN [Revised]

Bemidiji-Beltrami County Airport, MN
(Lat. 47°30′34″ N., long. 094°56′01″ W.)

Within a 4.6-mile radius of the Bemidiji-Beltrami County Airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airman. The effective date and time will thereafter be continuously published in the Airport/facility Director.

* * * * *

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AGL MN E5 Bemidiji, MN [Revised]

Bemidiji-Beltrami County Airport, MN
(Lat. 47°30′34″ N., long. 094°56′01″ W.)

That airspace extending upward from 700 feet above the surface with a 6.6-mile radius of Bemidiji-Beltrami County Airport.

* * * * *

Issued in Des Plaines, Illinois on October 15, 1999.

Christopher R. Blum,

Manager, Air Traffic Division.

[FR Doc. 99–28620 Filed 11–2–99; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 99–AGL–52]

Proposed Modification of Class E Airspace; Steubenville, OH

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This action proposes to modify Class E airspace at Steubenville, OH. A Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP), 293° helicopter point in space approach, has been developed for Trinity West Hospital. Controlled airspace extending upward from 700 to 1200 feet above ground level (AGL) is needed to contain aircraft executing the approach. This action proposes to modify the existing controlled airspace for Steubenville, OH, to the northeast in order to include the point in space approach serving Trinity West Hospital.

DATES: Comments must be received on or before December 17, 1999.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Office of the Assistant Chief Counsel, AGL–7, Rules Docket No. 99–AGL–52, 2300 East Devon Avenue, Des Plaines, Illinois 60018.

The official docket may be examined in the Office of the Assistant Chief Counsel, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois. An informal docket may also be examined during normal business hours at the Air Traffic Division, Airspace Branch, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois.

FOR FURTHER INFORMATION CONTACT: Denis C. Burke, Air Traffic Division, Airspace Branch, AGL–520, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (847) 294–7568.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments, to Airspace Docket No. 99–AGL–52.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket, FAA, Great Lakes Region, Office of the Assistant Chief Counsel, 2300 East Devon Avenue, Des Plaines, Illinois, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA–230, 800 Independence Avenue, SW, Washington, DC 20591, or by calling (202) 267–3484. Communications must identify the docket number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

the FAA is considering an amendment to 14 CFR part 71 to modify Class E airspace at Steubenville, OH, to accommodate aircraft executing the proposed GPS SIAP 293° helicopter point in space approach for Trinity West Hospital by modifying existing controlled airspace. Controlled airspace extending upward from 700 to 1200 feet AGL is needed to contain aircraft executing the approach. The area would be depicted on appropriate aeronautical charts. Class E airspace designations for airspace area extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9G dated September 1, 1999, and effective September 16, 1999,

which is incorporated by reference in 14 CFR 71.1. The Class E airspace designated listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore this, proposed regulation—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedure (44 FR 11034, February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRPSACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR part 71 of the Federal Aviation Administration Order 7400.9G, Airspace Designations and Reporting Points, dated September 1, 1999, and effective September 16, 1999, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AGL OH E5 Stuebenville, OH [Revised]

Steubenville, Jefferson County Airport, OH
(Lat. 40°21′34″ N., long. 080°42′00″ W.)
Trinity West Hospital, OH
Point In Space Coordinates
(Lat. 40°22′00″ N., long. 080°39′31″ W.)

That airspace extending upward from 700 feet above the surface within a 6.3–mile radius of Jefferson County Airport, and within a 6.0-mile radius of the point in space serving Trinity West Hospital, excluding the airspace within the Wheeling, WV, Class E airspace area.

* * * * *

Issued in Des Plaines, Illinois on October 15, 1999.

Christopher R. Blum,

Manager, Air Traffic Division.

[FR Doc. 99–28619 Filed 11–2–99; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 95–AGL–54]

Proposed Modification of Class E Airspace; Cooperstown, ND

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This action proposes to modify Class E airspace at Cooperstown, ND. A review of the controlled airspace within the State of North Dakota has indicated a small portion of Class G uncontrolled airspace in the vicinity of Cooperstown, ND. Controlled airspace extending upward from 1200 feet above ground level (AGL) is needed to allow the FAA to provide safe and efficient air traffic control services for aircraft executing enroute and terminal instrument procedures into and out of Grand Forks International Airport. This small portion of uncontrolled airspace, in the southwest quadrant of Grand Forks Approach Control airspace, causes confusion for both pilots and controllers and does not allow for consistent application of instrument flight rules in a critical area servicing the Grand Forks International Airport. This action proposes to eliminate the Class G airspace approximately 15 nautical miles to the southeast of Cooperstown Airport.

DATES: Comments must be received on or before December 17, 1999.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Office of the Assistant Chief Counsel, AGL–7, Rules Docket No. 99–AGL–54, 2300 East Devon Avenue, Des Plaines, Illinois 60018.

The official docket may be examined in the Office of the Assistant Chief Counsel, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois. An informal docket may also be examined during normal business hours at the Air Traffic Division, Airspace Branch, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois.

FOR FURTHER INFORMATION CONTACT: Denis C. Burke, Air Traffic Division, Airspace Branch, AGL–520, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (847) 294–7568.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 99–AGL–54.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket, FAA, Great Lakes Region, Office of the Assistant Chief Counsel, 2300 East Devon Avenue, Des Plaines, Illinois, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA–230, 800 Independence Avenue, SW, Washington, DC 20591, or by calling (202) 267–3484.

Communications must identify the docket number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to 14 CFR part 71 to modify class E airspace at Cooperstown, ND, to accommodate aircraft executing instrument flight procedures into and out of Grand Forks International Airport by modifying the existing controlled airspace. A small portion of uncontrolled airspace to the southeast of Cooperstown Airport would be eliminated. The area would be depicted on appropriate aeronautical charts. Class E airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9G dated September 1, 1999, and effective September 16, 1999, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore this, proposed regulation—(1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule will not have a significant economic impact as a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g),40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1964 Comp., P. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9G, Airspace Designations and Reporting Points, dated September 1, 1999, and effective September 16, 1999, is amended as follows:

* * * * *

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AGL ND E5 Cooperstown, ND [Revised]

Cooperstown Municipal Airport, ND
(Lat. 47°25′22″ N., long. 098°06′21″ W.)
Devils Lake VOR/DME
(Lat. 48°06′55″ N., long. 098°54′45″ W.)
Fargo, Hector International Airport, ND
(Lat. 46°55′10″ N., long. 096°48′54″ W.)
Grand Forks AFB, ND
(Lat. 47°57′40″ N., long. 097°24′04″ W.)
Jamestown VOR/DME
(Lat. 46°55′58″ N., long. 098°40′44″ W.)
Valley City, Barnes County Municipal Airport, ND
(Lat. 46°56′28″ N., long. 098°01′03″ W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Cooperstown Municipal Airport and that airspace extending upward from 1,200 feet above the surface within an area bounded on the north by V430; on the northeast by the 34.0-mile radius of Grand Forks AFB; on the southeast by the 40.0-mile radius of Fargo, Hector International Airport; on the south by V2–510 east of Valley City, ND, the 7.9-mile radius of Valley City, Barnes Municipal Airport, and V2–510 west of Valley City, ND; on the southwest by the 16.5-mile radius of the Jamestown VOR/DME; on the west by V170; and on the northwest by the 22.0-mile radius of the Devils Lake VOR/DME.

* * * * *

Issued in Des Plaines, Illinois on October 15, 1999.

Christopher R. Blum,

Manager, Air Traffic Division.

[FR Doc. 99–28618 Filed 11–2–99; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 99–AGL–51]

Proposed Establishment of Class E Airspace; Garrison, ND

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This action proposes to establish Class E airspace at Garrison, ND. A Global Positioning System (GPS) Standard Instruction Approach Procedure (SIAP) to Runway (Rwy) 13, and a GPS SIAP to Rwy 31, have been developed for Garrison Municipal Airport. Controlled airspace extending upward from 700 to 1200 feet above ground level (AGL) is needed to contain aircraft executing the approaches. This action would create controlled airspace for Garrison Municipal Airport.

DATES: Comments must be received on or before December 17, 1999.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Office of the Assistant Chief Counsel, AGL–7, Rules Docket No. 99–AGL–51, 2300 East Devon Avenue, Des Plaines, Illinois 60018.

The official docket may be examined in the Office of the Assistant Chief Counsel, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois. An informal docket may also be examined during normal business hours at the Air Traffic Division, Airspace Branch, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois.

FOR FURTHER INFORMATION CONTACT: Denis C. Burke, Air Traffic Division, Airspace Branch, AGL–520, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (847) 294–7568.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related

aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 99–AGL–51.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket, FAA, Great Lakes Region, Office of the Assistant Chief Counsel, 2300 East Devon Avenue, Des Plaines, Illinois, both before and after the closing date for comments. A report summarizing each substantive public contract with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of the Public Affairs, Attention: Public Inquiry Center, APA–230, 800 Independence Avenue, SW, Washington, DC 20591, or by calling (202) 267–3484. Communications must identify the docket number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to 14 CFR part 71 to establish Class E airspace at Garrison, ND, to accommodate aircraft executing the proposed GPS Rwy 13 SIAP and GPS Rwy 31 SIAP at Garrison Municipal Airport by creating controlled airspace for the airport. Controlled airspace extending upward from 700 to 1200 feet AGL is needed to contain aircraft executing the approaches. The area would be depicted on appropriate aeronautical charts. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9G dated September 1, 1999, and effective September 16, 1999, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore this, proposed regulation—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9G, Airspace Designations and Reporting Points, dated September 1, 1999, and effective September 16, 1999, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AGL ND E5 Garrison, ND [New]

Garrison Municipal Airport, ND
Lat. 47°39′22″ N, long. 101°26′17″ W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Garrison Municipal Airport.

* * * * *

Issued in Des Plaines, Illinois on October 15, 1999.

Christopher R. Blum,

Manager, Air Traffic Division.

[FR Doc. 99–28617 Filed 11–2–99; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

15 CFR Part 287

[Docket No. 981222315–8315–01]

RIN 0693–AB49

Proposed Guidance on Federal Conformity Assessment Activities

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Proposed policy guidance; request for comments.

SUMMARY: The Director of the National Institute of Standards and Technology (NIST), United States Department of Commerce, requests comments on the proposed addition of guidance on Federal conformity assessment activities. In February 1996, The National Technology Transfer and Advancement Act of 1995 was enacted by Congress. Section 12 of the Act changed the policies contained in the existing Office of Management and Budget (OMB) Circular A–119 into law, created additional reporting requirements, and directed NIST to coordinate conformity assessment activities of Federal, state and local entities thus eliminating any unnecessary duplication of conformity assessment activities. OMB Circular A–119, revised February 19, 1998, recognized the conformity assessment requirements and obligations defined in the Act and the role of the Department of Commerce in this area. The Circular directed the Secretary of Commerce to issue guidance to the agencies to ensure effective coordination of Federal conformity assessment activities. This document contains that guidance.

The Director of NIST has decided to include this guidance for conformity assessment activities in the Code of Federal Regulations (CFR). Inclusion in the CFR will make it easier for federal, state and local entities to find the guidance necessary for effective coordination of conformity assessment activities. The provisions are solely intended to be used as guidance for agencies in their conformity assessment activities.

DATES: Comments must be received no later than January 18, 2000.

ADDRESSES: All comments concerning this proposed guidance should be addressed to: Dr. Belinda Collins, Director, Office of Standards Services, National Institute of Standards and Technology, Building 820, Room 282, Gaithersburg, MD 20899.

FOR FURTHER INFORMATION CONTACT: Dr. Belinda L. Collins, Office of Standards Services, NIST, 301–975–4000, facsimile: 301–963–2871 or Maureen A. Breitenberg, Global Standards Program, NIST, 301–975–4031, facsimile: 301–963–2871.

SUPPLEMENTARY INFORMATION:

Background

Section 12 of the National Technology Transfer and Advancement Act of 1995, (Public Law 104–113 or ''the Act'') enacted by Congress in February 1996 established the policies of the existing Office of Management and Budget (OMB) Circular A–119 into law. The Act also directed the National Institute of Standards and Technology NIST) to coordinate conformity assessment activities of Federal, state and local entities thus eliminating unnecessary duplication of conformity assessment activities. OMB Circular A–119, which was revised and reissued on February 19, 1998, recognized the conformity assessment requirements and obligations defined in the Act and the role of the Department of Commerce in this area.

Conformity assessment is defined in the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) Guide 2 (1996), as: ''any activity concerned with determining directly or indirectly that relevant requirements are fulfilled.'' Conformity assessment includes: sampling and testing; inspection; certification; and quality and environmental management system assessment and registration. It also includes accreditation and recognition.

The Act states and OMB Circular A–119 reiterates that NIST is to ''coordinate Federal, State and local * * * conformity assessment activities, with private sector * * * conformity assessment activities. * * *'' This guidance is designed to improve the internal management of the Executive Branch with regard to its conformity assessment activities.

Purpose of This Guidance

This guidance outlines Federal agencies' responsibility for evaluating the efficacy and efficiency of their conformity assessment activities. Each agency is responsible for coordinating its conformity assessment activities with those of other appropriate government agencies and with those of the private sector to make more productive use of the increasingly limited Federal resources available for the conduct of conformity assessment activities and to reduce unnecessary duplication.

Applicability of This Guidance

This guidance applies to all agencies, which set policy for, manage, operate, or use conformity assessment activities and results, both domestic and international, except for activities carried out pursuant to treaties. ''Agency'' means any Executive Branch Department, independent commission, board, bureau, office, agency, government-owned or controlled corporation, or other establishment of the federal government. It also includes any regulatory commission or board, except for independent regulatory commissions subject to separate statutory requirements regarding policy setting, management, operation, and use of conformity assessment activities. It does not include the legislative or judicial branches of the Federal government.

Rulemaking Requirements

Under 5 U.S.C. 553(b)(A), this guidance is not subject to the notice and comment requirements of the Administrative Procedure Act. Furthermore, pursuant to 5 U.S.C. 553(d)(2), this guidance is not subject to the delayed effective date requirement of the Act. The Director has chosen to publish this document for comment only to obtain input from persons who may be affected by the guidance.

PRA Clearance

This policy statement does not contain a collection of information for purposes of the Paperwork Reduction Act.

Executive Order 12866

It has been determined that this action is significant for purposes of Executive Order 12866.

Regulatory Flexibility Act

This action is exempt from the analytical requirements of the Regulatory Flexibility Act because notice and comment are not required for this action by section 553 of the Administrative Procedure Act or any other law.

List of Subjects in 15 CFR Part 287

Conformity assessment, Procurement, Reporting and recordkeeping requirements.

Dated: October 22, 1999.

Karen H. Brown,

Deputy Director.

For the reasons set forth in the preamble, it is proposed that Part 287 be added to subchapter J of chapter II in Title 15 of the Code of Federal Regulations (CFR) to read as follows:

PART 287—GUIDANCE ON FEDERAL CONFORMITY ASSESSMENT

Authority: 15 U.S.C. *et seq.* Pub. L. 104–113, section 12.

§ 287.1 Purpose and scope of this guidance.

(a) This part provides guidance for each Federal agency to use in evaluating the efficacy and efficiency of its conformity assessment activities. Each agency should coordinate its conformity assessment activities with those of other appropriate government agencies and with those of the private sector to reduce unnecessary duplication. This guidance is intended to help Federal agencies improve the management and coordination of their own conformity assessment activities with respect to other government entities and the private sector. This will help ensure more productive use of the increasingly limited Federal resources available to conduct conformity assessment activities. This will also support the role of the U.S. Government in pursuing international trade and other related negotiations and agreements with foreign countries and U.S. industry in pursing agreements with foreign national and international private sector organizations.

(b) This guidance applies to all agencies, which set policy for, manage, operate, or use conformity assessment activities and results, both domestic and international, except for activities carried out pursuant to treaties.

(c) This guidance does not preempt the agencies' authority and responsibility to make regulatory or procurement decisions authorized by statute or required to meet programmatic objectives and requirements. These decision-making activities include: determining the level

of acceptable regulatory or procurement risk; setting the level of protection; balancing risk, cost and availability of technology (where statutes permit) in establishing regulatory and procurement objectives; and determining or implementing procurement or regulatory requirements necessary to meet programmatic or regulatory objectives. Each agency retains broad discretion in its selection and use of regulatory and procurement conformity assessment practices and may elect not to use or recognize alternative conformity assessment practices if the agency deems them to be inappropriate, inadequate, or inconsistent with statutory criteria or programmatic objectives and requirements. Each agency remains responsible for representation of the agency's views on conformity assessment in matters under its jurisdiction. Each agency also remains the primary point of contact for information on the agency's regulatory and procurement conformity assessment actions.

§ 287.2 Definitions [1].

Accreditation means a procedure used to provide formal notice that a body or person is competent to carry out specific tasks. These tasks include: sampling and testing; inspection; certification; and registration.

Agency means any Executive Branch Department, independent commission, board, bureau, office, agency, government-owned or controlled corporation, or other establishment of the Federal government. It also includes any regulatory commission or board, except for independent regulatory commissions subject to separate statutory requirements regarding policy setting, management, operation, and use of conformity assessment activities. It does not include the legislative or judicial branches of the Federal government.

Agency Standards Executive means an official designated by an agency as its representative on the Interagency Committee for Standards Policy (ICSP) and delegated the responsibility for agency implementation of OMB Circular A–119 and the guidance in this part.

Certification means a procedure used to provide written assurance that a product, process, service, or person's qualifications conforms to specified requirements.

Conformity assessment means any activity concerned with determining directly or indirectly that requirements are fulfilled. Requirements for products, services, and systems are those defined by law or regulation or by an agency in a procurement action. Conformity assessment includes: sampling and testing; inspection; certification; and quality and environmental management system assessment and registration. It also includes accreditation and recognition. Conformity assessment does not include mandatory administrative procedures (such as registration notification) for granting permission for a good or service to be produced, marketed, or used for a stated purpose or under stated conditions.

Inspection is defined as the evaluation by observation and judgment accompanied as appropriate by measurement, testing or gauging of the conformity of a product, process or service to specified requirements.

NIST means the National Institute of Standards and Technology, an agency within the United States Department of Commerce.

Recognition means a procedure used to provide formal notice that an accreditation body is competent to carry out specific tasks. These tasks include: the accreditation of testing laboratories and inspection, certification, and registration bodies. A governmental recognition system is a set of one or more procedures used by a Federal agency to provide recognition.

Registration means a procedure used to give written assurance that a system conforms to specified requirements. Such systems include those established for the management of product, process or service quality and environmental performance.

Sampling means the selection of one or more specimens of a product, process, or service for the purpose of evaluating the conformity of the product, process or service to specified requirements.

Testing means the action of carrying out one or more technical operations (tests) that determine one or more characteristics or performance of a given product, material, equipment, organism, person's qualifications, physical phenomenon, process, or service according to a specified technical procedure (test method).

§ 287.3 Responsibilities of the National Institute of Standards and Technology.

(a) Work with agencies through the Interagency Committee on Standards Policy (ICSP) to coordinate Federal, state and local conformity assessment activities with private sector conformity assessment activities. NIST chairs the ICSP; assists the ICSP in developing and publishing policies and guidance on conformity assessment related issues; collects and disseminates information on Federal, state and private sector conformity assessment activities; and increases public awareness of the importance of conformity assessment and nature and extent of national and international conformity assessment activities.

(b) Encourage participation in the ICSP by all affected agencies and ensure that all agency views on conformity assessment are considered.

(c) Review within three years from [EFFECTIVE DATE OF THE FINAL GUIDANCE] the effectiveness of the final guidance and recommend modifications to the Secretary as needed.

§ 287.4 Responsibilities of Federal agencies.

Each agency should:

(a) Implement the policies contained in the guidance in this part.

(b) Use the results of other governmental agency and private sector organization conformity assessment activities to enhance the safety and efficacy of proposed new conformity assessment requirements and measures. An example of this would be to collect and review information on similar activities conducted by other Federal, state and international organizations and agencies and private sector organizations to determine if the results of these activities can be used to improve the effectiveness of a proposed Federal agency conformity assessment activity.

(c) Use relevant guides or standards for conformity assessment practices published by domestic and international standardizing bodies as appropriate in meeting regulatory and procurement objectives. Guides and standards for sampling, testing, inspection, certification, quality and environmental management systems, management system registration and accreditation are issued by organizations which include, but are not limited to, the American National Standards Institute, the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), the International Telecommunications Union (ITU) and the Organization for Economic Cooperation and Development (OECD), the World Health Organization (WHO), and the Codex Alimentarius Commission. Each agency retains responsibility for determining

[1] Definitions of accreditation, certification, conformity assessment, inspection, registration and testing are based on the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC), Guide 2 (1996). In certain industrial sectors, it is recognized that organizations other than ISO or IEC may issue definitions relevant to conformity assessment, such as the Codex Alimentarius Commission with respect to the food industry sector.

which, if any, of these documents are relevant to its needs.

(d) Identify appropriate private sector conformity assessment practices and programs and consider using the results of such practices and/or programs as appropriate in existing regulatory and procurement actions. Responsibility for the determination of appropriateness rests with each agency. Example: An agency could use the results of private sector or other governmental conformity assessment activities to schedule procurement type audits more effectively. This could allow agencies to reduce the number and extent of audits conducted at companies which are performing in accordance with contract specifications and which are under review by a third party or another agency and to concentrate agency audit efforts on companies which have shown problems in conforming to contract specifications.

(e) Consider mutual recognition of the results of other agencies' conformity assessment procedures. Example: An agency could use the results of another agency's inspection/audit of a supplier to eliminate or reduce the scope of its own inspection/audit of that supplier.

(f) Participate in efforts designed to improve coordination among governmental and private sector conformity assessment activities. These efforts include, but are not limited to, the National Cooperation for Laboratory Accreditation (NACLA) organization, the National Environmental Laboratory Accreditation Conference (NELAC), and ICSP working groups dealing with conformity assessment issues.

(g) Work with other agencies to avoid unnecessary duplication and complexity in federal conformity assessment activities. Examples: An agency can participate in another agency's conformity assessment activities by conducting joint procurement audits/inspections of suppliers that sell to both agencies. An agency can share conformity assessment information with other agencies. An agency can use conformity assessment information provided by other agencies to the extent appropriate to improve the effectiveness and efficiency in its own conformity assessment activities. Conformity assessment information may include: conformity assessment procedures and results, technical data on the operation of conformity assessment programs, processing methods and requirements for applications, fees, facility site data, complaint review procedures, and confidentiality procedures.

(h) Encourage domestic and international recognition of U.S. conformity assessment results by supporting the work of the U.S. Government in international trade and related negotiations with foreign countries and U.S. industry in pursuing agreements with foreign national and international private sector organizations and any resulting activities/requirements resulting from those negotiations/agreements.

(i) Participate in the development of private sector conformity assessment standards to ensure that Federal viewpoints are represented.

(j) Work with other agencies to harmonize Federal requirements for quality and environmental management systems for use in procurement and regulation, including provisions which will allow the use of one quality or environmental management system per supplier facility in the Federal procurement process and the sharing and usage of audit results and related information as appropriate.

(k) Work with other ICSP members, NIST, and the private sector to develop national infrastructures for coordinating and harmonizing U.S. conformity assessment needs, practices and requirements in support of the efforts of the U.S. Government and U.S. industry to increase international market access for U.S. products.

(l) Work with other ICSP members, NIST, and the private sector as necessary and appropriate to establish criteria for the development and implementation of governmental recognition systems to meet government recognition requirements imposed by other nations and regional groups to support the efforts of the U.S. Government to facilitate international market access for U.S. products.

(m) Assign an Agency Standard Executive responsibility for coordinating the agency-wide implementation of the guidance in this part.

§ 287.5 Responsibilities of an Agency Standards Executive.

In addition to carrying out the duties described in OMB Circular A–119 related to standards activities, an Agency Standards Executive should:

(a) Promote the following goals:

(1) Effective use of agency conformity assessment related resources and participation in conformity assessment related activities of agency interest.

(2) Development and dissemination of agency technical and policy positions.

(3) Development of agency positions on conformity assessment related issues that are in the public interest.

(b) Ensure that agency participation in conformity assessment related activities is consistent with agency missions, authorities, priorities, and budget.

(c) Cooperate with NIST in carrying out agency responsibilities under the guidance in this part.

(d) Consult with NIST, as necessary, in the development and issuance of internal agency procedures and guidance implementing the policies in this part.

(e) Establish an ongoing process for reviewing his/her agency's existing conformity assessment activities and identifying areas where efficiencies can be achieved through coordination with other agency and private sector conformity assessment activities.

(f) Work with other parts of his/her agency to develop and implement improvements in agency conformity assessment related activities.

(g) Report to NIST, on a voluntary basis, on agency conformity assessment activities for inclusion in the annual report to the Office of Management and Budget (OMB) on the agency's implementation of OMB Circular A–119.

[FR Doc. 99–28496 Filed 11–2–99; 8:45 am]

BILLING CODE 3510–13–M

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 1

Use of Electronic Signatures by Customers, Participants and Clients of Registrants

AGENCY: Commodity Futures Trading Commission.

ACTION: Reopening of comment period.

SUMMARY: On August 30, 1999, the Commodity Futures Trading commission (the ''Commission'' or ''CFTC'') published in the **Federal Register** a request for public comment on proposed regulations to allow the use of electronic signatures in lieu of handwritten signatures for certain purposes under the commission's regulations. The original comment period expires October 29, 1999. 64 FR 47151 (August 30, 1999). By letter dated October 27, 1999, the Futures Industry Association Inc. requested an extension of the comment period. In order to insure that an adequate opportunity is provided for submission of meaningful comments, the Commission has determined to reopen the comment period for an additional two weeks for all interested parties.

DATES: Written comments must be received on or before November 12, 1999.

ADDRESSES: Comments on the proposed rule should be sent to Jean A. Webb, Secretary, Commodity Futures Trading Commission, Three Lafayette Center, 1155 21st Street, NW., Washington, DC 20581. Comments may be sent by facsimile transmission to (202) 418–5521, or by e-mail to secretary@cftc.gov. Reference should be made to ''Internet Account Opening Process.''

FOR FURTHER INFORMATION CONTACT: Lawrence B. Patent, Associate Chief Counsel, or Christopher W. Cummings, Special Counsel, Division of Trading and Markets, Commodity Futures Trading Commission, 1155 21st Street, NW., Washington, DC 20581. Telephone Number: (202) 418–5450. Facsimile Number: (202) 418–5547. Electronic Mail: tm@cftc.gov.

Issued In Washington, DC on October 27, 1999, by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 99–28605 Filed 11–2–99; 8:45 am]

BILLING CODE 6351–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. 99N–2550]

Medical Devices; Hearing Aids; Technical Data Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations governing hearing aid labeling to reference the most recent version of the consensus standard used to determine the technical data to be included in labeling for hearing aids. FDA is proposing to amend the regulation in order that manufacturers may use state-of-the-art methods to address technical data in hearing aid labeling. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**.

DATES: Submit written comments on or before January 18, 2000. If FDA receives any significant adverse comment regarding this rule, FDA will publish a document withdrawing the direct final rule within 30 days after the comment period ends. FDA then and will proceed to respond to the comments under this proposed rule using the usual notice and comment procedures. Any parties interested in commenting on this document should do so at this time.

If FDA receives no significant adverse comments within the specified comment period, the agency intends to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on the direct final rule ends. The direct final rule will be effective March 17, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: David A. Segerson, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850 301–594–2080.

SUPPLEMENTARY INFORMATION:

I. Regulatory Framework

This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. This companion proposed rule is substantively identical to the direct final rule. This proposed rule will provide a procedural framework to finalize the rule in the event the agency receives a significant adverse comment and the direct final rule is withdrawn. FDA is publishing the direct final rule because the rule contains noncontroversial changes, and FDA anticipates that it will receive no significant adverse comments. A detailed discussion of this rule is set forth in the preamble of the direct final rule. If no significant comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, FDA will publish a confirmation document within 30 days after the comment period ends confirming that the direct final rule will go into effect on March 17, 2000. Additional information about FDA's direct final rulemaking procedures is set forth in a guidance published in the **Federal Register** of November 21, 1997 (62 FR 62466).

If FDA receives a significant adverse comment regarding this rule, the agency will publish a document withdrawing the direct final rule within 30 days after the comment period ends and will proceed to respond to the comments under this rule using usual notice-and-comment procedures. The comment period for this companion proposed rule runs concurrently with the direct final rule's comment period. Any comments received under this companion proposed rule will also be considered as comments regarding the direct final rule. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered adverse under this procedure. For example, a comment requesting a change in provisions of the hearing aid rule unrelated to the subject matter addressed in the American National Standards Institute's (ANSI) standard will not be considered a significant adverse comment, because it is outside the scope of the rule. On the other hand, a comment recommending an additional change to the rule may be considered a significant adverse comment if the comment demonstrates why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule and that provision can be severed from the remainder of the rule, FDA may adopt as final those provisions of the rule that are not the subject of a significant adverse comment.

II. Background

In the **Federal Register** of February 15, 1977 (42 FR 9286), FDA published final regulations establishing requirements for professional and patient labeling of hearing aids (§ 801.420 (21 CFR 801.420)) and governing conditions for sale of hearing aids (§ 801.421 (21 CFR 801.421)). The regulations became effective on August 15, 1977. Section 801.421(b)(1) of the regulations provides that, before the sale of a hearing aid to a prospective user, a hearing aid dispenser is to provide the prospective user with a copy of the User Instructional Brochure. Section 801.420(c)(4) requires that technical data useful in selecting, fitting, and checking the performance of a hearing aid be provided in the brochure or in separate labeling that accompanies the device. The regulation further required that the technical data values provided in the brochure or other labeling be determined according to the test procedures established by the Acoustical Society of America (ASA) in the ''American National Standard

Specification of Hearing Aid Characteristics,'' ANSI S3.22–1976 (ASA 70–1976), which was incorporated by reference in the regulation.

ANSI S3.22 (ASA 70–1976) established measurement methods and specifications for several definitive hearing aid characteristics, and provided a method of ascertaining whether a hearing aid, after being manufactured and shipped, met the specifications and design parameters stated by the manufacturer for a particular model, within the tolerance stated by the standard.

In 1982, ASA revised the standard (ANSI S3.22–1982) (ASA 70–1982). In a final rule published in the **Federal Register** of July 24, 1985 (50 FR 30153), FDA incorporated the revised standard into § 801.420(c)(4). ASA revised the standard again in 1987 (ANSI S3.22–1987) (ASA 70–1987). In a final rule published in the **Federal Register** of December 21, 1989 (54 FR 52395). FDA incorporated the newly revised standard into § 801.420(c)(4).

In 1996, ASA revised the standard again (ANSI S3.22–1996) (ASA 70–1996). The standard describes air-conduction hearing aid measurement methods that are particularly suitable for specification and tolerance purposes. Among the test methods described are output sound pressure level (SPL with a 90-dB input SPL, full-on gain, frequency response, harmonic distortion, equivalent input noise, current drain, induction-coil sensitivity, and static and dynamic characteristics of automatic gain control hearing aids) the standard gives specific configurations for measuring the input SPL to a hearing aid. The standard also describes allowable tolerances in relation to values specified by the manufacturer for certain parameters. Appendices are provided to describe an equivalent substitution method, characteristics of battery simulators, and additional tests to characterize the electroacoustic performance of hearing aids more completely.

FDA is now incorporating the 1996 standard into § 801.420(c)(4). This will allow hearing aid manufacturers to use the up-to-date methods to determine the technical data values for hearing aids. In addition, FDA is removing from § 801.420(c)(4) the address for ''American National Standards Institute'' and is adding in its place the address for ''Acoustical Society of America.''

III. Environmental Impact

The agency has determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impact of the proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, this proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The proposed rule amends the existing hearing aid regulation to refer to the updated consensus standard that is used to determine the technical data in hearing aid labeling. Communications from manufacturers to FDA show that they are prepared to be in compliance with this standard immediately. The agency, therefore, certifies that this proposed rule, if finalized, will not have a significant economic impact on a substantial number of small entities. This proposed rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in an expenditure of $100 million or more by State, local, or tribal governments in the aggregate, or by the private sector, in any one year.

V. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Request for Comments

Interested persons may, on or before January 18, 2000, submit to the Dockets Management Branch (address above) written comments regarding this companion proposed rule. The comment period runs concurrently with the comment period for the direct final rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. Comments will be considered to determine whether to amend or revoke this proposed rule. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. All comments received will be considered as comments regarding the direct final rule and this proposed rule. In the event the direct final rule is withdrawn, all comments received regarding the direct final rule and this companion proposed rule will be considered comments on this proposed rule.

List of Subjects in 21 CFR Part 801

Hearing aids, Incorporation by reference, Medical devices, Professional and patient labeling.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 801 be amended as follows:

PART 801—LABELING

1. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360i, 360j, 371, 374.

2. Section 801.420 is amended by revising the second and third sentences in paragraph (c)(4) to read as follows:

§ 801.420 Hearing aid devices; professional and patient labeling.

* * * * *

(c) * * *

(4) * * * The determination of technical data values for the hearing aid labeling shall be conducted in accordance with the test procedures of the American National Standard ''Specification of Hearing Aid Characteristics,'' ANSI S3.22–1996 (ASA 70–1996) (Revision of ANSI S3.22–1987), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Standards Secretariat of the Acoustical Society of America, 120 Wall St., New York, NY 10005–3993, or are available for inspection at the Regulations Staff, CDRH (HFZ–215), FDA, 1350 Piccard Dr., rm. 240,

Rockville, MD 20580, and the Office of the Federal Register, 800 North Capitol St. NW. suite 700, Washington DC.

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Dated: October 19, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–28210 Filed 11–2–99; 8:45 am]

BILLING CODE 4160–01–F

FEDERAL MEDIATION AND CONCILIATION SERVICE

29 CFR Part 1401

RIN 3076–AA06

Freedom of Information Act Regulations

AGENCY: Federal Mediation and Conciliation Service.

ACTION: Proposed rule.

SUMMARY: The Federal Mediation and Conciliation Service (FMCS) proposes to amend its rules under the Freedom of Information Act (FOIA) primarily to effectuate various provisions under the 1996 Electronic FOIA Amendments. The proposed revisions include the new response time for FOIA requests, procedures for requesting expedited processing, the availability of certain public information on FMCS's web site, and express inclusion of electronic records and automated searches along with paper records and manual searches. In addition, FMCS's proposed amendments would update its fee schedule. FMCS is also updating the names and addresses of the various offices within the agency responsible for FOIA related activities. This rulemaking only deals with such matters at FMCS; it is not an executive branchwide regulation.

DATES: Written comments must be submitted to the office listed in the addresses section below on or before January 3, 2000.

ADDRESSES: Send comments to Jane Lorber, General Counsel, Federal Mediation and Conciliation Service, 2100 K Street, NW, Washington, DC 20427.

FOR FURTHER INFORMATION CONTACT: Jane Lorber, (202) 606–5444.

SUPPLEMENTARY INFORMATION: In this rulemaking, FMCS proposes to amend its regulations at 29 CFR part 1401, Subpart B under FOIA, 5 U.S.C. 552. The primary focus of these proposed amendments is to effectuate for this Agency various provisions under the 1996 Electronic FOIA Amendments, Public Law 104–231. New provisions implementing the amendments are found at § 1401.21(c) (electronic reading room), §§ 1401.34(b), (c), (e), (f) (timing of responses), § 1401.22 (deletion marking), § 1401.34(d) (volume estimation), § 1401.36(a)(3) (format of disclosure) and § 1401.36(a)(2) (electronic searches).

Proposed revisions to the Service's fee schedule can be found at §§ 1401.36(b)(1), (3)(v). The duplication charge will remain the same at twenty cents per page, while document search and review charges will increase to $4.00 and $10.00 for clerical and professional time, respectively. The amount at or below which the Service will not charge a fee will decrease from $50.00 to $14.00.

Sections 1401.22(d), 1401.31(a),(b) and 1401.32(b) are being revised to reflect organizational name changes within FMCS. Sections 1401.24 and 1401.37 are being removed because they are neither required by law nor necessary to interpret the law.

Regulatory Flexibility Act

The Director, in accordance with the Regulatory Flexibility Act (5 U.S.C. 606(b)), has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. Under FOIA, agencies may recover only the direct costs of searching for, reviewing, and duplicating the records processed for requesters. Thus, fees assessed by FMCS are nominal. Further, the ''small entities'' that make FOIA requests, as compared with individual requesters and other requesters, are relatively few in number .

Executive Order 12866

This regulation has been reviewed in accordance with Executive Order 12866. It is not classified as significant because it does not meet the criteria for significant regulatory action established by the Executive Order.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small Governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with Foreign-based companies in domestic and export markets.

List of Subjects in 29 CFR Part 1401

Administrative practice and procedure, Freedom of Information.

For the reasons set forth in the preamble, FMCS proposes to amend 29 CFR part 1401 as follows:

PART 1401—PUBLIC INFORMATION

1. The authority citation for part 1401 is revised to read as follows:

Authority: 5 U.S.C. 552.

2. Subpart B of part 1401 is revised to read as follows:

Subpart B—Production or Disclosure of Information

Subpart B—Production or Disclosure of Information

§ 1401.20 Purpose and scope.

This subpart contains the regulations of the Federal Mediation and Conciliation Service providing for public access to information from records of the Service. These regulations implement the Freedom of Information Act, 5 U.S.C. 552, and the policy of the FMCS to disseminate information on matters of interest to the public and to disclose on request information contained in agency records insofar as is compatible with the discharge of its responsibilities and the principle of confidentiality and neutrality of dispute resolution by third party neutrals.

§ 1401.21 Information policy.

(a) Except for matters specifically excluded by subsection 552(b) of title 5, United States Code, matters covered by the Privacy Act, or other applicable statutes, all documents and records maintained by this agency or in its custody shall be available to the public upon request filed in accordance with these regulations. To the extent permitted by other laws, the Service also will make available records which it is authorized to withhold under 5 U.S.C. 552(b) whenever it determines that such disclosure is in the public interest.

(b) Any document released for inspection under the provisions of this part may be manually copied by the requesting party. The Service shall provide facilities for copying such documents at reasonable times during normal working hours so long as it does not interfere with the efficient operation of the agency.

(c) The Service maintains a public reading room that contains the records that the FOIA requires to be made regularly available for public inspection and copying. FMCS shall maintain and make available for public inspection and copying a current subject-matter index of its reading room records. Each index shall be updated regularly, at least quarterly, with respect to newly included records. FMCS shall also make reading room records created by the Service on or after November 1, 1996, available electronically through FMCS's World Wide Web Site (which can be found at http://www.fmcs.gov)

(d) Records or documents prepared by the Service for routine public distribution, e.g., pamphlets and brochures, will be furnished upon request to Office of the Director, Federal Mediation and Conciliation Service, 2100 K Street, NW, Washington, DC 20427, as long as the supply lasts. The provisions of § 1401.36 (fees) is not applicable to such requests expect when the supply of such material is exhausted and it is necessary to reproduce individual copies upon specific request.

(e) All existing FMCS records are subject to routine destruction according to standard record retention schedules.

§ 1401.22 Partial disclosure of records.

(a) If a record contains both disclosable and nondisclosable information, the nondisclosable information will be deleted and the remaining record will be disclosed unless the two are so inextricably intertwined that it is not feasible to separate them or release of the disclosable information would compromise or impinge upon the nondisclosable portion of the record.

(b) Records disclosed in part shall be marked or annotated to show both the amount and the location of the information deleted wherever practicable.

§ 1401.23 Preparation of new records.

(a) The Freedom of Information Act and the provisions of this part apply only to existing records that are reasonably described in a request filed with the Federal Mediation and Conciliation Service pursuant to the procedures established in §§ 1401.31–1401.36.

(b) The Director may, in his or her discretion, prepare new records in order to respond to a request for information when he or she concludes that it is in the public interest and promotes the objectives of the Labor-Management Relations Act, 1947, as amended.

§ 1401.30 Applicability of procedures.

Requests for inspection or copying of information from records in the custody of the FMCS which are reasonably identifiable and available under the provisions of this part shall be made and acted upon as provided in the following sections of this subpart. The prescribed procedure shall be followed in all cases where access is sought to official records pursuant to the provisions of the Freedom of Information Act, except with respect to records for which a less formal disclosure procedure is provided specifically in this part.

§ 1401.31 Filing a request for records.

(a) Any person who desires to inspect or copy any record covered by this part shall submit a written request to that effect to the Office of the General Counsel, Federal Mediation and Conciliation Service, 2100 K Street, NW, Washington, DC 20427.

(b) The Office of the General Counsel will determine what office or division within FMCS is custodian of the records. The Office will then send the request to the appropriate FMCS office or division as provided in § 1401.32(b) of this part.

§ 1401.32 Logging of written request.

(a) All requests for records should by clearly and prominently identified as a request for information under the Freedom of Information Act, and if submitted by mail or otherwise submitted in an envelope or other cover, should be clearly and prominently identified as such on the envelope or other cover.

(b) Upon receipt of a request for records from the Office of the General Counsel, the FMCS office or division responding to the request shall enter it in a public log. The log shall state the date and time received, the name and address of person making the request, the nature of the records requested, the action taken on the request, the date of the determination letter sent pursuant to § 1401.34(b) and (d), the date(s) any records are subsequently furnished, the number of staff hours and grade levels of persons who spent time responding to the request, and the payment requested and received.

§ 1401.33 Description of information requested.

(a) Each request should reasonably describe the records being sought, in a way that they can be identified and located. A request should include all pertinent details that will help identify the records sought.

(b) If the description is insufficient, the officer processing the request will so notify the person making the request and indicate the additional information needed. Every reasonable effort shall be made to assist in the identification and location of the records sought.

§ 1401.34 Time for processing requests.

(a) All time limitations established pursuant to this section shall begin as of the time at which a request for records is logged in by the officer or employee processing the request pursuant to § 1401.32(b). An oral request for records shall not begin any time requirement. A written request for records sent to an office or division of FMCS other than the one having authority to grant or deny access to the records shall be redirected to the appropriate office for processing, and the time shall begin upon its being logged in there in accordance with § 1401.32(b).

(b) The officer or employee passing upon the request for records shall, within twenty (20) working days following receipt of the request, respond in writing to the requester, determining whether, or the extent to which, the Agency shall comply with the request.

(1) If all of the records requested have been located and a final determination has been made with respect to disclosure of all the records requested, the response shall so state.

(2) If all of the records have not been located or a final determination has not been made with respect to disclosure of all records requested, the response shall state the extent to which the records involved will be disclosed pursuant to the rules established in this part.

(3) If the request is expected to involve an assessed fee in excess of $50.00, the response shall specify or

estimate the fee involved and shall require prepayment before the records are made available.

(4) Whenever possible, the response relating to a request for records that involves a fee of less than $50.00, shall be accompanied by the requested records. Where this is not possible, the records shall be forwarded as soon as possible thereafter, consistent with other obligations of the Agency.

(c) Where the time limits for processing a request cannot be met because of unusual circumstances and FMCS determines to extend the time limit on that basis, FMCS will, as soon as practicable, notify the requester in writing of the unusual circumstances and of the date by which the processing can be expected to be completed. Where the extension is for more than 10 working days, FMCS will provide the requester with an opportunity either to modify the request so that it may be processed within the time limits or to arrange an alternative time period for processing the request or a modified request. If FMCS reasonably believes that multiple requests submitted by a requester, or by a group of requesters acting in concert, constitute a single request that would otherwise involve unusual circumstances, and the requests involve clearly related matters, they may be aggregated.

(d) If any request for records is denied in whole or in part, the response required by paragraph (b) of this section shall notify the requester of the denial. Such denial shall specify the reason therefor and also advise that the denial may be appealed to the Office of Deputy Director of the Agency as specified in § 1401.35. In addition, such denial shall include an estimate of the volume of records or information withheld, in numbers of pages or in some other reasonable form of estimation. This estimate does not need to be provided if the volume is otherwise indicated through deletions on records disclosed in part, or if providing an estimate would harm an interest protected by an applicable estimation.

(e) FMCS offices may use two or more processing tracks by distinguishing between simple and more complex requests based on the amount of work and or time needed to process the request. A person making a request that does not qualify for the fastest multitrack processing should be given an opportunity to limit the scope of the request in order to qualify for faster processing.

(f) Requests and appeals will be taken out of order and given expedited processing in cases where the requester demonstrates a compelling need.

(1) The term ''compelling need'' means:

(i) Circumstances in which failure to obtain copies of the requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or

(ii) An urgency to inform the public about an actual or alleged Federal Government activity, if the request is made by a person primarily engaged in disseminating information.

(2) A requester seeking expedited processing should so indicate in the initial request, and should state all the facts supporting the need to obtain the requested records quickly. The requester must also certify in writing that these facts are true and correct to the best of the requester's knowledge and belief.

(3) Within 10 calendar days of its receipt of a request for expedited processing, FMCS will notify the requester of its decision. If a request for expedited treatment is granted, the request shall be given priority and shall be processed as soon as practicable. If a request for expedited processing is denied, any appeal of that decision will be acted on expeditiously.

§ 1401.35 Appeals from denials of request.

(a) Whenever any request for records is denied, a written appeal may be filed with the Deputy Director, Federal Mediation and Conciliation Service, 2100 K Street, NW, Washington, DC 20427, within 30 days after the requester receives notification that the request has been denied or after the requester receives any records being made available, in the event of partial denial. The appeal shall state the grounds for appeal, including any supporting statements or arguments.

(b) Final action on the appeal shall be taken within 20 working days from the time of receipt of the appeal. Where novel and complicated questions have been raised or unusual difficulties have been encountered, the Deputy Director may extend the time for final action up to an additional 10 days, depending upon whether there had been an extension pursuant to § 1401.34(c) at the initial stage. In such cases, the applicant shall be notified in writing of the reasons for the extension of time and the approximate date on which a final response will be forthcoming.

(c) If on appeal the denial of the request for records is upheld in whole or in part, the Deputy Director shall notify the applicant of the reasons therefor, and shall advise the requester of the provisions for judicial review under 5 U.S.C. 552(a)(4) and (6).

§ 1401.36 Freedom of Information Act fee schedules.

(a) *Definitions.* For purpose of § 1401.36, the following definitions apply:

(1) *Direct costs* means those expenditures which are actually incurred in searching for and duplicating and, in the case of commercial use requesters, reviewing to respond to a FOIA request.

(2) *Search* means the process of looking for and retrieving records or information responsive to a request. It includes page-by-page or line-by-line identification of information within records and also includes reasonable efforts to locate and retrieve information from records maintained in electronic form or format.

(3) *Duplication* refers to the process of making a copy of a document necessary to respond to a FOIA request. Copies may be in various forms including machine readable documentation (e.g. magnetic tape or disk) among others. A requester's specified preference of form or format of disclosure will be honored if the record is readily reproducible with reasonable efforts in the requested form or format.

(4) *Review* refers to the process of examining documents located in response to a request that is for commercial use, to determine whether a document or any portion of any document located is permitted to be withheld. It includes processing any documents for disclosure to the requester, e.g., doing all that is necessary to excise them or otherwise prepare them for release.

(5) *Commercial use request* refers to a request from or on behalf of one who seeks information for a use or purpose that furthers the commercial trade or profit interest of the requester or the person on whose behalf the request is made.

(6) *Educational institution* refers to a preschool, a public or private elementary or secondary school, an institution of undergraduate higher education, an institution of graduate or professional education or an institution vocational education, which operates a program of programs of scholarly research.

(7) *Representative of the news media* refers to any person actively gathering news for an entity that is organized and operated to publish or broadcast news to the public. The term ''news'' means information that is about current events or that would be of current interest to the public. In the case of ''freelance'' journalists, they may be regarded as working for a news organization if they can demonstrate a reasonable

expectation of publication through the organization, even though not actually employed by it.

(8) *Non-commercial scientific institution* refers to an institution that is not operated on a commercial basis as defined under ''commercial use request'' in paragraph (a)(5) of this section, and which is operated solely for the purpose of conducting scientific research, the results of which are not intended to promote any particular product or industry.

(b) *Fee schedules and waivers.* Requests submitted shall be subject to direct costs, including search, duplication and review, in accordance with the following schedules, procedures and conditions.

(1) *Schedule of charges.*—(i) *Clerical time.* For each one-quarter hour or portion thereof of clerical time, $4.00.

(ii) *Professional time.* For each one-quarter hour or portion thereof of professional time, $10.00.

(iii) *Duplication.* For each sheet of duplication (not to exceed 8½ by 14 inches) of requested records, $.20.

(iv) *Computer time.* For computer time, $3.00 per minute of time expended for production programming, searching and production of any record. Computer time expressed in fractions of minutes will be rounded to the next whole minute.

(v) *Certification or authorization of records.* The fee per certification or authentication is $2.00.

(vi) *Forwarding material to destination.* No charge will be assessed for ordinary packaging and mailing costs. The FMCS may assess a charge if compliance with the request requires special handing procedures such as express mail or other unusual procedures. Such charges will be made on the basis of actual costs.

(vii) *Other costs.* All other direct costs of preparing a response to a request shall be charged to requester in the same amount as incurred by FMCS. Charges may also be assessed for searches even if the records requested are not found, or the records are determined to be exempted from disclosure.

(2) *Rules of construction.* (i) In providing the foregoing the schedules pursuant to the provisions of 5 U.S.C. 552(a)(4)(A), it is the intent of FMCS to apply 29 CFR part 70 and the user charge statute, 31 U.S.C. 9701, to cover those situations in which the Agency is performing for a requester services which are not required under the Freedom of Information Act.

(ii) For those matters coming within the scope of this regulation, the FMCS will look to the provisions of the guidance published by the Office of Management and Budget (52 FR 10012, March 27, 1987) and the Department of Justice (Attorney General's, memorandum on the 1986 Amendments to the Freedom of Information Act, December 1987) for making such interpretations as may be necessary.

(3) *Fee categories.* Fees shall be determined in accordance with the following categories of requesters.

(i) Commercial use requesters will be assessed charges to recover the full direct cost of searching for, reviewing for release, and duplicating the records sought. This includes the full direct costs of computer production programming, searching and production of records. Commercial use requesters are not entitled to 2 hours of free search time nor 100 free pages of reproduction of documents, as described below.

(ii) Educational and non-commercial scientific institution requesters will be assessed charges for the cost of duplication alone, excluding charges for the first 100 pages. To be eligible for inclusion in this category, requesters must show that the request is being made under the auspices of a qualifying institution pursuant to the criteria in paragraphs (a)(6) and (a)(8) of this section, and that the records are not sought for commercial use, but are sought in furtherance of scholarly or scientific research.

(iii) Requesters who are representatives of the news media will be assessed charges for the cost of duplication alone, excluding charges for the first 100 pages. To be eligible for inclusion in this category, a requester must meet the criteria in paragraph (a)(7) of this section, and the request must not be made for a commercial use. A request for records supporting the news dissemination function of the requester shall not be considered to be a request that is for commercial use.

(iv) All other requesters will be assessed charges to recover the full reasonable direct costs of searching for and reproducing records that are responsive to the request, including costs of computer production programming, searching and production, except that the first 100 pages of reproduction, and the first 2 hours of search time shall be furnished without charge.

(v) In no event shall fees be charged when the total charges are less than $14.00, which is the Agency cost of collecting and processing the fee itself.

(4) *Waiver or reduction of charge.* Documents are to be furnished without charge or at reduced levels if disclosure of the information is in the public interest; that is, because it is likely to contribute significantly to public understanding of the operations or activities of the Government and is not primarily in the commercial interest of the requester.

(c) *Fee payments.* (1) Payments shall be made by check or money order payable to ''Federal Mediation and Conciliation Service'' and shall be sent to: Director, Financial Management Staff, Federal Mediation and Conciliation Service, 2100 K Street NW, Washington, DC 20427.

(2) If a requester fails to pay chargeable fees that were incurred as a result of this Agency's processing of the information request, the Agency beginning on the 31st day following the date on which the notification of charges was sent, may assess interest charges against the requester in the manner prescribed in 31 U.S.C. 3717.

(3) The Agency may use the provisions of the Debt Collection Act of 1982, (Pub. L. 97–365, 29 CFR part 1450) including disclosure to consumer reporting agencies, for the purpose of obtaining payment.

(d) *Advance payments.* FMCS may require a requester to make an advance payment of anticipated fees under the following circumstances:

(1) If the anticipated charges are likely to exceed $250.00, FMCS may notify the requestor of the likely cost and obtain satisfactory assurance of full payment when the requester has a history of prompt payment of FOIA fees, or require an advance payment of an amount up to the full estimated charges in the case of requesters with no history of payments.

(2) If a requester has previously failed to pay fees that have been charged in processing a request, within 30 days of the date when the notification of fees was sent, the requester may be required to:

(i) Pay the entire amount of fees that are owed, plus any applicable interest as provided for in paragraph (c)(2) of this section, and

(ii) To make an advance payment of the full amount of the estimated fee before the Agency will process the new pending request.

Dated: October 28, 1999.

Vella M. Traynham,

Deputy Director.

[FR Doc. 99–28678 Filed 11–2–99; 8:45 am]

BILLING CODE 6372–01–U

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No.: 991008272–9272–01]

RIN 0651–AB07

Changes To Permit Payment of Patent and Trademark Office Fees by Credit Card

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Patent and Trademark Office (Office) is proposing to amend the rules of practice to provide for the payment of any patent or trademark fee by credit card. The Office previously limited payment by credit card to the fees required for information products or for an electronic submission with or in a trademark application. The Office is proposing to accept payment of any patent fee, trademark fee, or information product fee by credit card.

DATES: *Comment Deadline Date*: To be assured of consideration, written comments must be received on or before December 3, 1999. While comments may be submitted after this date, the Office cannot ensure that consideration will be given to such comments. No public hearing will be held.

ADDRESSES: Comments should be sent by electronic mail message over the Internet addressed to: ccard.comments@uspto.gov. Comments may also be submitted by mail addressed to: Box Comments—Patents, Assistant Commissioner for Patents, Washington, D.C. 20231, or by facsimile to (703) 308–6916, marked to the attention of Robert W. Bahr. Although comments may be submitted by mail or facsimile, the Office prefers to receive comments via the Internet. If comments are submitted by mail, the Office would prefer that the comments be submitted on a DOS formatted 3½ inch disk accompanied by a paper copy.

The comments will be available for public inspection at the Special Program Law Office, Office of the Deputy Assistant Commissioner for Patent Policy and Projects, located at Room 3–C23 of Crystal Plaza 4, 2201 South Clark Place, Arlington, Virginia, 22202, and will be available through anonymous file transfer protocol (ftp) via the Internet (address: ftp.uspto.gov). Since comments will be made available for public inspection, information that is not desired to be made public, such as an address or phone number, should not be included in the comments.

FOR FURTHER INFORMATION CONTACT: Concerning this proposed rule change: Robert W. Bahr, by telephone at (703) 305–9285, or by facsimile to (703) 308–6916 marked to the attention of Robert W. Bahr.

Concerning the payment of fees (by credit card or otherwise) in general: Matthew Lee, by telephone at (703) 305–8051, by e-mail at matthew.lee@uspto.gov, or by facsimile at (703) 305–8007 marked to the attention of Matthew Lee.

SUPPLEMENTARY INFORMATION: Patent and Trademark Office (Office) practice has been to accept payment of fees for information products by credit card, but not to accept patent fees or trademark fees by credit card. The Office recently revised 37 CFR 1.23 to expressly permit payment of money for fees ''in an electronically filed trademark application or electronic submission in a trademark application.'' *See Trademark Law Treaty Implementation Act Changes*, Final Rule Notice, 64 FR 48989, 48917 (September 8, 1999), 1226 *Off. Gaz. Pat. Office* 103, 120 (September 23, 1999). As explained in that final rule notice:

> Section 1.23 is also amended to add a paragraph (b), providing that payments of money for fees in electronically filed trademark applications, or electronic submissions in trademark applications, may also be made by credit card. The Office previously limited fee payment by credit card to the fees required for information products, and will continue to accept payment of information product fees by credit card.
>
> Section 1.23(b) will also provide that payment of a fee by credit card must specify the amount to be charged and such other information as is necessary to process the charge, and is subject to collection of the fee.
>
> Section 1.23(b) will further provide that the Office will not accept a general authorization to charge fees to a credit card. The Office cannot accept an authorization to charge ''all required fees'' or ''the filing fee'' to a credit card, because the Office cannot determine with certainty the amount of an unspecified fee (the amount of the ''required fee'' or the applicable ''filing fee'') within the time frame for reporting a charge to the credit card company. Also, the Office cannot accept charges to credit cards that require the use of a personal identification number (PIN) (*e.g.*, certain debit cards or check cards).
>
> Section 1.23(b) also contains a warning that if credit card information is provided on a form or document other than a form provided by the Office for the payment of fees by credit card, the Office will not be liable if the credit card number is made public. The Office currently provides an electronic form for use when paying a fee in an electronically filed trademark application or electronic submission in a trademark application. This form will not be included in the records open to public inspection in the file of a trademark matter. However, the inclusion of credit card information on forms or documents other than the electronic form provided by the Office may result in the release of credit card information.

See Trademark Law Treaty Implementation Act Changes, 64 FR at 48906–07, 1226 *Off. Gaz. Pat. Office* at 110. The Office is now proposing to revise the rules of practice to expressly accept payment of any patent fee, trademark fee, or information product fee by credit card, subject to actual collection of the fee.

The Office will provide a Credit Card Payment Form (PTO–2038) for use when paying a patent or trademark fee (or the fee for an information product) by credit card. The Office will not require customers to use this form when paying a patent or trademark fee by credit card. If, however, a customer provides a credit card charge authorization in another form or document (*e.g.*, a communication relating to the patent or trademark), the credit card information may become part of the record of an Office file that is open to public inspection. Information concerning fees in general is posted on the Office's Web site at http://www.uspto.gov, and information on completing the Credit Card Payment Form will be posted on the Office's Web site.

The Office will not include the Credit Card Payment Form (PTO–2038) among the records open to public inspection in the file of a patent, trademark registration, or other proceeding. The Credit Card Payment Form (PTO–2038) is the only form the Office uses to collect credit card information and is the only form the Office will not make available to the public as part of the file of a patent, trademark, or other proceeding. As discussed above, failure to use the Credit Card Payment Form (PTO–2038) when submitting a credit card payment may result in your credit card information becoming part of the record of a Patent and Trademark Office file that is open to public inspection. If the cardholder includes a credit card number on any form or document other than the Credit Card Payment Form, the Patent and Trademark Office will not be liable in the event that the credit card number becomes public knowledge.

Discussion of Specific Rules: Title 37 of the Code of Federal Regulations, Part 1, is proposed to be amended as follows:

Section 1.21: Section 1.21(m) is proposed to be amended to make the $50.00 fee for processing a check returned ''unpaid'' by a bank applicable to any payment refused or charged back by a financial institution. The burden of processing any payment refused or credit card transaction charged back by

a financial institution is the same as the burden of processing a check returned ''unpaid'' by a bank. The phrase ''payment refused * * * by a financial institution'' includes a check returned ''unpaid'' by a bank but also applies to the refusal by a financial institution of a payment by other means.

Section 1.23: Section 1.23(b) is proposed to be amended by revising the first sentence to eliminate the restriction that the payment of money required for Patent and Trademark Office fees by credit card be limited to fees ''in an electronically filed trademark application or electronic submission in a trademark application.''

Review under the Paperwork Reduction Act of 1995 and Other Considerations. This notice is in conformity with the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), Executive Order 12612 (October 26, 1987), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). It has been determined that this rulemaking is not significant for the purposes of Executive Order 12866 (September 30, 1993).

This notice involves information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the Patent and Trademark Office has submitted an information collection package to OMB for its review and approval. The title, description, and respondent description for this information collection is shown below with an estimate of the annual reporting burdens. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Patent and Trademark Office Fees.

Form Number: PTO–2038.

Type of Review: A new collection.

Affected Public: Individuals or households, businesses or other for-profit, not-for-profit institutions, farms, state, local or tribal governments, and the Federal Government.

Estimated Number of Respondents: 100,000 responses per year.

Estimated Time Per Response: 12 minutes.

Estimated Total Annual Respondent Burden Hours: 20,000 hours per year.

Needs and Uses: Persons submitting fees to the Patent and Trademark Office need to provide information concerning the purpose for the fee so that the Patent and Trademark Office is able to: (1) Apply the fee to the particular application, patent, trademark registration, or other proceeding, service or product; and (2) determine whether the person has submitted the fee(s) required by law or regulation. The Credit Card Form provides the public with a convenient manner of paying a patent application or service fee, trademark application or service fee, or information product fee by credit card.

Comments are invited on: (a) Whether the collection of information is necessary for proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information to respondents.

Interested persons are requested to send comments regarding the burden estimate or any other aspects of the information requirements, including suggestions for reducing the burden, to Robert J. Spar, Director, Special Program Law Office, Patent and Trademark Office, Washington, D.C. 20231, or to the Office of Information and Regulatory Affairs of OMB, New Executive Office Building, 725 17th Street, N.W., Room 10235, Washington, D.C. 20503, Attention: Desk Officer for the Patent and Trademark Office.

Notwithstanding any other provision of law, no person is required to respond to nor shall a 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 OMB control number.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy, Small Business Administration, that the changes proposed in this notice if adopted would not have a significant impact on a substantial number of small entities (Regulatory Flexibility Act, 5 U.S.C. 605(b)). The Office does not currently permit patent or trademark fees (except in an electronically filed trademark application or electronic submission in a trademark application) to be paid by credit card. The changes proposed in this notice if adopted would permit small entities as well as non-small entities the option of paying any patent or trademark fee by credit card. Small entities as well as non-small entities will continue to have the option of paying any patent or trademark fee by check, treasury note, money order, or charge to a deposit account. Based upon the number of small entities who pay fees to the Patent and Trademark Office each year and the percentage of fee payments that are by credit card (where currently permitted), the Office expects 16,000 small entities to pay a patent or trademark fee by credit card each year. Thus, the changes proposed in this notice if adopted would not have a significant economic impact on any business.

This notice of proposed rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 12612 (October 26, 1987).

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Courts, Freedom of Information, Inventions and patents, Reporting and recordkeeping requirements, Small businesses.

For the reasons set forth in the preamble, 37 CFR Part 1 is proposed to be amended as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

1. The authority citation for 37 CFR Part 1 is revised to read as follows:

Authority: 35 U.S.C. 6, unless otherwise noted.

2. Section 1.21 is amended by revising paragraph (m) to read as follows:

§ 1.21 Miscellaneous fees and charges.

* * * * *

(m) For processing each payment refused (including a check returned ''unpaid'') or charged back by a financial institution— $50.00

* * * * *

3. Section 1.23 is amended by revising the first sentence of paragraph (b) to read as follows:

§ 1.23 Method of payment.

* * * * *

(b) Payments of money required for Patent and Trademark Office fees may also be made by credit card. * * *

* * * * *

Dated: October 29, 1999.

Robert M. Anderson,

Acting Assistant Secretary of Commerce and Acting Commissioner of Patents and Trademarks.

[FR Doc. 99–28731 Filed 11–2–99; 8:45 am]

BILLING CODE 3510–16–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[TN–158–2–9942(b); TN–211–1–9943(b); TN–215–1–9944(b); TN–221–1–9945(b); FRL–6452–7]

Approval and Promulgation of Implementation Plans, Tennessee: Approval of Revisions to the Knox County Portion of the Tennessee SIP Regarding Use of LAER for Major Modifications and Revisions to the Tennessee SIP Regarding the Coating of Miscellaneous Metal Parts

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA proposes to take action on revisions to Sections 46.2 and 46.3.A. of the Knox County portion of the Tennessee State Implementation Plan (SIP) which were submitted by the Tennessee Department of Air Pollution Control (TDAPC), on May 23, 1995, and November 13, 1998, for purposes of revising the definition for Volatile Organic Compounds (VOC) and requiring the use of Lowest Achievable Emission Rate (LAER) for major modifications to existing sources of VOC. The EPA also proposes to approve revisions to the Tennessee SIP which were submitted by TDAPC on February 12, 1999, and May 17, 1999, for purposes of revising Rule 1200–3–18–.20 (Coating of Miscellaneous Metal Parts) to include a standard for the touch-up of heavy-duty trucks and revise the definition of ''high performance architectural coating.'' In the Final Rules Section of this **Federal Register**, the EPA is approving the State's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

DATES: Written comments must be received on or before December 3, 1999.

ADDRESSES: All comments should be addressed to: Allison Humphris at the EPA, Region 4 Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303.

Copies of the state submittal(s) are available at the following addresses for inspection during normal business hours:

Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460

Environmental Protection Agency, Region 4, Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303–8960. Allison Humphris, 404/562–9030

Tennessee Department of Environment and Conservation, Division of Air Pollution Control, L & C Annex, 9th Floor, 401 Church Street, Nashville, Tennessee 37243–1531. 615/532–0554

Knox County Department of Air Quality Management, City/County Building, Room 339, 400 Main Street, Knoxville, Tennessee, 37902–2405. 423/215–2488

FOR FURTHER INFORMATION CONTACT: Allison Humphris at 404/562–9030.

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule which is published in the Final Rules Section of this **Federal Register**.

Dated: September 23, 1999.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

[FR Doc. 99–27196 Filed 11–2–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[OK–8–1–5772b; FRL–6457–8]

Approval and Promulgation of Implementation Plans; Oklahoma; Recodification of Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to take direct final action approving a recodification of the Oklahoma Department of Environmental Quality (ODEQ) regulations in the Oklahoma State Implementation Plan (SIP).

In the ''Rules and Regulations'' section of this **Federal Register**, EPA is approving the State's SIP revision as a direct final rule without prior proposal because EPA views this as a noncontroversial revision and anticipates no adverse comment. The EPA has explained its reasons for this approval in the preamble to the direct final rule. If EPA receives no relevant adverse comment, EPA will not take further action on this proposed rule. If EPA receives relevant adverse comment, EPA will withdraw the direct final rule and it will not take effect. The EPA will address all public comments in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

DATES: Written comments must be received by December 3, 1999.

ADDRESSES: Written comments should be addressed to Mr. Thomas H. Diggs, Chief, Air Planning Section (6PD–L), at the EPA Region 6 Office listed below. Copies of documents relevant to this action are available for public inspection during normal business hours at the following locations. Anyone wanting to examine these documents should make an appointment with the appropriate office at least two working days in advance.

Environmental Protection Agency, Region 6, Air Planning Section (6PD–L), 1445 Ross Avenue, Dallas, Texas 75202–2733

Oklahoma Department of Environmental Quality, Air Quality Division, 707 North Robinson, P.O. Box 1677, Oklahoma City, Oklahoma 73101–1677

FOR FURTHER INFORMATION CONTACT: Bill Deese of the EPA Region 6 Air Planning Section at (214) 665–7253.

SUPPLEMENTARY INFORMATION: This document concerns a recodification of the ODEQ SIP-approved regulations. For further information, please see the information provided in the direct final action that is located in the ''Rules and Regulations'' section of this **Federal Register** publication.

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

Dated: September 23, 1999.

Jerry Clifford,

Acting Regional Administrator, Region 6.

[FR Doc. 99–27542 Filed 11–2–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[AL–050–9953(b); FRL–6461–9]

Approval and Promulgation of Implementation Plans: Revisions to the Alabama Department of Environmental Management (ADEM) Administrative Code for the Air Pollution Control Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA proposes to approve the State Implementation Plan (SIP) revision submitted on April 22, 1999, by the State of Alabama. These revisions were made to comply with the regulations set forth in the Clean Air Act (CAA). Included in this document are revisions to Chapter 335–3–1—General Provisions which establishes Credible Evidence regulations and Chapter 335–3–14—Air Permits which allows exemptions for projects which are found to be beneficial to the environment. In the Final Rules section of this **Federal Register**, the EPA is approving the State's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

DATES: Written comments must be received on or before December 3, 1999.

ADDRESSES: Written comments should be addressed to Kimberly Bingham, at the EPA Regional Office listed below. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day. Copies of the documents relative to this action are available for public inspection during normal business hours at the following locations.

Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

U.S. Environmental Protection Agency, Region 4, Atlanta Federal Center, Air, Pesticides, and Toxics Management Division, 61 Forsyth Street, Atlanta, Georgia 30303–3104.

FOR FURTHER INFORMATION CONTACT: Kimberly Bingham of the EPA Region 4, Air Planning Branch at (404) 562–9038 and at the above address.

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule which is published in the Final Rules section of this **Federal Register**.

Dated: October 5, 1999.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

[FR Doc. 99–27540 Filed 11–2–99; 8:45 am]

BILLING CODE 6560–50–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[VA 097–5041; FRL–6459–2]

Approval and Promulgation of Air Quality Implementation Plans; Virginia; Control of VOC Emissions From Solvent Metal Cleaning Operations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve State Implementation Plan (SIP) revisions submitted by the Commonwealth of Virginia. The revisions pertain to and clarify the Commonwealth's regulation to control of volatile organic compound (VOC) emissions from solvent metal cleaning operations using non-halogenated solvents, and update another of its regulations to incorporate certain federal regulations by reference. In the Final Rules section of this **Federal Register**, EPA is approving the Commonwealth's SIP revision requests as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by December 3, 1999.

ADDRESSES: Written comments should be addressed to David Arnold, Chief, Ozone and Mobile Sources Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia 23219.

FOR FURTHER INFORMATION CONTACT: Janice M. Lewis, (215) 814–2185, at the EPA Region III address above, or via e-mail at lewis.janice@epa.gov.

SUPPLEMENTARY INFORMATION: For further information, please see the information provided in the direct final action, with the same title, that is located in the ''Rules and Regulations'' section of this **Federal Register** publication.

Dated: September 30, 1999.

Thomas C. Voltaggio,

Acting Regional Administrator, Region III.

[FR Doc. 99–27676 Filed 11–2–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[NJ35–2–195b FRL–6461–6]

Approval and Promulgation of Air Quality Implementation Plans; New Jersey; Approval of National Low Emission Vehicle Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of New Jersey on February 22, 1999. That revision committed that the State will accept compliance with the National Low Emission Vehicle (National LEV) program requirements as a compliance option for new motor vehicles sold in the State. New Jersey has previously adopted the California Low Emission Vehicle (CAL LEV) program, but the State has made clear that National LEV is the preferred motor vehicle control

program. Auto manufacturers have agreed to sell cleaner vehicles meeting the National LEV standards throughout New Jersey for the duration of the manufacturers' commitments to the National LEV program. This SIP revision is required as part of the agreement between states and automobile manufacturers to ensure the continuation of the National LEV program to supply clean cars throughout most of the country, beginning with 1999 model year vehicles in Northeastern states and extending to other states beginning with 2001 model year vehicles.

In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Written comments must be received on or before December 3, 1999.

ADDRESSES: All comments should be addressed to: Raymond Werner, Acting Chief, Air Programs Branch, Environmental Protection Agency, Region 2 Office, 290 Broadway, New York, New York 10007–1866.

Copies of the State submittal are available at the following addresses for inspection during normal business hours:

Environmental Protection Agency, Region 2 Office, 290 Broadway, 25th Floor, New York, New York 10007–1866.

New Jersey Department of Environmental Protection, Bureau of Air Quality Planning, 401 East State Street, CN027, Trenton, New Jersey 08625.

FOR FURTHER INFORMATION CONTACT: Michael P. Moltzen, Air Programs Branch, Environmental Protection Agency, 290 Broadway, 25th Floor, New York, New York 10007–1866, (212) 637–4249.

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule which is located in the Rules section of this **Federal Register**.

Dated: September 27, 1999.

William J. Musynski,

Acting Regional Administrator, Region 2.

[FR Doc. 99–27794 Filed 11–2–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[IN106–1b; FRL–6446–6]

Approval and Promulgation of Implementation Plan; Indiana

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve an Indiana request to amend the Stage II Vapor Recovery rule as a revision to the State Implementation Plan (SIP). Indiana submitted the SIP revision request on April 6, 1999. The revision affects gasoline dispensing facilities in Clark, Floyd, Lake, and Porter Counties. Stage II Vapor Recovery systems lower Volatile Organic Compound (VOC) emissions from vehicle refueling operations. VOC emissions are a precursor of ground-level ozone, commonly known as smog.

In the final rules section of this **Federal Register**, the EPA is approving the State's request as a direct final rule without prior proposal because EPA views this action as noncontroversial and anticipates no adverse comments. A detailed rationale for approving the State's request is set forth in the direct final rule. The direct final rule will become effective without further notice unless the Agency receives relevant adverse written comment on this action. Should the Agency receive such comment, it will publish a final rule informing the public that the direct final rule will not take effect and such public comment received will be addressed in a subsequent final rule based on this proposed rule. If no adverse written comments are received, the direct final rule will take effect on the date stated in that document and no further activity will be taken on this proposed rule. EPA does not plan to institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

DATES: EPA must receive written comments by December 3, 1999.

ADDRESSES: You should mail written comments to: J. Elmer Bortzer, Chief, Regulation Development Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

You may inspect copies of the State submittal and EPA's analysis of it at: Regulation Development Section, Regulation Development Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Francisco J. Acevedo, Environmental Protection Specialist, Regulation Development Section, Regulation Development Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–3299.

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we'', ''us'', or ''our'' are used we mean EPA.

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I. What Action Is EPA Taking Today?

We are proposing to approve Indiana's April 6, 1999, State Implementation Plan revision request to amend the Stage II Vapor Recovery rules promulgated by Indiana in 1993 and approved by us on April 28, 1994. The amendments we are approving clarify the applicability of definitions pertaining to gasoline dispensing facilities.

II. Where Can I Find More Information About This Proposal and the Corresponding Direct Final Rule?

For additional information see the direct final rule published in the rules section of this **Federal Register**.

Dated: September 17, 1999.

Francis X. Lyons,

Regional Administrator, Region 5.

[FR Doc. 99–28040 Filed 11–2–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[OH 129–1b; FRL–6464–6]

Approval and Promulgation of Maintenance Plan Revisions; Ohio

AGENCY: United States Environmental Protection Agency (USEPA).

ACTION: Proposed rule.

SUMMARY: USEPA is proposing to approve an August 19, 1999, request from Ohio for a State Implementation

Plan (SIP) revision of the Columbiana County, Ohio ozone maintenance plan. The maintenance plan revision allocates a portion of the safety margin to the transportation conformity mobile source emissions budget for the year 2005. USEPA is approving the allocation of 0.5 tons per day of oxides of nitrogen (NO_X) to the area's 2005 mobile source emissions budget for transportation conformity purposes. This allocation will still maintain the total emissions for the area at or below the attainment level required by the transportation conformity regulations. In the Final Rules section of this **Federal Register**, USEPA is approving the State's SIP revision, as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If we receive no adverse comments in response to that direct final rule we plan to take no further activity in relation to this proposed rule. If USEPA receives significant adverse comments, in writing, which have not been addressed, we will withdraw the direct final rule and address all public comments received in a subsequent final rule based on this proposed rule. The USEPA will not institute a second comment period on this document.

DATES: Written comments must be received on or before December 3, 1999.

ADDRESSES: Send written comments to: J. Elmer Bortzer, Chief, Regulation Development Section, Air Programs Branch, (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois, 60604.

You may inspect copies of the documents relevant to this action during normal business hours at the following location: Regulation Development Section, Air Programs Branch, (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois, 60604.

Please contact Patricia Morris at (312) 353–8656 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Patricia Morris, Environmental Scientist, Regulation Development Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–8656.

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we'', ''us'', or ''our'' are used we mean USEPA.

This Supplementary Information section is organized as follows:

What action Is USEPA taking today?

Where can I find more information about this proposal and the corresponding direct final rule?

What Action is USEPA Taking Today?

In this action, we are proposing to approve a revision to the ozone maintenance plan for Columbiana County, Ohio. The revision will change the mobile source oxides of nitrogen emission budget that is used for transportation conformity purposes. The revision will keep the total emissions for the area at or below the attainment level required by law. This action will allow State or local agencies to maintain air quality while providing for transportation growth.

Where Can I Find More Information About This Proposal and the Corresponding Direct Final Rule?

For additional information see the direct final rule published in the rules section of this **Federal Register**.

Dated: October 20, 1999.

Francis X. Lyons,

Regional Administrator, Region 5.

[FR Doc. 99–28387 Filed 11–2–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL–6469–1]

Assessment of Visibility Impairment at the Grand Canyon National Park: Advance Notice of Proposed Rulemaking; Extension of Public Comment Period

AGENCY: Environmental Protection Agency.

ACTION: Advance notice of proposed rulemaking; extension of public comment period.

SUMMARY: The Environmental Protection Agency (EPA) is extending the comment period for an advance notice of proposed rulemaking, published June 17, 1999 (64 FR 32458), regarding visibility impairment at the Grand Canyon National Park (GCNP) and the possibility that the Mohave Generating Station (MGS) in Laughlin, Nevada may contribute to that impairment. In the June 17 notice, EPA requests information that it should consider in determining whether visibility problems at the GCNP can be reasonably attributed to MGS, and if so, what, if any, pollution control requirements should be applied.

The public comment period for the advance notice of proposed rulemaking was originally due to expire on August 16, 1999. On August 6, 1999 (64 FR 42891), September 14, 1999 (64 FR 49756), and October 1, 1999 (64 FR 53303), EPA published notices extending the public comment period on the advance notice of proposed rulemaking. Today, EPA is extending the public comment period for an additional 25 days.

DATES: The comment period on the advance notice of proposed rulemaking is extended until November 15, 1999.

ADDRESSES: Comments should be submitted (in duplicate, if possible) to: EPA Region IX, 75 Hawthorne Street (AIR2), San Francisco, CA 94105, Attn: Regina Spindler.

FOR FURTHER INFORMATION CONTACT: Regina Spindler (415) 744–1251, Planning Office (AIR2), Air Division, EPA Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

Dated: October 25, 1999.

Felicia Marcus,

Regional Administrator, Region 9.

[FR Doc. 99–28722 Filed 11–2–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[Region 2 Docket No. NY37–202, FRL–6469–7]

Approval and Promulgation of Implementation Plans; New York 15 and 9 Percent Rate of Progress Plans, Phase I Ozone Implementation Plan and 1996 and 1999 Transportation Conformity Budgets

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing action on a State Implementation Plan revision submitted by New York which is intended to meet several Clean Air Act requirements. EPA is proposing approval of the 1990 base year ozone emission inventory (for all ozone nonattainment areas in New York); the 1996 and 1999 ozone projection emission inventories; demonstration that emissions from growth in vehicle miles traveled will not increase motor vehicle emissions and, therefore, offsetting measures are not necessary; modeling efforts completed to date; transportation conformity budgets; photochemical assessment monitoring stations network; and enforceable commitments. EPA is also proposing

approval of New York's 15 Percent Rate of Progress Plan and the 9 Percent Reasonable Further Progress Plan. The intended effect of this action is to approve programs required by the Clean Air Act which will result in emission reductions that will help achieve attainment of the one-hour national ambient air quality standard for ozone.

DATES: Comments must be received on or before December 3, 1999.

ADDRESSES: All comments should be addressed to: Raymond Werner, Acting Chief, Air Programs Branch, Environmental Protection Agency, Region 2 Office, 290 Broadway, 25th Floor, New York, New York 10007–1866.

Copies of the New York submittals and EPA's Technical Support Document are available at the following addresses for inspection during normal business hours:

Environmental Protection Agency, Region 2 Office, Air Programs Branch, 290 Broadway, 25th Floor, New York, New York 10007–1866

New York State Department of Environmental Conservation, Division of Air Resources, 50 Wolf Road, Albany, New York 12233

FOR FURTHER INFORMATION CONTACT: Kirk J. Wieber, Air Programs Branch, Environmental Protection Agency, 290 Broadway, 25th Floor, New York, New York 10007–1866, (212) 637–4249

SUPPLEMENTARY INFORMATION:

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I. What Is Required by the Clean Air Act and How Does It Apply to New York?

Section 182 of the Clean Air Act (Act) specifies the required State Implementation Plan (SIP) submissions and requirements for areas classified as nonattainment for ozone and when these submissions and requirements are to be submitted to EPA by the states. EPA has issued the ''General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990'' (General Preamble) describing in detail EPA's preliminary views on how EPA intends to review SIPs and SIP revisions submitted under Title I of the Act, [see generally 57 FR 13498 (April 16, 1992) and 57 FR 18070 (April 28, 1992)]. Because EPA is describing its interpretations here only in broad terms, the reader should refer to the General Preamble for a more detailed discussion of the interpretations of Title I advanced in today's proposal and the supporting rationale.

New York was originally divided into six ozone nonattainment areas. These areas were the Albany-Schenectady-Troy Area, Buffalo-Niagara Falls Area, Essex County Area, Jefferson County Area, Poughkeepsie Area and the New York-Northern New Jersey-Long Island Area. The New York-Northern New Jersey-Long Island Area is classified as a severe ozone nonattainment area. The New York portion of the New York-Northern New Jersey-Long Island Area is composed of New York City and the counties of Nassau, Suffolk, Westchester and Rockland, referred to as the New York City Metropolitan Area (NYCMA), and certain towns in Orange County-Blooming Grove, Chester, Highlands, Monroe, Tuxedo, Warwick and Woodbury, referred to as the Lower Orange County Metropolitan Area (LOCMA). The primary focus of this **Federal Register** action is the New York portion of the New York-Northern New Jersey-Long Island Area (referred to as the New York Metropolitan Area). EPA is also acting on the 1990 base year emission inventories for the five upstate areas identified above.

II. What Was Included in New York's Submittal?

On February 2, 1999, Deputy Commissioner Johnson of the New York State Department of Environmental Conservation (NYSDEC) submitted to EPA a revision to the SIP to meet requirements related to attainment of the National Ambient Air Quality Standards (NAAQS) for ozone, referred to as Phase I. New York's submittal revised the previously submitted 15 Percent Rate of Progress (ROP) Plan dated November 15, 1993 and September 4, 1997. In addition, these revisions are intended to fulfill EPA's Phase I requirement (''Ozone Attainment Demonstrations,'' March 2, 1995 memo from Mary Nichols) and includes the following: revisions of the 1990 base year ozone emission inventory (for areas designated nonattainment for ozone since 1991 in New York); the 1996 and 1999 ozone projection emission inventories; 9 Percent Reasonable Further Progress (RFP) Plan; contingency measures; demonstration that emissions from growth in vehicle miles traveled will not increase motor vehicle emissions and, therefore, offsetting measures are not necessary; modeling efforts completed to date; enforceable commitments for Phase II; photochemical assessment monitoring stations network; and transportation conformity budgets. EPA will be acting on the contingency measures in a separate **Federal Register** notice.

A. What Emission Inventories Were Included in New York's Submittal and Do They Meet EPA's Guidance?

New York's submittal included revisions of the 1990 base year ozone emission inventory (for areas designated nonattainment for ozone since 1991 in New York) and the 1996 and 1999 ozone projection emission inventories.

1. 1990 Base Year Inventory

Based on EPA's review, New York has satisfied all of EPA's requirements of providing a comprehensive, accurate, and current inventory of actual emissions in the six ozone nonattainment areas. A more detailed discussion of how the emission inventory was reviewed and the results are presented in the technical support document (TSD). A summary of EPA's review is given below:

—New York submitted a final Inventory Preparation Plan for the ''Development of Ozone/CO SIP Inventory of Base Year 1990 Emissions,'' September 24, 1992. This Plan contained a Quality Assurance

Plan which was implemented and documented.

—The inventory is well documented. New York provided documentation detailing the methods used to develop emissions estimates for each category. In addition, New York identified the sources of data used in developing the inventory.

—The point and area source inventories are complete and were prepared/calculated in accordance with EPA guidance.

—New York biogenic emissions were prepared/calculated using the July 1991 version of PC–BEIS according to current EPA guidance.

—The method used to develop vehicle miles traveled (VMT) estimates was in accordance with EPA guidance and was adequately described and documented in the inventory report.

—The most current version of the Mobile model was used correctly for each of the eight vehicle classes.

—Emission estimates for the non-road mobile source categories were correctly prepared according to EPA guidance.

The revisions have been made in accordance with EPA guidance. Therefore, EPA is proposing to approve the revisions to the 1990 base year volatile organic compounds (VOC), nitrogen oxides (NOx) and carbon monoxide (CO) emission inventories.[1]

A summary of the emission inventories broken down by point, area, biogenic, on-road, and non-road mobile sources are presented in the Tables 1A–1F.

TABLE 1A.—NEW YORK METROPOLITAN AREA 1990 BASE YEAR OZONE SEASON EMISSIONS IN TONS/DAY

Pollutant	Area source emissions	Point source emissions	On-road mobile emissions	Non-road mobile emissions	Biogenic	Total emissions
VOC	381	103	484	167	103	1,238
NO_X	59	286	400	178	N/A	923
CO	40	45	3,890	1,333	N/A	5,308

TABLE 1B.—ALBANY-SCHENECTADY-TROY AREA 1990 BASE YEAR OZONE SEASON EMISSIONS IN TONS/DAY

Pollutant	Area source emissions	Point source emissions	On-road mobile emissions	Non-road mobile emissions	Biogenic	Total emissions
VOC	48.27	78.66	54.40	23.5	222.11	426.79
NO_X	4.84	73.34	73.10	23.35	N/A	174.63
CO	3.16	15.04	474.6	174.32	N/A	667.12

TABLE 1C.—BUFFALO-NIAGARA FALLS AREA 1990 BASE YEAR OZONE SEASON EMISSIONS IN TONS/DAY

Pollutant	Area source emissions	Point source emissions	On-road mobile emissions	Non-road mobile emissions	Biogenic	Total emissions
VOC	67.11	156.45	50.5	32.70	61.06	367.85
NO_X	9.54	116.53	75.3	29.55	N/A	230.92
CO	5.13	69.06	437.7	24.12	N/A	536.00

TABLE 1D.—POUGHKEEPSIE AREA 1990 BASE YEAR OZONE SEASON EMISSIONS IN TONS/DAY

Pollutant	Area source emissions	Point source emissions	On-road mobile emissions	Non-road mobile emissions	Biogenic	Total emissions
VOC	31.70	15.73	39.27	13.45	56.51	156.66
NO_X	4.0	66.47	50.69	15.42	N/A	136.58
CO	1.9	5.73	338.00	23.35	N/A	368.98

TABLE 1E.—ESSEX COUNTY AREA 1990 BASE YEAR OZONE SEASON EMISSIONS IN TONS/DAY

Pollutant	Area source emissions	Point source emissions	On-road mobile emissions	Non-road mobile emissions	Biogenic	Total emissions
VOC	1.98	.29	2.97	.97	182.22	188.43
NO_X	.18	2.50	4.89	.83	N/A	8.4
CO	.36	1.45	25.06	7.61	N/A	34.48

[1] EPA's March 1991 guidance document, ''Emission Inventory Requirements for Ozone State Implementation Plans'' (EPA–450/4–91–010), requires the base year inventory summary contain emission estimates of VOC, NOx and CO.

TABLE 1F.—JEFFERSON COUNTY AREA 1990 BASE YEAR OZONE SEASON EMISSIONS IN TONS/DAY

Pollutant	Area source emissions	Point source emissions	On-road mobile emissions	Non-road mobile emissions	Biogenic	Total emissions
VOC	5.53	1.5	7.00	2.88	83.08	99.99
NO_X	.56	3.43	12.6	2.69	N/A	19.28
CO	.33	.23	61.90	21.72	N/A	84.18

2. 1996 and 1999 Projection Year Inventories for the New York Metropolitan Area

A projection of 1990 VOC anthropogenic emissions to 1996 for the New York Metropolitan Area is required to determine the reductions needed for the 15 Percent ROP Plan. In addition, projection of the 1990 VOC and NOx anthropogenic emissions to 1999 are required to determine the reductions needed for the 9 Percent RFP Plan with NOx substitution. The 1996 and 1999 projection year emission inventories are calculated by multiplying the 1990 base year inventory by factors which estimate growth from 1990 to 1996 and 1990 to 1999. A specific growth factor for each source type in the inventory is required since sources typically grow at different rates.

The difference between the most current 1990 base year inventory and the 1996 and 1999 projection inventories are the emissions growth estimates. Based on the difference between the 1990 base year inventory and the 1996 and 1999 projection year inventories, the total 1990–1996 and 1990–1999 VOC growth for the four source categories is estimated at 40 tons per day (tpd) and 81 tpd, respectively, in the New York Metropolitan Area. The total 1990–1996 and 1990–1999 NOx growth for the four source categories is estimated at 79 tpd and 125 tpd, respectively, in the New York Metropolitan Area.

Projection Methodology. Point Sources. For the point source category, New York projected 1990 base year emissions to 1996 and 1999 for each facility using Bureau of Economic Analysis (BEA) growth indicators available from New York State at the two-digit Standard Industrial Classification (SIC) Code level.

Since BEA growth indicators are one of the preferred growth indicators to use, as outlined in ''Procedures for Preparing Emissions Projections,'' July 1991, EPA finds New York's 1996 and 1999 point source projection methodologies to be acceptable.

Area Sources. For the area source category, New York projected emissions from 1990 to 1996 and 1999 using population and BEA growth rates where applicable. This is in accordance with EPA's recommended growth indicators for projecting emissions for area source categories outlined in ''Procedures for Preparing Emissions Projections,'' July 1991.

Non-Road Mobile Sources. For the non-road mobile source category, New York projected emissions utilizing EPA's guidance documents. New York included reductions anticipated from reformulated gasoline and new engine standards. Population growth rates were utilized to project the subcategory emissions except for light commercial, industrial and construction equipment which used the BEA growth rates. EPA finds New York's methodology for projecting nonroad mobile sources to be acceptable.

On-Road Mobile Sources. For the highway mobile source category, the primary indicator and tool for developing on-road mobile growth and expected emissions are VMT and EPA's mobile emissions model Mobile 5b. 1996 and 1999 VOC and NO_X emission factors were generated by Mobile 5b and applied to the New York State Department of Transportation (NYSDOT) VMT projections.

NYSDOT projected VMT by county and functional roadway classification based upon linear regression of historical Highway Performance Monitoring System (HPMS) VMT data. NYSDOT's method is in accordance with EPA's recommended growth indicators for projecting emissions for on-road mobile source categories outlined in ''Procedures for Preparing Emissions Projections,'' July 1991.

The 1996 and 1999 projection year emission inventories were calculated in accordance with EPA guidance. Therefore, EPA is proposing to approve the 1996 and 1999 projection year inventories. A more detailed discussion of how the emission inventories were reviewed and the results are presented in the TSD.

Tables 2A and 2B show 1996 and 1999 VOC and NO_X projection emission inventories using the aforementioned growth indicators/methodologies.

TABLE 2A.—NEW YORK METROPOLITAN AREA 1996 PROJECTION YEAR EMISSIONS INVENTORY IN TONS/DAY

Pollutant	Area source emissions	Point source emissions	On-road mobile emissions	Non-road mobile emissions	Total emissions
VOC	388	109	506	172	1,175
NO_X	61	311	443	187	1,002

TABLE 2B.—NEW YORK METROPOLITAN AREA 1999 PROJECTION YEAR EMISSIONS INVENTORY IN TONS/DAY

Pollutant	Area source emissions	Point source emissions	On-road mobile emissions	Non-road mobile emissions	Total emissions
VOC	393	113	534	176	1,216
NO_X	62	327	467	192	1,048

B. What Are the Act Requirements for an Approvable 15 Percent Rate of Progress Plan and What Does New York's 15 Percent Plan Consist of?

Section 182(b)(1) of the Act as amended in 1990 requires ozone nonattainment areas with classifications of moderate and above to develop plans to reduce area-wide VOC emissions by 15 percent from a 1990 adjusted baseline. The plans were to be submitted by November 15, 1993 and the reductions were required to be achieved within six years of enactment or by November 15, 1996. The Act also sets limitations on the creditability of certain types of reductions. Specifically, states cannot take credit for reductions achieved by Federal Motor Vehicle Control Program (FMVCP) measures (new car emissions standards) promulgated prior to 1990 and Reid Vapor Pressure (RVP) programs promulgated prior to 1990. Furthermore, the Act does not allow credit for corrections to vehicle Inspection and Maintenance Programs (I/M) or corrections to reasonably available control technology (RACT) rules (RACT fix-ups) that were required to have been made to meet requirements in effect prior to 1990.

The target emission reductions were calculated in accordance with EPA guidance. The reader is referred to ''Guidance On The Adjusted Base Year Emissions Inventory and The 1996 Target For The 15 Percent Rate of Progress Plans,'' (EPA–452/R–92–005). New York's 15 Percent ROP Plan is summarized in Table 3A.

The reader should note that the differences in VOC emissions between 1990 and 1996, in the New York Metropolitan Area as depicted in Tables 1A and 2A, are not the same as the emission reductions for the same time period depicted in Table 3A, Summary of 15 Percent ROP Plan. This is because the emissions changes between 1990 and 1996 have been adjusted for purposes of the 15 Percent ROP Plan to eliminate emission changes not creditable according to the Act. These adjustments are explained in detail in the previously referenced guidance.

TABLE 3A.—SUMMARY OF 15 PERCENT ROP PLAN

	New York metropolitan area VOC (tons/day)
Required VOC reductions to meet 15 Percent Plan	197.2
Creditable Reductions—Mobile Source control measures:	
Non-Road:	
Reformulated Gasoline	4.0
New Engine Standard	12.0
On-Road:	
Reformulated Gasoline	56.6
Tier I—New Vehicle Program	4.1
Low Emission Vehicle	3.3
Enhanced Inspection & Maintenance, July 1999 Emission Reduction Using Phase-in Cutpoints	22.2
Pressure/Purge Programs July 1999 Emission Reduction	19.8
Full Inspection Cycle Completed in November 1999	30.6
Stationary Source control measures: Parts 212, 228, 229, 234—VOC RACT	24.34
Area Source control measures:	
Auto Body Refinishing	5.7
Commercial Bakeries (Part 212)	2.1
Consumer Products	12.1
Graphic Art Facilities	0.7
Stage II for 1.2 to 2.5K Gal/Yr Stations	1.6
Stage II for LOCMA	0.4
Transit/Loading Losses	0.5
Total VOC reductions	200.04
Surplus	2.84
Reductions not credited in today's action—Stationary Source control measures: Capped/shut down Emissions	2.27

Measures Achieving the Projected Reductions. New York has provided a plan to achieve the reductions required for the New York Metropolitan Area. The following is a concise description of each control measure New York used to achieve emission reduction credit within its 15 Percent ROP Plan. All of the New York measures have been adopted and submitted as SIP revisions. EPA has previously approved most of the control measures, including interim approval of the enhanced vehicle I/M program.

Mobile source control measures. Reformulated Gasoline. Section 211(k) of the Act requires that after January 1, 1995 in severe and above ozone nonattainment areas, only reformulated gasoline (RFG) be sold or dispensed. RFG is reformulated to burn cleaner and produce fewer evaporative emissions. Specifically, RFG Phase I (1995—1999) must achieve reductions in VOCs of 15 to 17 percent and no increase in NOx from 1990 baseline gasoline emission levels. RFG Phase II (2000+) must achieve reductions in VOCs of 25 to 29 percent and reductions in NOx of five to seven percent from 1990 baseline emissions. EPA agrees with the reductions toward New York's ROP that were calculated due to the sale of RFG for both on-road and off-road use.

New Engine Standards. In November 1994, EPA provided guidance entitled, ''Future Nonroad Emission Reduction Credits for Court-Ordered Nonroad Standard'' for calculating future years' emission benefits from new engines proposed standards. The small gasoline engine standards, except recreational marine vessels, are being implemented in two phases starting with 1997 engine model year for both VOC and NOx and additional phase II exhaust and evaporative emission standards effective by 2001 engine model year. On

September 7, 1994, EPA issued a memo entitled, ''Advance Emission Reduction Credits for Small Nonroad Gasoline Engines'', which stated that advance reductions are available starting in 1994 based upon manufacturers introducing lower-emitting small gasoline engines into the market earlier than required by EPA's phase I rule. New York calculated the expected emission reductions from the proposed new engine standards for VOC and NOx based upon EPA's guidance. Further, on July 3, 1995 (60 FR 34581), EPA promulgated the first phase and on March 30, 1999 (64 FR 15208), EPA promulgated the second phase of the regulations to control emissions from new nonroad spark-ignition engines. These regulations are contained in the Code of Federal Regulations (CFR), Title 40, ''Part 90—Control of Emissions From Nonroad Spark-Ignition Engines.''

EPA has determined that the first phase of the new nonroad standards will cause a reduction of VOC emissions by 13.1 percent in 1997, 19.5 percent in 1998 and 23.9 percent in 1999 nationally. New York's estimated emission reductions, based upon EPA's earlier guidance, is conservative with respect to the reductions estimated by EPA in the 1995 Phase I regulations for new nonroad spark-ignition engines. EPA agrees with New York's calculated emission reductions associated with the Phase I new engine standards.

Tier I—New Vehicle Standards & Low Emission Vehicle Program. EPA promulgated standards for 1994 and later model year light-duty vehicles and light-duty trucks (56 FR 25724). Since the standards were adopted after the Clean Air Act Amendments of 1990, the resulting emission reductions are creditable toward the 15 percent reduction goal. On April 28, 1992, New York adopted revisions to Part 218, ''Emission Standards for Motor Vehicles and Motor Vehicle Engines'' to incorporate the California low emission vehicle (LEV) standards as a part of New York's new motor vehicle emission control program. The New York State effective date as a result of the revisions to Part 218 was November 22, 1992. On January 6, 1995 (60 FR 2025), EPA published a final notice approving the revisions to Part 218 as a revision to the SIP. EPA agrees that the State's adopted LEV program will provide additional reductions which can be attributed to New York's 1996 ROP plan. EPA agrees with the emission reductions calculated by New York due to vehicle turnover combined with the FMVCP and the LEV program.

Enhanced I/M. On March 27, 1996 New York submitted revisions to its existing Inspection and Maintenance (I/M) program to satisfy applicable requirements of the Act and the 1995 National Highway Systems Designation Act (NHSDA). On November 27, 1996 (61 FR 60242) EPA proposed conditional interim approval of this submittal. The reader is referred to that proposal for the details on the enhanced I/M program and EPA's findings. Conditional approval was proposed because the March 27, 1996 New York submittal did not include (1) an indication of when the Consumer Price Index adjustments to the $450 repair cost waiver would take effect; (2) the modeling demonstrating that the proposed I/M program would achieve the required emission reductions; and (3) written test procedures, pass/fail standards, and equipment specifications. That notice called for New York to commit within 30 days to correct these major deficiencies in the submittal as identified above, by specific dates. On December 20, 1996, New York committed to correct the deficiencies by the timelines stipulated in EPA's November 27, 1996 proposed conditional interim approval. New York has since submitted the necessary material as committed to in the December 20, 1996 letter. On October 24, 1997 (62 FR 55343) EPA granted a final interim approval of New York's enhanced I/M program under section 110 which strengthens the SIP, as well as an interim approval under section 348 of the NHSDA. Interim approval was granted for 18 months, or until May 24, 1999, for New York to correct six minor, or de minimus, deficiencies related to the Act requirements for enhanced I/M and provide EPA with an enhanced I/M program effectiveness demonstration. The reader is referred to EPA's October 24, 1997 interim approval for the details on the enhanced I/M program supplemental submittals and EPA's findings.

On May 20, 1999, New York submitted to EPA a final revision to the New York enhanced I/M program which addressed the six minor, or de minimus, deficiencies relating to the Act requirements for enhanced I/M. In addition, on May 24, 1999 New York submitted to EPA an enhanced I/M program evaluation report/program effectiveness demonstration. EPA is in the process of reviewing these submittals for technical adequacy and approvability and will be acting on these submittals in a separate **Federal Register** notice.

By today's action, EPA proposes to approve emission credits for the 15 Percent ROP and 9 Percent RFP Plans, pending EPA's verification of New York's enhanced I/M program's effectiveness, under section 348 of the NHSDA. If EPA determines New York's enhanced I/M program effectiveness demonstration indicates a shortfall in emission reductions compared to the emission reductions credited in the 15 Percent ROP and/or 9 Percent RFP Plans, EPA will propose to disapprove the 15 Percent ROP and/or 9 Percent RFP Plans. EPA final action will be based on EPA's evaluation of New York's demonstration of the enhanced I/M program's effectiveness. If New York's demonstration indicates a shortfall in emission reductions compared to the emission reductions credited in the 15 Percent ROP and 9 Percent RFP Plans, New York would need to find additional emission reduction credits. Failure of New York to make up for an emission shortfall may subject them to sanctions and imposition of a Federal Implementation Plan. The credits provided by the enhanced I/M program for those plans may be adjusted based on EPA's evaluation of the enhanced I/M Program's performance.

Enhanced I/M ''as soon as practicable''. Section 182(b)(1) of the Act requires that states containing ozone nonattainment areas classified as moderate or above prepare SIPs that provide for a 15 percent VOC emissions reduction by November 15, 1996. Most of the 15 Percent ROP Plans originally submitted to EPA contained enhanced I/M programs because this program achieves more VOC emission reductions than most, if not all other, control strategies. However, many states became concerned over the cost and convenience issues related to enhanced I/M programs as they were originally envisioned.

In a response to these concerns in September 1995, EPA finalized revisions to its enhanced I/M rule allowing states significant flexibility in designing I/M programs appropriate for their needs. Subsequently, Congress enacted the NHSDA, which provided states significantly more flexibility in determining the design of their respective enhanced I/M programs. The substantial lead time required for states to redesign and set up the necessary infrastructure of enhanced I/M programs in accordance with the NHSDA precluded them from obtaining emission reductions from such revised programs by November 15, 1996.

Given the heavy reliance by many states upon enhanced I/M programs to help achieve the 15 percent VOC emissions reduction required under section 182(b)(1), and the recent NHSDA and regulatory changes

regarding enhanced I/M programs, EPA recognized that it was no longer possible for many states to achieve the portion of the 15 percent reductions that is attributed to I/M by November 15, 1996. Under these circumstances, disapproval of the 15 Percent ROP Plans would serve no purpose. Consequently, under certain circumstances, EPA will propose to allow states that pursue redesign of enhanced I/M programs to receive emission reduction credit from these programs within their 15 Percent ROP Plans, even though the emissions reductions from the enhanced I/M program will occur after November 15, 1996.

Specifically, EPA can propose approval of 15 Percent ROP Plans if the emissions reductions from the revised, enhanced I/M programs, as well as from the other 15 Percent ROP Plan measures, will achieve the 15 percent level as soon as practicable after November 15, 1996. To make this ''as soon as practicable'' determination, EPA must determine that the SIP contains all VOC control strategies that are practicable for the nonattainment area in question and that meaningfully accelerate the date by which the 15 percent level is achieved. EPA does not believe that measures meaningfully accelerate the 15 percent date if they provide only an insignificant amount of reductions.

In the case of New York, they have submitted a 15 Percent ROP Plan that would achieve the amount of reductions needed from enhanced I/M by November 15, 1999. New York has submitted a 15 Percent ROP Plan that achieves all other reductions by 1996. In addition, EPA is pursuing federal rulemaking on a national scope which will result in additional emission reductions. EPA proposes to determine that this SIP does contain all measures, including enhanced I/M, that achieves the required reductions as soon as practicable.

EPA has examined other potentially available SIP measures to determine if they are practicable for New York and if they would meaningfully accelerate the date by which the area reaches the 15 percent level of reductions. In most cases New York has already adopted and implemented stationary control measures that other states are considering or which other states have included in their 15 Percent ROP Plans. Moreover, there are no measures that would achieve the 15 Percent reduction faster than the measures in New York's SIP. EPA proposes to determine that the SIP does contain the appropriate measures.

Pressure/Purge Programs. The 1992 I/M regulation requires that the enhanced I/M program include measures to curtail evaporative emissions from vehicle fueling systems. One such measure includes a functional check of the fuel tank integrity through pressurization. For a fraction of the emission reduction credit, EPA later allowed use of a test that checks only the integrity of the vehicle gas cap. New York has opted to perform this version of the test and submitted calculated emission reductions based on its use.

Full Inspection Cycle. In November 1998, New York began mandatory testing under the new inspection program. Although initial operating problems were identified, most of the vehicles covered under the program have thus far been tested. A legal challenge to the State's authority by non-implementing stations briefly allowed the use of the old test procedure during the early part of 1999. However, only a small portion of the covered vehicles was affected and New York estimates that the vast majority of the vehicles will have been tested by November 1999. Pending the verification of New York's enhanced I/M program's effectiveness, this will allow New York to meet the emission credit portion calculated in its 15 percent plan submittal.

Stationary source control measures. Parts 212, 228, 229, 234—VOC RACT. New York has submitted adopted revisions to Part 212, ''General Process Emission Sources'' which expanded the coverage of the regulation to require RACT on all major VOC process sources not covered in EPA issued control techniques guidelines (CTG) documents (referred to as ''non-CTG major sources'') and NO_X process sources throughout New York State and those not previously regulated in the New York Metropolitan Area. The New York State effective date as a result of the amendments to Part 212 was September 22, 1994. Although Part 212 is pending EPA rulemaking action, EPA agrees with the reductions projected in the New York 15 Percent ROP Plan due to the implementation of this rule.

New York submitted adopted revisions to Part 228, ''Surface Coating Processes,'' Part 229, ''Petroleum and Volatile Organic Liquid Storage,'' and Part 234, ''Graphic Arts'' which became New York State effective on April 4, 1993. These revisions extended the applicability of New York's RACT rules for sources covered by pre-enactment CTGs statewide and also added control requirements for some non-CTG RACT sources. On December 23, 1997 (62 FR 67004), EPA published a final notice approving these rules as a revision to the SIP. EPA agrees with the reductions projected in the New York 15 Percent ROP Plan due to the implementation of these rules.

Area source control measures: Auto Body Refinishing. On September 11, 1998 (63 FR 48806), EPA promulgated a national rule to control VOC emissions from solvent evaporation through reformulation of coatings used in auto body refinishing processes. These coatings are typically used by small businesses, or by vehicle owners. VOC emissions emanate from the evaporation of solvents used in the coating process. Use of emissions reductions from EPA's national rule is creditable toward ROP and RFP plans. EPA agrees with the reductions projected in the New York 15 Percent ROP Plan due to the implementation of this rule.

Commercial Bakeries (Part 212). As stated above, New York submitted adopted revisions to Part 212 ''General Process Emission Sources.'' Commercial bakeries had previously been exempt from the control requirements of Part 212, however, the revisions to Part 212 subject commercial bakeries to control requirements and includes a provision which sets forth a deadline in which bakeries must apply for a certificate to operate. Although Part 212 is pending EPA rulemaking action, EPA agrees with the reductions projected in the New York 15 Percent ROP Plan due to the implementation of this rule.

Consumer Products. On September 11, 1998 (63 FR 48819) EPA promulgated a national rule to control VOC emissions from household consumer products, such as cleaning products, personal care products, and a variety of insecticides. EPA's regulation is based on best available controls, as defined under the Act, and sets specific VOC content limits on 24 consumer product categories (some product categories are divided into subcategories). VOC limits would be met by the pollution prevention method of product reformulation. Use of emissions reductions from EPA's national rule is creditable toward ROP and RFP plans. EPA agrees with the reductions projected in the New York 15 Percent ROP Plan due to the implementation of this rule.

Graphic Arts Facilities (Part 234). As stated above, New York submitted adopted revisions to Part 234, ''Graphic Arts'', which became New York State effective on April 4, 1993. These amendments extended the applicability of regulations currently in force in the NYCMA to the major VOC facilities in LOCMA. Control requirements for screen printing operations and

lithographic printing processes (both which are non-CTG categories) have been mandated. Part 234 also has opacity limitations and provisions for the handling, storage, and disposal of VOC. EPA agrees with the reductions projected in the New York 15 Percent ROP Plan due to the implementation of this rule.

Stage II for 1.2 to 2.5K Gal/Yr Stations (Part 230). New York submitted adopted revisions to Part 230 ''Gasoline Dispensing Sites and Transport Vehicles'' which became New York State effective on September 22, 1994. The revisions to Part 230 lowered the applicability of the Stage II gasoline vapor recovery systems, which capture gasoline vapors during the refueling of motor vehicles, within the NYCMA. On April 30, 1998 (63 FR 23665), EPA published a final notice approving the revisions to Part 230 into the SIP. EPA agrees with the reductions projected in the New York 15 Percent ROP Plan due to the implementation of this rule.

Stage II for LOCMA (Part 230). New York submitted adopted revisions to Part 230 ''Gasoline Dispensing Sites and Transport Vehicles'' which became New York State effective on September 22, 1994. The revisions to Part 230 expanded the applicability of all the gasoline vapor control measures which are required in the NYCMA, into the LOCMA and expanded the applicability to cover additional gas stations. On April 30, 1998 (63 FR 23665), EPA published a final notice approving the revisions to Part 230 into the SIP. EPA agrees with the reductions projected in the New York 15 Percent ROP Plan due to the implementation of this rule.

Transit/Loading Losses. New York submitted adopted revisions to Part 230 ''Gasoline Dispensing Sites and Transport Vehicles'' which became New York State effective on September 22, 1994. The revisions to Part 230 expanded the requirements of Stage I gasoline vapor recovery systems to gasoline dispensing facilities located in the LOCMA. All gasoline transport vehicles which convey gasoline either to or from gasoline loading terminals or gasoline bulk plants are to be equipped with a vapor control system or equivalent method. On April 30, 1998 (63 FR 23665), EPA published a final notice approving the revisions to Part 230 into the SIP. EPA agrees with the reductions projected in the New York 15 Percent ROP Plan due to the implementation of this rule.

Measures Not Creditable in Today's Action. Capped/shutdown emissions. Certain facilities chose permit limits on their hours of operation to ''cap'' their facilities potential emissions below an annual level which reflected their actual hours of operation and emissions. These ''capping out'' provisions are included in a number of New York VOC and NO_X RACT regulations. The ''capping out'' provision exempts the facility from RACT requirements and/or Title V permitting requirements. In the projection inventory, New York adjusted emissions to account for those facilities that have ''capped out''. In addition, New York adjusted emissions to account for those facilities that have ceased or shutdown operations since the 1990 base year emissions inventory was compiled.

While EPA acknowledges that capped/shutdown facilities may have resulted in emission reductions, the documentation New York provided is not sufficient to determine whether these reductions are real, permanent and enforceable. Further, without this documentation, EPA is unable to verify whether the emission reduction credits associated with capped/shutdown facilities are not ''double counted'' or, more simply, used more than once (i.e., reductions cannot be used for offsets and to meet the 15 percent ROP requirement). Because of the uncertainties associated with both capped and shutdown emissions, EPA is considering these emissions reductions to be noncreditable at this time with respect to New York's Phase I Ozone SIP.

15 Percent ROP Plan Evaluation. New York has identified the control measures necessary for achieving the required emission reductions and all the measures have been adopted and implemented. EPA is proposing to find that the 15 Percent ROP Plan contains the necessary measures as identified in Table 3A to achieve the required emission reductions. The Plan also satisfies the requirement of achieving these reductions ''as soon as practicable'' and there are no remaining measures which could be implemented any sooner to offset the delay in the enhanced I/M program. Therefore, EPA proposes to approve emission credits for the 15 Percent ROP, pending EPA's verification of New York's enhanced I/M program's effectiveness. If EPA determines New York's enhanced I/M program effectiveness demonstration indicates a shortfall in emission reductions compared to the emission reductions credited in the 15 Percent ROP Plan, EPA will propose to disapprove the 15 Percent ROP Plan. EPA final action will be based on EPA's evaluation of New York's demonstration of the enhanced I/M program's effectiveness.

C. What Are the Act Requirements for an Approvable 9 Percent Reasonable Further Progress Plan and What Does New York's 9 Percent Plan Consist Of?

Section 182(c)(2)(B) of the Act requires ozone nonattainment areas with classifications of serious and above to develop plans to reduce area-wide VOC emissions by 3 percent per year averaged over the next three-year period (1997–1999) from a 1990 baseline. This is referred to as the 9 Percent RFP Plan. The plan was to be submitted by November 15, 1994 and the reductions are required to be achieved by November 15, 1999. The Act also sets limitations on the creditability of certain types of reductions.

The target emission reductions were calculated in accordance with EPA guidance. The reader is referred to ''Guidance On The Post 1996 Rate of Progress Plan and the Attainment Demonstration,'' (EPA–452/R–93–015).

Section 182(c)(2)(C) of the Act allows NO_X reductions to be substituted for VOC reductions for RFP demonstrations provided states demonstrate through modeling that NO_X reductions are needed in the nonattainment area. New York has shown that NO_X reductions will contribute toward attaining the ozone standard (See section IV. A., Modeling discussion below). New York has demonstrated that every ton of NO_X is equivalent to approximately 1.2 tons of VOC in the New York Metropolitan Area on percent of total inventory basis. Table 3B includes columns showing the VOC and NO_X reductions that will result from the implementation of the control measures.

TABLE 3B.—SUMMARY OF NEW YORK'S 9 PERCENT RFP PLAN

	New York metropolitan area (tons/day)	
	VOC [2]	NO_X [2]
Required VOC reductions needed to meet 9 Percent Plan	130.76	.....

TABLE 3B.—SUMMARY OF NEW YORK'S 9 PERCENT RFP PLAN—Continued

	New York metropolitan area (tons/day)	
	VOC [2]	NO_X [2]
Creditable Reductions—1996 Surplus	5.11	
Mobile source control measures:		
Non-Road:		
Reformulated gasoline and New Engine Standards	9	5
On-Road:		
Reformulated gasoline	4	3.9
Tier I—New Vehicle Program	20.3	43.4
Low Emission Vehicle	3.2	7.4
Enhanced Inspection & Maintenance July 1999 Emission Reduction Using Phase-in Cutpoints		22.2
Full Inspection Cycle Completed in November 1999		15.3
Stationary source control measures:		
Parts 212, 228, 229—VOC RACT	0.32	
MACT (Federal Measures)	3.19	
OTC Phase II Baseline (Part 227–3)		135.65
Part 227–2		6.89
Area source control measures:		
Consumer Products	0.1	
Hospital Sterilizers	0.1	
Municipal Solid Waste Landfills	4.9	
Surface Cleaning	18.3	
Total reductions	68.52	[3] 239.74
VOC Shortfall	62.24	
VOC and NO_X Equivalent Surplus	75.44	[4] 62.87
Reductions not credited in today's action—Capped/Shutdown Emissions	0.15	2.95

[2] VOC emission reductions claimed occur from 1997 through 1999. NO_X emission reductions claimed occur from 1990 through 1999.
[3] Of the available 239.74 tpd NO_X emissions reductions credits, 125 tpd are used to meet the growth in NO_X emissions and 51.87 tpd to cover the VOC shortfall (51.87 tpd of NO_X is equivalent to 62.24 tpd VOC), 62.87 tpd NO_X are surplus.
[4] 62.87 tons/day of NO_X surplus converts to 75.44 tons/day of VOC equivalent in the New York Metropolitan Area.

Measures Achieving the Projected Reductions. New York has provided a plan to achieve the reductions required for the New York Metropolitan Area. The following is a concise description of each control measure New York used to achieve the emission reduction credit within its 9 Percent RFP Plan. All of the State's measures used in the 9 Percent RFP Plan have been adopted and submitted as SIP revisions. EPA has previously approved most of the control measures, including interim approval of the enhanced vehicle I/M program.

Mobile Source Measures: New Engine Standard. This is the same measure as contained in New York's 15 Percent ROP Plan except New York's 9 Percent RFP Plan is only taking the additional VOC credit that would be generated for the years 1997–1999 and utilizing the substitution of the NO_X emission reduction credits generated for the years 1990–1999. EPA agrees with the calculated emission reductions associated with the New Engine Standard.

Reformulated Gasoline. This is the same measure as contained in New York's 15 Percent ROP Plan except New York's 9 Percent RFP Plan is only utilizing the substitution of the NO_X emission reduction credits generated for the years 1990–1999. EPA agrees with the calculated emission reductions associated with reformulated gasoline.

Enhanced Inspection and Maintenance. This is the same measure as contained in New York's 15 Percent ROP Plan except New York's 9 Percent RFP Plan is utilizing the substitution of the NO_X emission reduction credits generated for the years 1990–1999. See above discussion for EPA's action on New York's enhanced I/M emission credits for the 9 Percent RFP Plan.

Low Emissions Vehicle Program. This is the same measure as contained in New York's 15 Percent ROP Plan except New York's 9 Percent RFP Plan is utilizing the substitution of the NO_X emission reduction credits generated for the years 1990–1999. EPA agrees with the calculated emission reductions associated with New York's low emission vehicle program.

Stationary Source Control Measures. Parts 212, 228, 229—VOC RACT. This is the same measure as contained in New York's 15 Percent ROP Plan except New York's 9 Percent RFP Plan is only taking the additional VOC credit that would be generated for the years 1997–1999. EPA agrees with the calculated emission reductions associated with these VOC RACT measures.

OTC Phase II Baseline (Part 227–3)—NO_X MOU/NO_X RACT. On January 12, 1999, New York adopted revisions to Part 227–3 ''Pre 2003 Nitrogen Oxides Emissions Budget and Allocation Program,'' which incorporate the NO_X MOU requirements. The OTC NO_X MOU calls for states to reduce NO_X emissions from boilers and indirect heat exchangers with heat inputs greater than 250 million BTU per hour. These emission reductions will be realized in two phases, first in 1999 and again in 2003. Part 227–3 became effective on March 5, 1999 and sources are required to be in compliance with the first phase by May 1, 1999. On April 29, 1999, NYSDEC submitted to EPA a SIP revision which included the revisions to Part 227–3. EPA will be acting on the April submittal in the near future. EPA agrees with the calculated emission reductions associated with this NO_X RACT measure, however, only the first phase of reductions will be creditable towards New York's 9 Percent RFP Plan.

Part 227–2—NO_X RACT. On January 19, 1994 and January 27, 1999, New York adopted revisions to Part 227–2, ''Stationary Combustion Installations'' to comply with the Act provisions to implement NO_X RACT. On April 29, 1999, NYSDEC submitted to EPA a SIP

revision which included the revisions to Part 227–2. Subpart 227–2 requires the following major source of NO_X to achieve RACT by May 31, 1995: (1) very large boilers (>250 mmBTU/hr); (2) large boilers (>100–250 mmBTU/hr); (3) Mid-size boilers (>50–100 mmBTU/hr); (4) small boilers (<50 mmBTU/hr); (5) combustion turbines; (6) stationary internal combustion engines; (7) other combustion sources (not specifically covered under separate New York regulations). EPA will be acting on the April submittal in the near future. EPA agrees with the calculated emission reductions associated with this NO_X RACT measure.

MACT (Federal Measures). For the 1999 projected emissions reductions, VOC emissions reductions from specific source categories were adjusted according to RACT (promulgated New York regulations discussed previously) and Maximum Achievable Control Technology (MACT—promulgated federal regulations regarding National Emission Standards for Hazardous Air Pollutants). In most cases there was a New York rule in place and RACT was applied. Where MACT was in effect and it was more stringent than RACT, it took the place of RACT. In order for RACT or MACT to have been creditable, it had to have a compliance date prior to November 15 of the projection year (*i.e.*, 1999 for creditable reductions towards the 9 Percent RFP plan). New York took credit for the following MACT standards in the 9 Percent RFP plan:

(1) 40 CFR 63.190 subpart I—Organic Hazardous Air Pollutants for Certain Processes Subject to the Negotiated Regulation for Equipment Leaks (59 FR 19402).

(2) 40 CFR 63.1310 subpart JJJ—Standards for Group IV Polymer and Resins (61 FR 48208).

(3) 40 CFR 63.100 subpart F—Organic Hazardous Air Pollutants From the Synthetic Organic Chemical Manufacturing Industry (59 FR 19402).

(4) 40 CFR 63.460 subpart T—Halogenated Solvent Cleaning (59 FR 61801).

(5) 40 CFR 63.640 subpart CC—Petroleum Refineries (60 FR 43244).

(6) 40 CFR 63.820 subpart KK—Standards for the Printing and Publishing Industry (61 FR 27131).

(7) 40 CFR 63.420 subpart R: Gasoline Distribution (59 FR 64303).

EPA agrees with the calculated emission reductions associated with the federal MACT standards.

Area Source Control Measures: Consumer Products. This is the same measure as contained in New York's 15 Percent ROP Plan except New York's 9 Percent RFP Plan is only taking the additional VOC credit that would be generated for the years 1997–1999. EPA agrees with the calculated emission reductions associated with consumer products.

Hospital Sterilizers. For 1999 the New York Metropolitan Area will be affected by the federal MACT for ethylene oxide sterilizers. The MACT requires all ethylene oxide sterilizers to be permitted. This permit requirement subsequently subjects them to the control requirements of Part 212, ''General Process Emission Sources''. EPA agrees with the calculated emission reductions associated with hospital sterilizers.

Municipal Solid Waste Landfills. For 1999, federally adopted New Source Performance Standards and a New York State adopted regulation for Municipal Solid Waste Landfills will be in effect for certain new and existing landfills respectively in the New York Metropolitan Area. On March 12, 1996 (61 FR 9919), the EPA promulgated in the **Federal Register** standards of performance for new sources for municipal solid waste landfills and emission guidelines for existing municipal solid waste landfills. These regulations and guidelines were promulgated as subparts WWW and Cc of 40 CFR part 60. On September 22, 1998, New York adopted revisions to Part 360.2 ''Landfills'', which became effective on November 21, 1998. These revisions make enforceable the requirements as outlined in EPA's emission guidelines. On July 19, 1999 (64 FR 38582), EPA published a final notice approving the revisions to Part 360.2. EPA agrees with the calculated emission reductions associated with the Municipal Solid Waste Landfills.

Surface Cleaning. For 1999, facilities located in the New York Metropolitan Area will be subject to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for halogenated solvent cleaning (NESHAP—40 CFR 63.460, subpart T). Subpart T applies to facilities that use any of the following halogenated hazardous air pollutant solvents, which have also been identified as VOC's: (1) trichloethylene (TCE); (2) carbon tetrachloride (CT); and (3) chloroform (C). EPA agrees with the calculated emission reductions associated with surface cleaning.

Measures Not Creditable in Today's Action. Capped/shutdown emissions. As discussed under the 15 Percent ROP Plan section, because of the uncertainties associated with both capped and shutdown emissions, EPA is considering these emissions reductions to be noncreditable at this time with respect to New York's Phase I Ozone SIP.

9 Percent RFP Plan Evaluation. New York has identified the control measures necessary for achieving the required emission reductions and all the measures have been adopted and implemented. EPA is proposing to find that the 9 Percent RFP Plan contains the necessary measures as identified in Table 3B to achieve the required emission reductions. EPA proposes to approve emission credits for the 9 Percent RFP Plan, pending EPA's verification of New York's enhanced I/M program's effectiveness. However, as discussed under the 15 Percent ROP Plan section, if EPA determines New York's enhanced I/M program effectiveness demonstration indicates a shortfall in emission reductions compared to the emission reductions credited in the 9 Percent RFP Plan, EPA will propose to disapprove the 9 Percent RFP Plan. EPA final action will be based on EPA's evaluation of New York's demonstration of the enhanced I/M program's effectiveness.

IV. What Other Phase I Required Elements Has New York Satisfied in Their Submittal?

New York's submittal is intended to fulfill EPA's Phase I requirements (''Ozone Attainment Demonstrations,'' March 2, 1995 memo from Mary Nichols) and in addition to the previously mentioned SIP elements, includes the following Phase I required elements: modeling efforts completed to date; Ozone Transport Commission NO_X MOU; enforceable commitments for Phase II; clean fuel fleet program; analysis of growth in emissions due to increases in VMT; and photochemical assessment monitoring stations network.

A. What Modeling Work Was Submitted by New York?

As part of New York's initial submittal of the 15 and 9 percent plans, New York submitted a preliminary modeling analysis using assumptions about transported ozone and precursors, as required by the March 2, 1995 memo.

Photochemical grid modeling is used to support New York's submittal in two ways: first, meet the requirements set out in EPA's March 2, 1995 memo for a preliminary modeling analysis and to support the State's ability to use reductions in VOC and NO_X emissions as part of its ROP and RFP Plans.

The modeling predicts that ozone will be reduced if emissions of VOC or of NO_X are reduced. This is based on modeling the impact of proportionally reducing emissions of VOC and NO_X together and separately and showing

that the peak ozone concentration is reduced. Thus, emissions of either VOC and NO_X can be reduced to improve ozone air quality in New York and either can be used in the 15 Percent ROP and 9 Percent RFP Plans to the extent allowed in the Act.

New York has since submitted additional modeling analyses as part of their Phase II Ozone Attainment Plan. EPA will act on the Phase II Ozone Attainment Plan in a separate **Federal Register** notice.

EPA is proposing to accept New York's modeling efforts as fulfilling EPA's Phase I requirements.

B. Did New York Satisfy the Ozone Transport Commission NO_X MOU Requirement?

EPA is proposing that New York has satisfied EPA's Phase I requirement for NO_X Memorandum of Understanding (MOU). In September 1994, the Ozone Transport Commission agreed to develop a regional program to achieve significant reduction in NO_X emissions from large combustion sources. On September 27, 1994, New York signed the MOU which formalized this program. EPA's March 2, 1995 policy requires states to provide an enforceable commitment to implement the NO_XMOU, which New York did in a June 15, 1995 letter to EPA. On January 12, 1999, New York adopted revisions to Part 227–3 ''Pre 2003 Nitrogen Oxides Emissions Budget and Allocation Program,'' which incorporate the NO_X MOU requirements. Part 227–3 became effective on March 5, 1999. On April 29, 1999, NYSDEC submitted to EPA a SIP revision which included the revisions to Part 227–3. EPA will be acting on the April submittal in the near future.

C. What Commitments to Future Actions Were Included in New York's Submittal?

As part of New York's submittal of the Phase I SIP revision, New York made commitments to the following EPA March 2, 1995 policy requirements: (1) participate in the consultative process to address regional transport; (2) adopt additional control measures as necessary to attain the ozone standard, meet rate of progress requirements, and eliminate significant contribution to nonattainment downwind; and (3) identify any reductions that are needed from upwind areas for the area to meet the ozone standard.

New York has since submitted a Phase II Ozone Attainment Plan which address the commitments made in their Phase I plan. EPA is proposing to accept the commitments made by New York as satisfying EPA's Phase I requirements and will act on these elements in conjunction with Phase II in the near future.

D. Has New York Satisfied the Phase I Clean Fuel Fleet Requirement?

With regards to fulfilling EPA's Clean Fuel Fleet Program (CFFP) Phase I requirement (''Ozone Attainment Demonstrations,'' March 2, 1995 memo from Mary Nichols), New York has done so by adopting and submitting to EPA a LEV program to be used as a substitute measure for CFFP.

Section 182(c)(4) of the Act requires that serious or above ozone and carbon monoxide nonattainment areas implement a CFFP. The Federal CFFP requires that light and heavy duty fleets of ten or more vehicles in the covered areas assure that a percentage of their annual new vehicle purchases be clean fueled vehicles. The Act also allows states to opt out of the CFFP with a substitute program or programs which achieve equivalent long term emission reductions. On January 6, 1995 (60 FR 2022) EPA approved New York's opt out of the light duty CFFP with its LEV program. The LEV program will cover all the vehicles in the New York Metropolitan Area (as well as the rest of New York State), of which the light duty vehicles covered by the CFFP would be only a subset. Since that time New York has proposed to also opt out of the heavy duty portion of the CFFP with the LEV program. New York is confident that the LEV program will generate enough long term emission reduction credits to be used as a substitute measure for the heavy duty CFFP as well and still have surplus credit left over from the far reaching LEV program. EPA will be acting on the heavy duty CFFP opt-out in a separate **Federal Register** notice. New York is taking credit for the LEV program in the 1996 and 1999 ROP plans and no credit is being assigned to the CFFP program in these plans (*i.e.*, there is no ''double counting'' of credits). EPA agrees with this treatment of the LEV program. With respect to New York's use of LEV as a substitute for the CFFP, equivalency is measured in the long term, *i.e.* by the year 2010, therefore its use in that capacity will have no bearing on the State's 1996 and 1999 ROP plans.

E. Does New York Need To Offset Growth in Emissions From Growth in VMT?

New York has indicated in its Phase I SIP submittal, that it will not need to offset growth in emissions from growth in VMT until at least the year 2007, the year New York is required to demonstrate attainment. New York has also chosen to comply with the Act's RFP milestone and attainment requirements using measures other than Transportation Control Measures (TCMs).

Section 182(d)(1)(A) of the Act requires states containing ozone nonattainment areas classified as ''severe'' under section 181(a) of the Act to adopt TCMs in order to offset growth in emissions from growth in VMT, and to attain reductions in motor vehicle emissions as necessary to comply with the Act's RFP milestone and attainment requirements.

Because current modeling does not indicate a need for TCMs to offset a growth in emissions before 2007, EPA is proposing to approve the part of the ozone SIP that determines that New York is not required to adopt specific, enforceable TCMs to meet the TCM offset requirement. EPA is also proposing to approve the states decision to comply with the RFP milestone and attainment requirements using measures other than TCMs.

F. Has New York Submitted an Approvable Photochemical Assessment Monitoring Station Network?

NYSDEC submitted its photochemical assessment monitoring station network (PAMS) Network Plan which was reviewed and found approvable on September 21, 1998 by EPA and was judged to satisfy the requirements of 40 CFR 58.40(a).

Section 182(c)(1) of the Act and the General Preamble (57 FR 13515) require that EPA promulgate rules for enhanced monitoring of ozone, NO_X and VOCs (see 58 FR 8452, February 12, 1993) and that states classified serious and above develop and operate a PAMS. NYSDEC has been establishing its PAMS network according to its approved Work Plan and implementation schedule. The two PAMS sites approved by EPA, one in the Bronx and the other in Queens, have been operating since 1994 and 1997, respectively. EPA is proposing to approve New York's PAMS network.

V. Are New York's Transportation Conformity Budgets Approvable?

By virtue of proposing approval of the 15 Percent ROP Plan and 9 Percent RFP Plan, EPA is also proposing approval of the motor vehicle conformity emissions budgets for VOC and NO_X. For the 1999 analysis year and later, conformity determinations addressing VOC and NO_X must demonstrate consistency with the 9 Percent RFP Plan revision's VOC and NO_X motor vehicle emissions budget. Table 4 summarizes New York's Emission Budgets.

TABLE 4.—EMISSION BUDGETS FOR CONFORMITY

County	1996		1999	
	VOC tons/day	tons/ dayNO_X	VOC tons/day	NO_X tons/day
Bronx	22.2	23.6	18.0	20.6
Kings	36.5	31.8	29.7	27.6
Nassau	71.0	69.2	60.0	61.4
New York	35.1	21.0	27.9	18.5
Orange (LOCMA)	5.1	9.2	4.9	8.7
Queens	47.9	44.4	39.0	38.8
Richmond	13.0	13.1	11.1	11.9
Rockland	16.9	20.5	14.3	18.4
Suffolk	62.3	75.7	53.6	68.0
Westchester	43.1	54.5	36.1	48.7
Total	353.2	362.8	294.7	322.6

EPA is proposing to approve New York's emission budgets.

VI. What Are EPA's Phase I Findings?

On July 3, 1996, EPA notified the Governor of New York that EPA was making a finding of failure to submit all the Act elements required to fulfill the March 2, 1995 ''Ozone Attainment Demonstration'' policy as committed to by New York. With New York's submittals of September 4, 1997 and February 2, 1999 (Phase I SIP revision), and December 19, 1997 (Clean Fuel Fleets Program SIP revision), New York has now submitted all the Phase I requirements.

VII. What Are EPA's Conclusions?

EPA has evaluated these submittals for consistency with the Act, applicable EPA regulations, and EPA policy. EPA is proposing approval of New York's: revisions to the 1990 base year ozone emission inventory (for all ozone nonattainment areas in New York); the 1996 and 1999 ozone projection emission inventories; photochemical assessment monitoring station network; demonstration that emissions from growth in vehicle miles traveled will not increase motor vehicle emissions; modeling efforts completed to date; transportation conformity budget; and enforceable commitments for Phase II. EPA is also proposing to approve emission credits for the 15 Percent ROP and 9 Percent RFP Plans, pending EPA's verification of New York's enhanced I/M program's effectiveness. If EPA determines New York's enhanced I/M program effectiveness demonstration indicates a shortfall in emission reductions compared to the emission reductions credited 15 Percent ROP and/or 9 Percent RFP Plans, EPA will propose to disapprove the 15 Percent ROP and/or 9 Percent RFP Plans. EPA final action will be based on EPA's evaluation of New York's demonstration of the enhanced I/M program's effectiveness.

VIII. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order (E.O.) 12866, entitled ''Regulatory Planning and Review.''

B. Executive Orders on Federalism

Under Executive Order 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a state, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 12875 requires EPA to provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected state, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of state, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create a mandate on state, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

On August 4, 1999, President Clinton issued a new executive order on federalism, Executive Order 13132, [64 FR 43255 (August 10, 1999),] which will take effect on November 2, 1999. In the interim, the current Executive Order 12612, [52 FR 41685 (October 30, 1987),] on federalism still applies. This rule will not have a substantial direct effect on states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 12612. The rule affects only one state, and does not alter the relationship or the distribution of power and responsibilities established in the Act.

C. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

EPA interprets E.O. 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This proposed SIP approval is not subject to E.O. 13045 because it proposes approval of a state program implementing a Federal standard, and it is not economically significant under E.O. 12866.

D. Executive Order 13084

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If EPA the mandate is unfunded, EPA must provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) 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. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This proposed rule will not have a significant impact on a substantial number of small entities because SIP approvals under section 110 and subchapter I, part D of the Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not create any new requirements, EPA certifies that this action will not have a significant economic impact on a substantial number of small entities. Moreover, due to the nature of the Federal-State relationship under the Act, preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.,* versus *U.S. EPA,* 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

F. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a federal mandate that may result in estimated annual costs to state, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the proposed approval action does not include a federal mandate that may result in estimated annual costs of $100 million or more to either state, local, or tribal governments in the aggregate, or to the private sector. This federal action approves pre-existing requirements under state or local law, and imposes no new requirements. Accordingly, no additional costs to state, local, or tribal governments, or to the private sector, result from this action.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

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

DatedD: October 21, 1999.

William J. Muszynski,

Acting Regional Administrator, Region 2.

[FR Doc. 99–28725 Filed 11–2–99; 8:15 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[MD054–3044b; FRL–6456–7]

Approval and Promulgation of State Air Quality Plans for Designated Facilities and Pollutants; Maryland; Proposed Revision to Section 111(d) Plan Controlling Total Reduced Sulfur Emissions From Existing Kraft Pulp Mills

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve a revision to Maryland's Section 111(d) plan for the purpose of controlling total reduced sulfur (TRS) emissions from existing kraft pulp mills. In the final rules section of the **Federal Register**, EPA is approving this plan revision. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated in relation to this rule. If EPA receives relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

DATES: Comments must be received in writing by December 3, 1999.

ADDRESSES: Comments may be mailed to Harold A. Frankford, Office of Air Programs, Mail Code 3AP20, Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the documents relevant to this action are available for public inspection during normal business hours at the following locations: Air Protection Division, Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; and the Maryland Department of the Environment, 2500 Broening Highway, Baltimore, Maryland, 21224.

FOR FURTHER INFORMATION CONTACT: Harold A. Frankford (215) 814–2108, or by e-mail at frankford.harold@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: See the information provided in the direct final rule which is located in the Rules and Regulations section of the **Federal Register**.

Dated: September 30, 1999.

Thomas Voltaggio,

Acting Regional Administrator, EPA Region III.

[FR Doc. 99–26852 Filed 11–2–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 63 and 68

[FRL–6466–5]

Approval and Promulgation of State Program Delegation; Ohio

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing approval of the State of Ohio's request for delegation of the Accidental Release Prevention Program under section 112(r)(7) of the Clean Air Act.

In the final rules section of this **Federal Register**, EPA is approving the State's request for delegation as a direct final rule without prior proposal because EPA views this action as noncontroversial and anticipates no adverse comments. A detailed rationale for approving the State's request is set forth in the direct final rule. The direct final rule will become effective without further notice unless EPA receives relevant adverse written comment. Should EPA receive such comment, we will publish a timely withdrawal informing the public that the direct final rule will not take effect and such public comment received will be addressed in a subsequent final rule based on the proposed rule. If no adverse written comments are received, the direct final rule will take effect on the date stated in that document, and no further action will be taken.

EPA does not plan to institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

DATES: Written comments must be received on or before December 3, 1999.

ADDRESSES: Written comments may be mailed to Mark J. Horwitz, Chief, Office of Chemical Emergency Preparedness and Prevention, Superfund Division (SC–6J), Region 5, at the address listed below.

Copies of the materials submitted by the Ohio Environmental Protection Agency may be examined during normal business hours at the following location: Office of Chemical Emergency Preparedness and Prevention, Superfund Division (SC–6J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois, 60604.

FOR FURTHER INFORMATION CONTACT: Bob Mayhugh, Environmental Protection Specialist, Office of Chemical Emergency Preparedness and Prevention, Superfund Division(SC–6J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, 312–886–5929.

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule published in the final rules section of this **Federal Register**.

Dated: October 21, 1999.

David A. Ullrich,

Acting Regional Administrator, Region 5.

[FR Doc. 99–28312 Filed 11–2–99; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 20, and 43

[CC Docket No. 99–301, FCC 99–283]

Local Competition and Broadband Reporting

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: In this document, the Federal Communications Commission proposes to collect basic information about the status of local telephone service competition and the deployment of advanced telecommunications capability, also known as broadband. The Commission seeks comment on all aspects of the proposal, including how it can best structure such a program to satisfy its needs without overburdening those entities that would be required to file.

DATES: Comments are due on or before December 3, 1999. Reply comments are due on or before December 20, 1999. Written comments by the public on the proposed information collections are due on or before December 3, 1999. Written comments must be submitted by the Office of Management and Budget (OMB) on the proposed and/or modified information collections on or before January 3, 2000.

ADDRESSES: Comments and reply comments should be sent to the Office of the Secretary, Federal Communications Commission, 445 12th Street, SW, Washington, DC 20554, with a copy to Ms. Terry Conway of the Common Carrier Bureau, Federal Communications Commission, 445 12th Street, SW, 6A–100, Washington, DC 20554. Parties should also file one copy of any documents filed in this docket with the Commission's copy contractor, International Transcription Services, Inc. (ITS), 1231 20th Street, NW, Washington, DC 20037. Parties may file electronically through the Internet at <http://www.fcc.gov/e-file/ecfs.html>. 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, Room 1–C804, 445 12th Street, SW, Washington, DC 20554, or via the Internet to jboley@fcc.gov, and to Virginia Huth, OMB Desk Officer, 10236 NEOB, 725—17th Street, NW, Washington, DC 20503 or via the Internet to VHuth@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT: Dr. Ellen Burton, Industry Analysis Division, Common Carrier Bureau, at (202) 418–0958, or Thomas Beers, Deputy Chief of the Industry Analysis Division, Common Carrier Bureau, at (202) 418–0952. For additional information concerning the information collections contained in the Notice of Proposed Rulemaking (NPRM) contact Judy Boley at 202–418–0214, or via the Internet at jboley@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rulemaking (NPRM) released October 22, 1999 (FCC 99–283). The full text of the NPRM is available for inspection and copying during normal business hours in the FCC Reference Center, Room CY–A257, 445 12th Street, SW, Washington, DC 20554. The complete text also may be purchased from the Commission's copy contractor, International Transcription Services, Inc. (202) 857–3800, 1231 20th Street, NW, Washington, DC 20037. Additionally, the complete item is available on the Commission's website at <http://www.fcc.gov/Bureaus/Common_Carrier/Notices/1999/>.

Paperwork Reduction Act

The NPRM summarized here contains either a proposed or modified information collection. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collection contained in the NPRM, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. Public and agency comments are due at the same time as other comments on the NPRM; OMB notification of action is due 60 days from date of publication of this NPRM 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.

OMB Approval Number: 3060–0816.

Title: ''Local Competition and Broadband Reporting, CC Docket No. 99–301.''

Form Number: FCC Form 477.

Type of Review: Revision of Existing Collection.

Respondents: Business or Not-for-profit institutions, including small businesses.

Burden Estimate:

	Number of respondents	Estimated time per response	Total annual burden
(1) Local Competition and Broadband Reporting:			
(a) Entities completing entire data collection except section VI	Up to 75	120–576	Up to 19,144.
(b) Entities completing only section VI	Up to 70	32–236	Up to 4,792.

Total Annual Burden: Up to 23,936 person-hours.

Estimated Costs per Respondent: $0.00.

Needs and Uses: The information collection for which approval is sought would be used by the Commission to gather information on the state of the development of local competition and broadband deployment. Without such information, the Commission faces significant difficulty in assessing the development of these markets and, therefore, is less able to fulfill its statutory responsibilities in accordance with the Communications Act of 1934, as amended.

Summary of the Notice of Proposed Rulemaking

1. In the NPRM summarized here, we propose to collect basic information about the status of local telephone service competition and the deployment of advanced telecommunications capability, also known as broadband. We tentatively concludes that we need timely and reliable information about the pace and extent of developing local competition in different geographic areas in order to evaluate the effectiveness of actions that this Commission and the states are taking to promote local competition. We also tentatively conclude that we need timely and reliable information to assess the deployment of broadband services, as required by section 706 of the Telecommunications Act of 1996.

2. Moreover, we tentatively conclude that this information would allow us to avoid ''one size fits all'' regulation, and, specifically, to reduce regulation wherever we can pursuant to new sections 10 and 11 of the Act. 47 U.S.C. 160, 161. The Commission proposes a simple filing that should enable it to make better informed decisions, while placing as low a burden as possible on reporting entities. A proposed data collection form is attached to the NPRM as Attachment A. Currently, the Commission does not gather data of the type requested under this proposed program.

3. Throughout the NPRM, we seek comment on all of the tentative conclusions we reach. We also encourage commenters to propose alternative means of collecting the needed information. The following text represents a brief summary of issues set out for discussion and comment in the NPRM.

4. *Types of Entities that Must Report:* In the NPRM, we discuss the types of entities that should be required to report data describing the extent and intensity of local competition and the extent of broadband services deployment. Based on our determination that we need comprehensive data about developing local services competition, we tentatively conclude that large and medium incumbent local exchange carriers (LECs)—as well as their wireline and fixed wireless telephony competitors, and also their mobile wireless telephony potential competitors—should complete sections I–III of the survey if the reporting entity is a wireline or fixed wireless LEC and section VI if the entity is a mobile wireless telephony carrier. Consistent with our need for comprehensive local competition information, we tentatively conclude that the obligation to complete the survey should not depend on the type of technology that an incumbent LEC or competitive LEC uses to provide local service. We tentatively conclude that we should require carriers with 50,000 or more local access lines or channels (of any capacity) nationwide, or 50,000 or more subscribers nationwide to file information pursuant to this program. Further, we propose to collect information about certain mobile wireless services because of their potential to become substitutes for wireline service. Thus, we propose to require any carrier who provides mobile telephony (defined here as, real time, two-way switched voice service that is interconnected with the public switched network utilizing an in-network switching facility that enables the provider to reuse frequencies and accomplish seamless handoffs of subscriber calls) to report if such an entity has more than 50,000 subscribers nationwide. We note that providers of mobile telephony services may include facilities-based providers of cellular, broadband personal communications service (PCS), specialized mobile radio services (SMR), as well as providers using satellite technology. We ask commenters to address whether the 50,000 nationwide access line/subscribers threshold that we propose is sufficient to provide the information that the Commission needs, while not burdening smaller entities.

5. We next turn to a consideration of those entities that should report data on deployment of broadband services. The Notice tentatively concludes that given our broad statutory mandate under section 706 of the Telecommunications Act of 1996, to evaluate the deployment of broadband services, regardless of the transmission media or technology employed, the survey should include questions about the deployment of what we term ''full broadband'' services. For purposes of the proposed data collection, ''full broadband'' service is defined, consistent with the *Advanced Telecommunications Report,* as having an information carrying capacity of over 200 Kilobits per second (Kbps) in each direction, simultaneously. *An Inquiry Concerning the Deployment of Advanced Telecommunications Capabilities to All Americans in a Reasonable and Timely Fashion,* 14 FCC 2d 2398, paragraphs 20–25 (*Advanced Telecommunications Report*). The Notice recognizes, however, that entities may provide services with bandwidth that exceeds voice grade (*i.e.* 48 Kbps) but is less than 200 Kbps, and seeks

comment on the extent to which the Commission should consider services deployed in this range of bandwidth in assessing the progress of broadband deployment. Actual or potential providers of broadband services may include: LECs (incumbent and competitive, both resale and facilities-based, regardless of the technology used), cable television companies, utilities, MMDS/MDS/''wireless cable'' carriers, mobile wireless carriers (both terrestrial and satellite-based), fixed wireless providers, and others. We believe that only by casting our net wide enough to include all such entities can we discern progress, or the lack of it, in meeting the goals stated in the *Advanced Telecommunications Report.* We also tentatively conclude, that any entity that provides at least 1,000 full broadband service lines (or wireless channels), or has at least 1,000 full broadband subscribers, should be required to complete all relevant parts of the survey, regardless of whether that entity meets the criterion for reporting local competition data (*i.e.*, at least 50,000 nationwide local access lines or telephony subscribers). Therefore, it is possible, for example, that a LEC with fewer than 50,000 local access lines in service could have 1,000 or more full broadband lines in service, in which case that LEC would complete both the sections of the survey related to broadband services and the sections concerning local competition.

6. *Frequency of Reports:* We also ask commenters to address the frequency with which the Commission should gather the information sought by this proposed program. The majority of commenters to our *Local Competition Public Notice* proceeding concluded that for the program to be effective, the information should be collected quarterly. *Public Notice*, 63 FR 29409, CC Docket No. 91–141, DA 98–839, 13 FCC Rcd 9279 (May 28, 1998). We ask for comment on whether quarterly, semi-annual or annual reporting would best serve the goals of this information collection program.

7. *Exempting Smaller Entities:* We want to explore whether we can totally exempt some carriers from reporting without materially affecting our ability to effectively assess the development of local competition. Thus, we again ask commenters to address the desirability of the proposed threshold levels for local competition and broadband reporting. With regard to cable companies providing local exchange telephony, we seek comment on how best to measure the threshold for complying with our proposed reporting requirement.

8. With respect to broadband, we tentatively conclude that we should establish a more comprehensive reporting requirement for providers of broadband services. We promised in the *Advanced Telecommunications Report* to keep a close watch on deployment of broadband services to rural and other insular groups. Thus, to ensure that we do not miss broadband deployment by smaller entities, we seek comment on whether our threshold of 1,000 customers will allow us to accurately gauge its deployment, particularly to rural America.

9. Finally, we seek comment on whether, to reduce reporting burdens even further, we should allow an incumbent LEC *of any size* to file a brief letter in lieu of reporting local competition and broadband deployment data for states where that incumbent faces no local service competition and if it provides a *de minimis* number of broadband lines. We tentatively conclude that such an approach would reduce reporting burdens imposed on carriers without compromising our ability to get necessary information.

10. *Definition of Reporting Area:* To minimize the burden the reporting requirement places on reporting entities, we tentatively conclude that information should be reported by state. The Commission recognizes that collecting information about competitive activity and broadband services deployment in smaller geographic areas *might* yield sharper pictures of the extent and intensity of these developments. At the same time, we recognize that companies may regard such information as confidential, and we seek comment on whether a requirement that they disclose such information is appropriate to the extent such confidentiality concerns exist. Therefore, we seek comment on whether a level more narrowly defined than state level would be appropriate.

11. *Confidentiality of Data:* We think it extremely important that *all* local competition and broadband information collected pursuant to the proposed survey be made available to the public. Public availability will assist Commission staff in interpreting and utilizing such data, and it will facilitate Commission publication of data and analysis in Commission reports. Notwithstanding our belief that submitted information will not ordinarily raise legitimate protection issues, we cannot prevent parties submitting data from asserting confidentiality or other claims and seeking protection from public release. We, of course, expect such parties to follow Commission rules and guidelines when seeking protection pursuant, primarily, to relevant sections of the Freedom of Information Act. We seek comment on our tentative conclusions regarding the confidentiality of the type of information to be gathered.

12. *Electronic Filing:* Because we seek to ensure that the filing requirement does not impose undue burdens on those entities that must complete the form and to allow the staff of the Commission to more efficiently analyze the data, we tentatively conclude that data should be submitted in spreadsheet form, utilizing Excel format. Additionally, we propose that filers make their submissions to an e-mail address over the Internet. We ask commenters about the desirability of such an e-mail/spreadsheet-based electronic filing system, as well as other electronic filing systems.

13. *Survey Modification and Termination:* We expect the local services and broadband services markets will become increasingly dynamic as competition develops. Therefore, it may be necessary to make changes to the form, content, or reporting obligations of this information collection to ensure its continuing value, while minimizing filing burdens on respondents. Finally, to ensure that the program does not outlive its usefulness, we ask commenters whether it would be best to ''sunset'' this program, or perhaps to require a regular review process.

14. *Data to be Reported:* We describe and seek comment on, in the NPRM, the specific items set out in the proposed data collection form. A brief description of the proposed data collection form follows, with greater detail found in the complete NPRM.

15. Section I of the survey collects information about: (1) The number of voice grade and equivalent wireline or fixed wireless lines/channels in service that connect residential and, separately, non-residential end users to the public switched telephone network (for convenience, ''voice grade lines''); and (2) the extent to which LECs use their own facilities, and the facilities or services of other LECs, in providing these lines.

16. Section II of the survey collects information about numbers of voice grade lines served from LEC switching centers, as defined in Attachment A of the NPRM, in which local service competitors have operational collocation arrangements.

17. Section III of the survey collects information from LECs about the number of high capacity lines or channels in service connecting end users to the public switched network (for convenience, ''high-capacity lines'').

High capacity lines are defined as lines with information carrying capacity capability to the customer's premises in excess of 200 Kbps in at least one direction, and at least 48 Kbps (*i.e.*, voice grade) in the other direction.

18. Providers of mobile telephony services (including mobile telephony affiliates of LECs) would not report data in sections I, II or III, but would instead report data on number of subscribers to voice grade mobile telephony service in section VI.

19. Sections IV and V of the survey collect information about the number of broadband lines in service to consumers. This includes information about both ''full broadband'' lines, with information carrying capacity in excess of 200 Kbps in both directions, simultaneously, and asymmetric ''one way broadband'' lines, with information carrying capacity in excess of 200 Kbps in one direction but not both. Section IV collects information about broadband lines in service to all customers, and section V collects information about broadband lines in service to residential customers. From the total and residential information, we will be able to derive information about broadband deployment to all other customers, such as business, government, and institutional customers.

20. The Notice seeks comment on whether answers to the survey questions are necessary and sufficient to describe and understand the state of local competition and deployment of broadband services in diverse areas of the nation.

Procedural Matters

A. Initial Paperwork Reduction Act of 1995 Analysis

21. The NPRM summarized here contains a proposed or modified information collection. As part of its 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 the NPRM, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. Public and agency comments are due at the same time as other comments on the NPRM; OMB comments are due 60 days from the date of the publication of this summary of the NPRM 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 collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

B. Initial Regulatory Flexibility Act

22. As required by the Regulatory Flexibility Act (RFA), the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities of the policies and rules proposed in the NPRM. A copy of the IRFA is attached to this summary. 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 and they must have a separate and distinct heading, designating the comments as responses to the IRFA. The Office of Public Affairs, Reference Operations Division, will send a copy of the NPRM, including the IRFA, to the Chief Counsel for Advocacy of the Small Business Administration.

23. This proceeding will be treated as a ''permit-but-disclose'' proceedings subject to the ''permit-but-disclose'' requirements under § 1.1206 of the Commission's rules, as revised. Additional rules pertaining to oral and written presentations are set forth in § 1.1206.

C. Notice and Comment Provisions

24. *General.* Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments on or before December 3, 1999, and reply comments on or before Decemeber 20, 1999. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) or by filing paper copies.

25. 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.

26. 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 12th St. SW, Washington, DC 20554, with a copy to: Ms. Terry Conway, Common Carrier Bureau, Industry Analysis Division, 445 12th St. SW, Room 6A–100, Washington, DC 20554. Written comments by the public on the proposed information collection are due on or before December 3, 1999. Written comments must be submitted by the Office of Management and Budget (OMB) on the proposed information collection on or before January 3, 2000. In addition to filing comments with the Secretary, a copy of any comments on the information collection contained herein should be submitted to Judy Boley, Federal Communications Commission, Room 1–C804, 445 12th Street, SW, Washington, DC 20554, or via the Internet to jboley@fcc.gov and to Virginia Huth, OMB Desk Officer, 10236 NEOB, 725—17th Street, NW, Washington, DC 20503 or via the Internet to VHuth@omb.eop.gov.

27. Parties who choose to file by paper should also submit their comments on diskette. These diskettes should be submitted to: Ms. Terry Conway, Common Carrier Bureau, Industry Analysis Division, 445 12th St. SW, Room 6A–100, 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 labelled with the commenter's name, proceeding (CC Docket No. 99–301), 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 pleading, preferably in a single electronic file. In addition, commenters must send diskette copies to the Commission's copy contractor, International Transcription Service,

Inc., 1231 20th Street, NW, Washington, DC 20037.

Initial Regulatory Flexibility Act Analysis

28. As required by the Regulatory Flexibility Act (RFA), the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) of any possible significant economic impact on small entities by the policies and rules proposed in the Notice. Written public comments are requested on the IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments on the Notice, which are set out in paragraph 91 of the Notice. The Commission will send a copy of the Notice, including the IRFA, to the Chief Counsel for Advocacy of the Small Business Administration. In addition, the Notice and IRFA (or summaries thereof) will be published in the **Federal Register**.

I. Need for, and Objectives of, the Proposed Action

29. The Commission has initiated this proceeding to determine whether it should require certain providers of communications services to report a limited amount of information about the development of local telephone competition and the deployment of broadband services as mandated by the Telecommunications Act of 1996. The 1996 Act—in particular, sections 251 and 271—tasked this Commission and the states with important roles in opening up local telephone markets to competition. The Commission needs timely and reliable information about the pace and extent of developing competition in different geographic markets in order to evaluate the effectiveness of the actions this Commission and the states are taking to promote local telephone competition. Moreover, the Commission tentatively concluded that gathering broadband deployment information is critical given that section 706 of the 1996 Act requires the Commission to issue periodic reports on the state of broadband deployment.

II. Legal Basis

30. The legal basis for the action as proposed for this rulemaking is contained in sections 1–5, 10, 11, 201–205, 215, 218–220, 251–271, 303(r), 332, and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 151–155, 160, 161, 201–205, 215, 218–220, 251–271, 303(r), 332 and 403, and pursuant to section 706 of the Telecommunications Act of 1996, 47 U.S.C. 157 nt.

III. Description and Estimate of the Number of Small Entities to Which the Proposed Action May Apply

31. The Commission tentatively concludes that local exchange carriers and providers of mobile telephony services that serve 50,000 or more subscribers, and any entity that provides at least 1,000 full broadband lines, should comply with the proposed reporting requirement. Based on data available to it at present, the Commission estimates that fewer than 50 of the nation's largest local exchange carriers and between 40 and 70 mobile telephony providers would be required to comply with the proposed requirement. Nevertheless, and out of an abundance of caution, we set out below a detailed description of the types of entities that could possibly be required to comply with the proposed reporting requirement and we detail our understanding of the number of small entities within each of these categories.

32. To estimate the number of small entities that may be affected by the proposed rules, we first consider the statutory definition of ''small entity'' under the RFA. The RFA generally defines ''small entity'' as having the same meaning as the term ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act, unless the Commission has developed one or more definitions that are appropriate to its activities. Under the Small Business Act, a ''small business concern'' is one that: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) meets any additional criteria established by the Small Business Administration (SBA). The SBA has defined a small business for Standard Industrial Classification (SIC) categories 4812 (Radiotelephone Communications) and 4813 (Telephone Communications, Except Radiotelephone) to be small entities when they have no more than 1,500 employees. We first discuss the number of small telephone companies falling within these SIC categories, then attempt to refine further those estimates to correspond with the categories of telephone companies that are commonly used under our rules.

33. The most reliable source of information regarding the total numbers of common carrier and related providers nationwide, as well as the numbers of commercial wireless entities, appears to be data the Commission publishes annually in its *Carrier Locator* report, derived from filings made in connection with the Telecommunications Relay Service (TRS). According to data in the most recent report, there are 3,604 interstate carriers. These carriers include, *inter alia*, local exchange carriers, wireline carriers and service providers, interexchange carriers, competitive access providers, operator service providers, pay telephone operators, providers of telephone toll service, providers of telephone exchange service, and resellers.

34. We have included small incumbent LECs in the present RFA analysis. As noted above, a ''small business'' under the RFA is one that, *inter alia*, meets the pertinent small business size standard (e.g., a telephone communications business having 1,500 or fewer employees), and ''is not dominant in its field of operation.'' The SBA's Office of Advocacy contends that, for RFA purposes, small incumbent LECs are not dominant in their field of operation because any such dominance is not ''national'' in scope. We have therefore included small incumbent LECs in the RFA analysis, although we emphasize that the RFA action has no effect on FCC analyses and determinations in other, non-RFA contexts.

35. *Total Number of Telephone Companies Affected.* The United States Bureau of the Census (''the Census Bureau'') reports that, at the end of 1992, there were 3,497 firms engaged in providing telephone services, as defined therein, for at least one year. This number contains a variety of different categories of carriers, including local exchange carriers, interexchange carriers, competitive access providers, cellular carriers, mobile service carriers, operator service providers, pay telephone operators, PCS providers, covered SMR providers, and resellers. It seems certain that some of those 3,497 telephone service firms may not qualify as small entities or small incumbent LECs because they are not ''independently owned and operated.'' For example, a PCS provider that is affiliated with an interexchange carrier having more than 1,500 employees would not meet the definition of a small business. It seems reasonable to conclude, therefore, that fewer than 3,497 telephone service firms are small entity telephone service firms or small incumbent LECs that may be affected by the decisions and rules proposed in the Notice.

36. *Wireline Carriers and Service Providers.* SBA has developed a definition of small entities for telephone communications companies other than radiotelephone companies. The Census Bureau reports that, there were 2,321

such telephone companies in operation for at least one year at the end of 1992. According to SBA's definition, a small business telephone company other than a radiotelephone company is one employing no more than 1,500 persons. All but 26 of the 2,321 non-radiotelephone companies listed by the Census Bureau were reported to have fewer than 1,000 employees. Thus, even if all 26 of those companies had more than 1,500 employees, there would still be 2,295 non-radiotelephone companies that might qualify as small entities or small incumbent LECs. Although it seems certain that some of these carriers are not independently owned and operated, we are unable at this time to estimate with greater precision the number of wireline carriers and service providers that would qualify as small business concerns under SBA's definition. Consequently, we estimate that there are fewer than 2,295 small entity telephone communications companies other than radiotelephone companies that may be affected by the decisions and rules proposed in the Notice.

37. *Local Exchange Carriers, Interexchange Carriers, Competitive Access Providers, Operator Service Providers, and Resellers.* Neither the Commission nor SBA has developed a definition of small local exchange carriers (LECs), interexchange carriers (IXCs), competitive access providers (CAPs), operator service providers (OSPs), or resellers. The closest applicable definition for these carrier-types under SBA rules is for telephone communications companies other than radiotelephone (wireless) companies. The most reliable source of information regarding the number of these carriers nationwide of which we are aware appears to be the data that we collect annually in connection with the Telecommunications Relay Service (TRS). According to our most recent data, there are 1,410 LECs, 151 IXCs, 129 CAPs, 32 OSPs, and 351 resellers. Although it seems certain that some of these carriers are not independently owned and operated, or have more than 1,500 employees, we are unable at this time to estimate with greater precision the number of these carriers that would qualify as small business concerns under SBA's definition. Consequently, we estimate that there are fewer than 1,410 small entity LECs or small incumbent LECs, 151 IXCs, 129 CAPs, 32 OSPs, and 351 resellers that may be affected by the decisions and rules proposed in the Notice.

38. *Wireless (Radiotelephone) Carriers.* SBA has developed a definition of small entities for radiotelephone (wireless) companies. The Census Bureau reports that there were 1,176 such companies in operation for at least one year at the end of 1992. According to SBA's definition, a small business radiotelephone company is one employing no more than 1,500 persons. The Census Bureau also reported that 1,164 of those radiotelephone companies had fewer than 1,000 employees. Thus, even if all of the remaining 12 companies had more than 1,500 employees, there would still be 1,164 radiotelephone companies that might qualify as small entities if they are independently owned are operated. Although it seems certain that some of these carriers are not independently owned and operated, we are unable at this time to estimate with greater precision the number of radiotelephone carriers and service providers that would qualify as small business concerns under SBA's definition. Consequently, we estimate that there are fewer than 1,164 small entity radiotelephone companies that may be affected by the decisions and rules proposed in the Notice.

39. *Cellular, PCS, SMR and Other Mobile Service Providers.* In an effort to further refine our calculation of the number of radiotelephone companies that may be affected by the rules adopted herein, we consider the data that we collect annually in connection with the TRS for the subcategories Wireless Telephony (which includes Cellular, PCS, and SMR) and Other Mobile Service Providers. We will utilize the closest applicable definition under SBA rules—which, for both categories, is for telephone companies other than radiotelephone (wireless) companies, however, to the extent that the Commission has adopted definitions for small entities providing PCS and SMR services, we discuss those definitions below. According to our most recent TRS data, 732 companies reported that they are engaged in the provision of Wireless Telephony services and 23 companies reported that they are engaged in the provision of Other Mobile Services. Although it seems certain that some of these carriers are not independently owned and operated, or have more than 1,500 employees, we are unable at this time to estimate with greater precision the number of Wireless Telephony Providers and Other Mobile Service Providers, except as described in paragraphs 40–52, that would qualify as small business concerns under SBA's definition. Consequently, we estimate that there are fewer than 732 small entity Wireless Telephony Providers and fewer than 23 small entity Other Mobile Service Providers that might be affected by the decisions and rules proposed in the Notice.

40. *Broadband PCS Licensees.* The broadband PCS spectrum is divided into six frequency blocks designated A through F, and the Commission has held auctions for each block. The Commission defined ''small entity'' for Blocks C and F as an entity that has average gross revenues of less than $40 million in the three previous calendar years. For Block F, an additional classification for ''very small business'' was added, and is defined as an entity that, together with its affiliates, has average gross revenues of not more than $15 million for the preceding three calendar years. These regulations defining ''small entity'' in the context of broadband PCS auctions have been approved by SBA. No small businesses within the SBA-approved definition bid successfully for licenses in Blocks A and B. There were 90 winning bidders that qualified as small entities in the Block C auctions. A total of 93 small and very small business bidders won approximately 40% of the 1,479 licenses for Blocks D, E, and F. However, licenses for Blocks C through F have not been awarded fully, therefore there are few, if any, small businesses currently providing PCS services. Based on this information, we estimate that the number of small broadband PCS licenses will include the 90 winning C Block bidders and the 93 qualifying bidders in the D, E, and F blocks, for a total of 183 small PCS providers as defined by SBA and the Commissioner's auction rules.

41. *SMR Licensees.* Pursuant to 47 CFR 90.814(b)(1), the Commission has defined ''small entity'' in auctions for geographic area 800 MHz and 900 MHz SMR licenses as a firm that had average annual gross revenues of less than $15 million in the three previous calendar years. The definition of a ''small entity'' in the context of 800 MHz SMR has been approved by the SBA, and approval for the 900 MHz SMR definition has been sought. The proposed rules may apply to SMR providers in the 800 MHz and 900 MHz bands that either hold geographic area licenses or have obtained extended implementation authorizations. We do not know how many firms provide 800 MHz or 900 MHz geographic area SMR service pursuant to extended implementation authorizations, nor how many of these providers have annual revenues of less than $15 million. Consequently, we estimate, for purposes of this IRFA, that all of the extended implementation authorizations may be

held by small entities, some of which may be affected by the decisions and rules proposed in the Notice. The Commission recently held auctions for geographic area licenses in the 900 MHz SMR band. There were 60 winning bidders who qualified as small entities in the 900 MHz auction. Based on this information, we estimate that the number of geographic area SMR licensees that may be affected by the decisions and rules proposed in the Notice includes these 60 small entities. No auctions have been held for 800 MHz geographic area SMR licenses. Therefore, no small entities currently hold these licenses. A total of 525 licenses will be awarded for the upper 200 channels in the 800 MHz geographic area SMR auction. The Commission, however, has not yet determined how many licenses will be awarded for the lower 230 channels in the 800 MHz geographic area SMR auction. There is no basis, moreover, on which to estimate how many small entities will win these licenses. Given that nearly all radiotelephone companies have fewer than 1,000 employees and that no reliable estimate of the number of prospective 800 MHz licensees can be made, we estimate, for purposes of this IRFA, that all of the licenses may be awarded to small entities, some of which may be affected by the decisions and rules proposed in the Notice.

42. *220 MHz Radio Service—Phase I Licensees.* The 220 MHz service has both Phase I and Phase II licenses. There are approximately 1,515 such non-nationwide licensees and four nationwide licensees currently authorized to operate in the 220 MHz band. The Commission has not developed a definition of small entities specifically applicable to such incumbent 220 MHZ Phase I licensees. To estimate the number of such licensees that are small businesses, we apply the definition under the SBA rules applicable to Radiotelephone Communications companies. According to the Bureau of the Census, only 12 radiotelephone firms out of a total of 1,178 such firms which operated during 1992 had 1,000 or more employees. Therefore, if this general ratio continues to 1999 in the context of Phase I 220 MHz licensees, we estimate that nearly all such licensees are small businesses under the SBA's definition, some of which may be affected by the decisions and rules proposed in the Notice.

43. *220 MHz Radio Service—Phase II Licensees.* The Phase II 220 MHz service is a new service, and is subject to spectrum auctions. In the 220 MHz *Third Report and Order* we adopted criteria for defining small businesses and very small businesses for purposes of determining their eligibility for special provisions such as bidding credits and installment payments. We have defined a small business as an entity that, together with its affiliates and controlling principals, has average gross revenues not exceeding $15 million for the preceding three years. Additionally, a very small business is defined as an entity that, together with its affiliates and controlling principals, has average gross revenues that are not more than $3 million for the preceding three years. An auction of Phase II licenses commenced on September 15, 1998, and closed on October 22, 1998. 908 licenses were auctioned in 3 different-sized geographic areas: three nationwide licenses, 30 Regional Economic Area Group Licenses, and 875 Economic Area (EA) Licenses. Of the 908 licenses auctioned, 693 were sold. Companies claiming small business status won: one of the Nationwide licenses, 67% of the Regional licenses, and 54% of the EA licenses. As of October 7, 1999, the Commission had granted 681 of the Phase II 220 MHz licenses won at a first auction and an additional 221 Phase II licenses won at a second auction.

44. *Paging.* The Commission has adopted a two-tier definition of small businesses in the context of auctioning licenses in the Common Carrier Paging and exclusive Private Carrier Paging services. A small business is defined as either (1) an entity that, together with its affiliates and controlling principals, has average gross revenues for the three preceding years of not more than $3 million, or (2) an entity that, together with affiliates and controlling principals, has average gross revenues for the three preceding calendar years of not more than $15 million. The SBA approved this definition for paging services on December 12, 1999. At present, there are approximately 24,000 Private Paging licenses and 74,000 Common Carrier Paging licenses. According to the most recent *Carrier Locator* data, 137 carriers reported that they were engaged in the provision of either paging or messaging services, which are placed together in the data. We do not have data specifying the number of these carriers that meet this two-tiered definition, and thus are unable at this time to estimate with greater precision the number of paging carriers that would qualify as small business concerns under the SBA's definition. Consequently, we estimate that there are fewer than 137 small paging carriers that may be affected by the decisions and rules proposed in the Notice.

45. *Narrowband PCS.* The Commission has auctioned nationwide and regional licenses for narrowband PCS. There are 11 nationwide and 30 regional licensees for narrowband PCS. The Commission does not have sufficient information to determine whether any of these licensees are small businesses within the SBA-approved definition for radiotelephone companies. At present, there have been no auctions held for the major trading area (MTA) and basic trading area (BTA) narrowband PCS licenses. The Commission anticipates a total of 561 MTA licenses and 2,958 BTA licenses will be awarded by auction. Such auctions have not yet been scheduled, however. Given that nearly all radiotelephone companies have no more than 1,500 employees and that no reliable estimate of the number of prospective MTA and BTA narrowband licensees can be made, we assume, for purposes of this IRFA, that all of the licenses will be awarded to small entities, as that term is defined by the SBA.

46. *Rural Radiotelephone Service.* The Commission has not adopted a definition of small entity specific to the Rural Radiotelephone Service. A significant subset of the Rural Radiotelephone Service is the Basic Exchange Telephone Radio Systems (BETRS). We will use the SBA's definition applicable to radiotelephone companies, *i.e.*, an entity employing no more than 1,500 persons. There are approximately 1,000 licensees in the Rural Radiotelephone Service, and we estimate that almost all of them qualify as small entities under the SBA's definition.

47. *Air-Ground Radiotelephone Service.* The Commission has not adopted a definition of small entity specific to the Air-Ground Radiotelephone Service. Accordingly, we will use the SBA's definition applicable to radiotelephone companies, *i.e.*, an entity employing no more than 1,500 persons. There are approximately 100 licensees in the Air-Ground Radiotelephone Service, and we estimate that almost all of them qualify as small entities under the SBA definition.

48. *Private Land Mobile Radio (PLMR).* PLMR systems serve an essential role in a range of industrial, business, land transportation, and public safety activities. These radios are used by companies of all sizes operating in all U.S. business categories. The Commission has not developed a definition of small entity specifically

applicable to PLMR licensees due to the vast array of PLMR users. For the purpose of determining whether a licensee is a small business as defined by the SBA, each licensee would need to be evaluated within its own business area. The Commission is unable at this time to estimate the number of, if any, small businesses that could be impacted by the proposed rules. However, the Commission's 1994 Annual Report on PLMRs indicates that at the end of fiscal year 1994 there were 1,087,267 licensees operating 12,481,989 transmitters in the PLMR bands below 512 MHz. Because any entity engaged in a commercial activity is eligible to hold a PLMR license, the proposed rules in this context could potentially impact every small business in the United States. We note, however, that because the vast majority of these licensees are end-users, not providers of telephony or broadband services, they would not be directly affected by the rules proposed in this Notice.

49. *Fixed Microwave Services.* Microwave services include common carrier, private-operational fixed, and broadcast auxiliary radio services. At present, there are approximately 22,015 common carrier fixed licensees in the microwave services. The Commission has not yet defined a small business with respect to microwave services. For purposes of this IRFA, we will utilize the SBA's definition applicable to radiotelephone companies—*i.e.*, an entity with no more than 1,500 persons. We estimate, for this purpose, that all of the Fixed Microwave licensees (excluding broadcast auxiliary licensees) would qualify as small entities under the SBA definition for radiotelephone companies.

50. *Offshore Radiotelephone Service.* This service operates on several UHF TV broadcast channels that are not used for TV broadcasting in the coastal area of the states bordering the Gulf of Mexico. At present, there are approximately 55 licensees in this service. We are unable at this time to estimate the number of licensees that would qualify as small entities under the SBA's definition for radiotelephone communications.

51. *Wireless Communications Services.* This service can be used for fixed, mobile, radio location and digital audio broadcasting satellite uses. The Commission defined ''small business'' for the wireless communications services (WCS) auction as an entity with average gross revenues of $40 million for each of the three preceding years, and a ''very small business'' as an entity with average gross revenues of $15 million for each of the three preceding years. The Commission auctioned geographic area licenses in the WCS service. In the auction, there were seven winning bidders that qualified as very small business entities, and one that qualified as a small business entity. We conclude that the number of geographic area WCS licensees that may be affected by the decisions and rules proposed in the Notice includes these eight entities.

52. *Satellite Services.* The Commission has not developed a definition of small entities applicable to satellite service licensees. Therefore, the applicable definition of small entity is generally the definition under the SBA rules applicable to Communications Services, Not Elsewhere Classified (NEC). This definition provides that a small entity is expressed as one with $11.0 million or less in annual receipts. According to the Census Bureau, there were a total of 848 communications services providers, NEC, in operation in 1992, and a total of 775 had annual receipts of less than $9.999 million. The Census report does not provide more precise data.

53. In addition to the estimates provided in paragraphs 40–52, we consider certain additional entities that may be affected by the data collection from broadband service providers. Because section 706 requires us to monitor the deployment of broadband regardless of technology or transmission media employed, we anticipate that some broadband service providers will not provide telephone service. Accordingly, we describe in paragraphs 54–61 other types of firms that may provide broadband services, including cable companies, MDS providers, and utilities, among others.

54. *Cable Services or Systems:* The SBA has developed a definition of small entities for cable and other pay television services, which includes all such companies generating $11 million or less in revenue annually. This definition includes cable systems operators, closed circuit television services, direct broadcast satellite services, multipoint distribution systems, satellite master antenna systems and subscription television services. According to the Census Bureau data from 1992, there were 1,788 total cable and other pay television services and 1,423 had less than $11 million in revenue.

55. The Commission has developed its own definition of a small cable system operator for the purposes of rate regulation. Under the Commission's rules, a ''small cable company'' is one serving fewer than 400,000 subscribers nationwide. Based on our most recent information, we estimate that there were 1,439 cable operators that qualified as small cable system operators at the end of 1995. Since then, some of those companies may have grown to serve over 400,000 subscribers, and others may have been involved in transactions that caused them to be combined with other cable operators. Consequently, we estimate that there are fewer than 1,439 small entity cable system operators.

56. The Communications Act also contains a definition of a small cable system operator, which is ''a cable operator that, directly or through an affiliate, serves in the aggregate fewer than 1 percent of all subscribers in the United States and is not affiliated with any entity or entities whose gross annual revenues in the aggregate exceed $250,000,000.'' The Commission has determined that there are 66,000,000 subscribers in the United States. Therefore, we found that an operator serving fewer than 660,000 subscribers shall be deemed a small operator, if its annual revenues, when combined with the total annual revenues of all of its affiliates, do not exceed $250 million in the aggregate. Based on available data, we find that the number of cable operators serving 660,000 subscribers or less totals 1,450. We do not request nor do we collect information concerning whether cable system operators are affiliated with entities whose gross annual revenues exceed $250,000,000, and thus are unable at this time to estimate with greater precision the number of cable system operators that would qualify as small cable operators under the definition in the Communications Act. It should be further noted that recent industry estimates project that there will be a total of 66,000,000 subscribers, and we have based our fee revenue estimates on that figure.

57. *Multipoint Distribution Systems (MDS):* The Commission has defined ''small entity'' for the auction of MDS as an entity that, together with its affiliates, has average gross annual revenues that are not more than $40 million for the preceding three calendar years. This definition of a small entity in the context of MDS auctions has been approved by the SBA. The Commission completed its MDS auction in March 1996 for authorizations in 493 basic trading areas (BTAs). Of 67 winning bidders, 61 qualified as small entities.

58. MDS is also heavily encumbered with licensees of stations authorized prior to the auction. The SBA has developed a definition of small entities for pay television services, which includes all such companies generating $11 million or less in annual receipts. This definition includes multipoint

distribution systems, and thus applies to MDS licensees and wireless cable operators which did not participate in the MDS auction. Information available to us indicates that there are 832 of these licensees and operators that do not generate revenue in excess of $11 million annually. Therefore, for purposes of this IRFA, we find there are approximately 892 small MDS providers as defined by the SBA and the Commission's auction rules, some which may be affected by the decisions and rules proposed in the Notice.

59. *Electric Services (SIC 4911):* The SBA has developed a definition for small electric utility firms. The Census Bureau reports that a total of 1379 electric utilities were in operation for at least one year at the end of 1992. According to SBA, a small electric utility is an entity whose gross revenues did not exceed five million dollars in 1992. The Census Bureau reports that 447 of the 1379 firms listed had total revenues below five million dollars.

60. *Electric and Other Services Combined (SIC 4931):* The SBA has classified this entity as a utility whose business is less than 95% electric in combination with some other type of service. The Census Bureau reports that a total of 135 such firms were in operation for at least one year at the end of 1992. The SBA's definition of a small electric and other services combined utility is a firm whose gross revenues did not exceed five million dollars in 1992. The Census Bureau reported that 45 of the 135 firms listed had total revenues below five million dollars.

61. *Combination Utilities, Not Elsewhere Classified (SIC 4939):* The SBA defines this utility as providing a combination of electric, gas, and other services which are not otherwise classified. The Census Bureau reports that a total of 79 such utilities were in operation for at least one year at the end of 1992. According to SBA's definition, a small combination utility is a firm whose gross revenues did not exceed five million dollars in 1992. The Census Bureau reported that 63 of the 79 firms listed had total revenues below five million dollars.

IV. Description of Proposed Reporting, Recordkeeping, and Other Compliance Requirements

62. The very focus of this proceeding is whether the Commission should require certain providers of communications services to report a limited amount of information about the development of local telephone competition and the deployment of broadband services. The Notice tentatively concludes that the Commission should undertake such a data collection and that local exchange carriers and providers of mobile telephony services that serve 50,000 or more subscribers, and any entity that provides at least 1,000 full broadband lines, should report specifically targeted information. The Notice sets out in detail, and seeks comment on, the Commission's tentative conclusions about the types of carriers that should report, exempting smaller carriers, frequency of reports, data to be reported, and methods (such as electronic filing) of reporting. In particular, the Commission has tentatively concluded that given the comprehensive data to be obtained from large and medium-size carriers, it can exempt most small carriers from completing the survey without materially affecting its ability to assess the development of local competition and the deployment of broadband services.

V. Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

63. The Commission makes specific provision to exempt most smaller carriers from the proposed requirement to report local telephone competition data. The Commission tentatively concludes that carriers with fewer than 50,000 nationwide local access lines (or mobile telephony subscribers, in the case of mobile telephony providers) should be exempted from the proposed reporting requirement. Based on this exemption, the Commission estimates that fewer than 50 of the nation's largest service providers would remain subject to the proposed requirement. The Commission provides a detailed explanation for this proposed exemption and seeks comment on the 50,000 local access line threshold in the Notice.

64. With respect to broadband service, and irrespective of the criteria for reporting local competition data, the Commission tentatively concludes that entities that provide full broadband services to at least 1,000 customers should report. The Commission tentatively concludes that this more comprehensive reporting requirement is necessary to monitor broadband developments by smaller entities, for example, in rural areas. The Commission seeks comment on this proposed threshold and invites commenters to suggest alternative thresholds.

65. Among significant alternatives, the Commission considers whether it might rely on publicly available data or voluntary surveys, in lieu of a mandatory data collection program. The Commission tentatively concludes other publicly available information sources present less than complete pictures of actual conditions and trends in developing local service markets and in the deployment of broadband. Further, the Commission considers the need for, and size of, its proposed exemptions for small entities. The Commission tentatively concludes that the proposed thresholds will allow it exempt most small entities from completing the survey without materially affecting its ability to assess the development of local competition and the deployment of broadband services.

VI. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rule

66. None.

Ordering Clause

67. Accordingly, *it is ordered* that, pursuant to sections 1–5, 10, 11, 201–205, 215, 218–220, 251–271, 303(r), 332, and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 151–155, 160, 161, 201–205, 215, 218–220, 251–271, 303(r), 332, and 403, and pursuant to section 706 of the Telecommunications Act of 1996, 47 U.S.C. 157 nt, this notice of proposed rulemaking is hereby adopted.

68. *It is further ordered* that the Commission's Office of Public Affairs, Reference Operations Division, shall send a copy of this notice of proposed rulemaking, including the regulatory flexibility certification, to the Chief Counsel for Advocacy of the Small Business Administration in accordance with paragraph 603(a) of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* (1981).

List of Subjects

47 CFR Parts 1 and 43

Communications common carriers, Reporting and recordkeeping requirements, Telecommunications, Telephone.

47 CFR Part 20

Communications common carriers.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 99–28792 Filed 11–1–99; 11:13 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 99–2272; MM Docket No. 99–312; RM–9735]

Radio Broadcasting Services; Jersey Shore, Mill Hall, and Pleasant Gap, PA

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition filed by Forever Broadcasting, LLC, proposing the reallotment of Channel 249A from Jersey Shore to Mill Hall, Pennsylvania, and the modification of Station WVRT(FM)'s license accordingly. Petitioner also requests the reallotment of Channel 254A from Mill Hall to Pleasant, Gap, Pennsylvania, and the modification of Station WZRZ(FM)'s license accordingly. Channel 249A can be reallotted to Mill Hall in compliance with the Commission's minimum distance separation requirements without the imposition of a site restriction at petitioner's requested site. The coordinates for Channel 249A at Mill Hall are 41–08–03 North Latitude and 77–28–09 West Longitude. *See* **SUPPLEMENTARY INFORMATION**, *infra*.

DATES: Comments must be filed on or before December 13, 1999, reply comments on or before December 28, 1999.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioners, or their counsel or consultants, as follows: Allan G. Moskowitz, Esq., Kaye, Scholer, Fierman, Hays & Handler, LLP, 901 15th Street, NW., Suite 1100, Washington, DC 20005 (Counsel for Petitioner).

FOR FURTHER INFORMATION CONTACT: Sharon P. McDonald, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 99–312, adopted October 13, 1999, and released October 22, 1999. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Information Center (Room CY–A257), 445 12th Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., (202) 857–3800, 1231 20th Street, NW., Washington, DC 20036.

Additionally, Channel 245A can be reallotted to Pleasant Gap, Pennsylvania, without the imposition of a site restriction at petitioner's requested site. The coordinates for Channel 252 A at Pleasant Gap are 40–55–58 North Latitude and 77–45–40 West Longitude. Since Mill Hall and Pleasant Gap are located within 320 kilometers (200 miles) of the U.S.-Canadian border, concurrence of the Canadian government has been requested. In accordance with section 1.420(i) of the Commission's Rules, we will not accept competing expressions of interest in the use of Channel 249A at Mill Hall, Pennsylvania, or Channel 252A at Pleasant Gap, Pennsylvania.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 99–28628 Filed 11–2–99; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 99–2272; MM Docket No. 99–314; RM–9754]

Radio Broadcasting Services; Metropolis, IL, and Paducah, KY

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition filed by Sun Media, Inc., proposing the reallotment of Channel 252C1 from Metropolis, Illinois to Paducah, Kentucky, and the modification of Station WRIK–FM's construction permit accordingly. Channel 252C1 can be reallotted to Paducah in compliance with the Commission's minimum distance separation requirements without the imposition of a site restriction at petitioner's authorized construction permit site. The coordinates for Channel 252C1 at Paducah are 36–45–09 North Latitude and 88–29–58 West Longitude. In accordance with section 1.420(i), of the Commission's Rules, we will not accept competing expressions of interest in the use of Channel 244A at Paducah, Kentucky.

DATES: Comments must be filed on or before December 13, 1999, reply comments on or before December 28, 1999.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioners, or their counsel or consultants, as follows: Dawn M. Sciarrino, Fisher, Wayland, Cooper, Leader & Zaragoza, L.L.P., 2001 Pennsylvania Ave., NW., Suite 400, Washington, DC 20006 (Counsel for Petitioner).

FOR FURTHER INFORMATION CONTACT: Sharon P. McDonald, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 99–314, adopted October 13, 1999, and released October 22, 1999. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Information Center (Room CY–A257), 445 12th Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., (202) 857–3800, 1231 20th Street, NW., Washington, DC 20036.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 99–28627 Filed 11–2–99; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AF43

Endangered and Threatened Wildlife and Plants; Reopening of the Comment Period on the Proposed Delisting of the Douglas County Population of the Columbian White-Tailed Deer

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; notice of reopening of comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), pursuant to the Endangered Species Act of 1973, as amended (Act), provide notice of the reopening of the comment period for the proposed delisting of the Douglas County, Oregon population of the Columbian white-tailed deer (*Odocoileus virginianus leucurus*). The comment period has been reopened in order to conduct a peer review of the proposed rule.

DATES: Comments from all interested parties must be received by November 18, 1999.

ADDRESSES: Written comments, materials, data, and reports concerning this proposal should be sent to the Supervisor, U.S. Fish and Wildlife Service, Southwest Oregon Field Office, 2900 NW Stewart Parkway, Roseburg, Oregon 97470. Comments and materials received will be available for public inspection, by appointment, during normal business hours, at the above address.

FOR FURTHER INFORMATION CONTACT: David Peterson, at the address listed above (telephone 541/957–3474; facsimile 541/957–3475).

SUPPLEMENTARY INFORMATION:

Background

The Columbian white-tailed deer (*Odocoileus virginianus leucurus*) resembles other white-tailed deer subspecies, ranging in size from 39 to 45 kilograms (kg) (85 to 100 pounds (lbs) for females and 52 to 68 kg (115 to 150 lbs) for males. Generally a red-brown color in summer, and gray in winter, the species has white rings around the eyes and a white ring just behind the nose. Its tail is long and triangular in shape, and is brown on the dorsal (upper) surface, fringed in white, and the ventral (under) portion is white (Oregon Department of Fish and Wildlife (ODFW) 1995). The species was formerly distributed throughout the bottomlands and prairie woodlands of the lower Columbia, Willamette, and Umpqua River basins in Oregon and southern Washington (Bailey 1936). It is the westernmost representative of the 38 subspecies of white-tailed deer. Early accounts suggested this deer was locally common, particularly in riparian areas along the major rivers (Gavin 1978). The decline in deer numbers was rapid with the arrival and settlement of pioneers in the fertile river valleys. Conversion of brushy riparian land to agriculture, urbanization, uncontrolled sport and commercial hunting, and perhaps other factors apparently caused the extirpation of this deer over most of its range by the early 1900s (Gavin 1984). Only a small herd of 200 to 400 animals in the lower Columbia River area of Clatsop and Columbia counties, Oregon, and Cowlitz and Wahkiakum counties, Washington, and a disjunct population of unknown size in Douglas County, Oregon, survived. These two remnant populations are geographically separated by about 320 kilometers (km) (200 miles (mi)) of unsuitable or discontinuous habitat.

Population declines led to classification of this subspecies as endangered in 1967 under the Endangered Species Protection Act of 1966 (32 FR 4001). The subspecies was automatically included in the lists of threatened and endangered species when the Endangered Species Act was authorized in 1973 (16 U.S. C. 1531 *et seq.*). Prior to 1977, only the Columbia River population was listed as endangered since the Douglas County population was considered a black-tailed deer (*Odocoileus hemionus columbiana*) or a hybrid between the black-tailed deer and the Columbian white-tailed deer by the State of Oregon. In 1978, the State of Oregon recognized the white-tailed deer population in Douglas County as the Columbian white-tailed deer and prohibited hunting of white-tailed deer in that county (ODFW 1995). The Columbian White-tailed Deer Recovery Plan (Recovery Plan) was approved by us in 1976, and a revised version was approved in 1983 (Service 1983). Because of the distance between the Douglas County and Columbia River populations, and differences in habitats and threats, the Recovery Plan addresses the recovery of these two populations separately.

Crews (1939) estimated the population in the 1930s in Douglas County at 200 to 300 individuals within a range of about 78 square kilometers (sq km) (30 square miles (sq mi)). In 1970, ODFW estimated that 450 to 500 deer were present. By 1983, the number had increased to about 2,500 (Smith 1985). The population has continued to grow, and are presently are estimated to be between 5,900 to 7,900 deer (ODFW 1999).

Along with this increase in numbers, the range also has expanded. The deer have expanded to the north and west in the last 10 years, and now occupy an area of approximately 800 sq km (308 sq mi) (ODFW 1995).

Most habitat for the Douglas County population is on private lands. Approximately 3,880 hectares (ha) (9,586 acres (ac)) of suitable habitat are presently considered secure on Federal, County and private lands. For the purpose of delisting, habitat is considered secure if it is protected by legally binding measures or law from adverse human activities for the foreseeable future.

The current total population size is estimated as approximately six times the population size required for downlisting, which greatly reduces the risk to the population. It is also anticipated that as habitat management and restoration activities are implemented by the Bureau of Land Management, which contains the majority of secure lands, the carrying capacity and numbers of deer on these lands will increase accordingly. The Douglas County population has met the objectives in the Recovery Plan, and greatly exceeded the habitat objectives.

We published a proposed rule to delist the Douglas County population of the Columbian white-tailed deer on May 11, 1999 (64 FR 25263). The original comment period closed on June 25, 1999. We will conduct a peer review of this proposal and solicit the opinions of three appropriate and independent specialists regarding the data, assumptions, and supportive information presented for the Columbian white-tailed deer, per our Interagency Cooperative Policy for Peer Review in Endangered Species Act Activities (59 FR 34270).

References Cited

Bailey, V. 1936. The mammals and life zones of Oregon. North American Fauna. U.S. Department of Agriculture, Washington DC 55: 89–91.

Crews, A.K. 1939. A study of the Oregon white-tailed deer, *Odocoileus virginianus leucurus* (Douglas). M.S. thesis. Oregon State College. Corvallis. 46 pp.

Gavin, T.A. 1984. Pacific Northwest. *in*: White-tailed deer, ecology and management. L.K. Halls, editor. A Wildlife Management Institute publication. Pages 491–492.

Gavin, T.A. 1978. Status of the Columbian white-tailed deer: some quantitative uses of biogeographic data. Pages 185–202 *in*: Threatened Deer. IUCN. Morges, Switzerland. 434 pp.

Oregon Department of Fish Wildlife. 1999. Deer census and population trend data. Unpublished ODFW report, Southwest Regional Office. 4 pages.

Oregon Department of Fish and Wildlife. 1995. Columbian white-tailed deer biological status assessment. Report to Oregon Fish and Wildlife Commission. 83 pp.

Smith, W.P. 1985. Current geographic distribution and abundance on the Columbian white-tailed deer, *Odocoileus virginianus leucurus* (Douglas). Northwest Science 59:243–251.

U.S. Fish and Wildlife Service. 1983. Revised Columbian white-tailed deer recovery plan. Portland, Oregon. 75 pp.

Author: The primary author of this notice is Barbara Behan of the Regional Office, U.S. Fish and Wildlife Service, 911 N.E. 11th Avenue, Portland, Oregon 97232–4181 (telephone 503/231–6131).

Authority

The authority of this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: October 26, 1999.

Thomas Dwyer,

Regional Director, Fish and Wildlife Service.

[FR Doc. 99–28696 Filed 11–2–99; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[I.D. 102699G]

Groundfish Fisheries of the Gulf of Alaska and the Bering Sea/Aleutian Islands Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notification of draft alternatives; extension of scoping and comment period.

SUMMARY: NMFS is publishing draft alternatives to be analyzed in a programmatic supplemental environmental impact statement (SEIS) on Federal groundfish fishery management in the Exclusive Economic Zone (EEZ) off Alaska. This document also provides an extension of the scoping period from November 15 until December 15, 1999.

DATES: Written comments must be received on or before December 15, 1999.

ADDRESSES: Written comments should be sent to Lori Gravel, Sustainable Fisheries Division, National Marine Fisheries Service, P.O. Box 21668, Juneau, AK 99802. Comments may also be hand delivered to Room 457–1 Federal Office Building, 907 West 9 Street, Juneau, AK.

FOR FURTHER INFORMATION CONTACT: Steven Davis, NMFS, (907) 271-3523 or steven.k.davis@noaa.gov.

SUPPLEMENTARY INFORMATION: NMFS published in the **Federal Register**, a notice of intent to prepare an SEIS on Federal groundfish fishery management in the EEZ off Alaska and announced scoping meetings (64 FR 53305, October 1, 1999). The reason for undertaking the analysis, and the issues to be analyzed, are detailed in the notice of intent and are not repeated here. In the notice, NMFS indicated that, prior to the scoping meetings, NMFS will publish in the **Federal Register** draft alternatives to be developed further during the scoping process.

NMFS manages the Bering Sea and Aleutian Islands (BSAI) and Gulf of Alaska (GOA) groundfish fisheries to achieve the goals and objectives of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) and the Fishery Management Plans (FMPs) for the Groundfish Fisheries in the BSAI Area, and the Groundfish of the GOA. The goals and objectives reflect the complicated array of often competing concerns that affect the Alaska groundfish fisheries. In some instances, contradictory objectives are articulated within a single goal. For example, paraphrasing from the Magnuson-Stevens Act and the FMPs, we find they generally contain the following goals and objectives: Assure continuing availability of food supply and recreational opportunities; minimize irreversible adverse effects on fishery resources and the marine environment, including essential fish habitat; maximize economic benefits to the Nation and to the states; provide for sustained participation of fishing communities; minimize waste, reduce bycatch and the mortality of bycatch, encourage development of underused fisheries; control effort; promote equitable allocations; keep management options open for the future; prevent overfishing and rebuild overfished stocks; manage stocks as a unit; promote protection of the safety of human life at sea; promote regulatory and fishing efficiency; use the best available data; account for all fishery related removals. In deciding on particular new management measures, NMFS and the North Pacific Fishery Management Council review reasonable alternatives for achieving one or more of those goals and objectives, then base decisions according to the views of competing interests and concerns.

With this programmatic environmental impact analysis, NMFS will evaluate how successfully the current management regime achieves those goals and objectives. The SEIS will support these determinations by presenting an analysis of the environmental impacts of the current regime and compare them to configurations of alternatives management measures that would also achieve those goals and objectives.

Alternatives

NMFS has chosen to analyze broad thematic alternatives that will provide, in a programmatic sense, a conceptual framework for understanding how effectively alternative harvest management regimes achieve the articulated goals and objectives and what their environmental impacts would be. The SEIS will look at the themes: (1) Who harvests groundfish; (2) what groundfish is harvested; (3) when and where is groundfish harvested; and (4) how groundfish is harvested. Sub-alternatives will be developed for each theme. The alternatives and sub-alternatives NMFS is currently considering include the following:

Allocative Schemes (Who harvests groundfish?)

Sub-alternative 1 - Status quo: Allocation of groundfish harvest is currently based on the species or species group and is made to individuals, cooperatives, and Olympic-style fisheries (i.e., non-Community Development Quota (CDQ), non-Individual Fishing Quota (IFQ) fisheries) by sector.

Sub-alternative 2 - IFQ: Expand or reduce allocations to individuals by species or species group.

Sub-alternative 3 - Cooperatives: Expand or reduce allocations to cooperatives by species or species group.

Sub-alternative 4 - Open access: Reduce or remove limited access systems.

Sub-alternative 5 - Allocation: Expand or reduce the use of sector allocations or alter the amounts of allocations.

Sub-alternative 6 - License Limitation: Expand or reduce the use of license limitation.

Harvest Level (What is harvested?)

Sub-alternative 1 - Status quo: Total Allowable Catch levels (TACs) are set by species or species group and the sum of the TACs must stay within the OY of the groundfish complex.

Sub-alternative 2 - Increase the TACs: Set fishing mortality equal to the maximum acceptable biological catch (going above OY of the groundfish complex).

Sub-alternative 3 - Decrease the TACs: Set fishing mortality equal to 50 percent of the maximum acceptable biological catch.

Sub-alternative 4 - Stabilize the TACs: Set fishing mortality equal to the 1994–1998 average fishing mortality.

Sub-alternative 5 - Authorize zero harvest: Set the TACs at zero.

Time/Area Closures (When and Where does harvest occur?)

Sub-alternative 1 - Status quo: Numerous time/area closure schemes are currently in use serving to achieve various conservation objectives. Among the purposes served are closures to minimize fishery interactions with species listed under the Endangered Species Act, prohibited species, and crab habitat.

Sub-alternative 2 - Steller sea lion focus: Add additional closures based on their potential to minimize indirect interactions with Steller sea lion foraging habitat.

Sub-alternative 3 - Prohibited species focus: Add additional closures based on their potential to minimize take of prohibited species.

Sub-alternative 4 - Habitat focus: Add additional closures based on their potential to minimize disturbance of marine substrates.

Sub-alternative 5 - Market focus: Modify seasonal and area restrictions to increase value of harvest and/or improve the efficiency of fishing operations.

Gear Limitations (How is groundfish harvested?)

Sub-alternative 1 - Status quo. Fishing gear as described in regulations with sector allocations made in annual total allowable catch specifications.

Sub-alternative 2 - Further restrict fishing gear contact with the sea floor by banning non-pelagic trawl gear in flatfish fisheries.

Sub-alternative 3 - Restrict use of trawl, longline, and/or pot gear to habitat areas with substrates composed of unconsolidated sediments.

Sub-alternative 4 - Restrict authorized fishing gear to those capable of minimizing bycatch significantly below levels presently considered clean for each directed fishery.

Sub-alternative 5 - Allow all gear types and allow fishermen to select the most effective type.

Public Involvement

Scoping for the programmatic SEIS began with publication of a Notice of Intent in the **Federal Register** on October 1, 1999. This notice extends the scoping period from November 15, to December 15, 1999, to provide the public and NMFS with additional time to refine these alternatives.

Dated: October 27, 1999.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 99–28643 Filed 11–2–99; 8:45 am]

BILLING CODE 3510–22–F

Notices

Federal Register

Vol. 64, No. 212

Wednesday, November 3, 1999

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.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

October 28, 1999.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) The accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) Ways to enhance the quality, utility and clarity of the information to be collected; (d) Ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20503 *and* to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–6746.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Rural Housing Service

Title: 7 CFR Part 3550, Direct Single Family Housing Loan and Grant Programs, HB–1–3550, and HB–2–3550.

OMB Control Number: 0575–0172.

Summary of Collection: The Rural Housing Service (RHS) is a credit agency for rural housing and community development within the Rural Development mission area of the Department of Agriculture. Section 501 of Title V of the Housing Act of 1049, as amended, authorizes the Secretary of Agriculture to administer such programs and to prescribe regulations to ensure that these loans and grants provided with Federal Funds are made to eligible applicants for authorized purposes, and that subsequent servicing and benefits provided to borrowers are consistent with the authorizing statute. RHS offers a supervised credit program to extend financial assistance to construct, improve, alter, repair, replace or rehabilitate dwellings, which will provide modest, decent, safe, and sanitary housing to eligible individuals living in rural areas. To assist individuals in obtaining affordable housing, a borrower's house payment may be subsidized to an interest rate as low as 1%. The information requested by RHS is vital to be able to process applications for RHS assistance and make prudent credit and program decisions. RHS will collect information using several forms.

Need and Use of the Information: RHS will collect information to verify program eligibility requirements; verify continued eligibility requirements for borrower assistance; service loans; to determine eligibility for special servicing assistance such as: payment subsidies, moratorium (stop) on payments, delinquency workout agreements; liquidation of loans; and, debt settlement. The information is used to ensure that the direct Single Family Housing programs are administered in a manner consistent with legislative and administrative requirements. Without this information RHS would be unable to determine if a borrower would qualify for services or if assistance has been granted to which the customer would not be eligible under current regulations and statutes.

Description of Respondents: Individuals or households; business or other for-profit; not-for-profit institutions; State, Local or Tribal Government.

Number of Respondents: 500,000.

Frequency of Responses: Reporting: On occasion; annually.

Total Burden Hours: 923,053.

Agricultural Research Service

Title: Continuing Survey of food Intakes by Individuals (CSFII) 1999–2002.

OMB Control Number: 0518–0023.

Summary of Collection: During the past decade the U.S. diet has been undergoing changes unprecedented in scope and rapidity. Changes reflect increased interest by consumers in foods (variety and taste), nutrition and health, convenience, and availability of new or modified foods or meals from which they may choose. In the next decade, new information will be received on relationships among foods, nutrients, and health which will influence food consumption patterns and nutritional interventions. The objective of the Continuing Survey of Food Intakes by Individuals (CSFII) is to measure current levels and shifts in the food and nutrients consumed by individuals and the nutritional adequacy of diets, signal changes taking place, and provide information for use in evaluating dietary status. The CSFII is a major component of the National Nutrition Monitoring and Related Research Program (NNMRRP). The NNMRRP, which was developed in the early eighties at the request of Congress, was formally established following the passage of the National Nutrition Monitoring and Related Act of 1990 (Pub. L. 101–445). The Agricultural Research Service (ARS) will collect information using telephone surveys and questionnaires.

Need and Use of the Information: ARS will collect information to meet requirements for information on food consumption and dietary status as well as information on foods eaten at home and away. If the information is not collected many regulatory, research, and other programs would be severely limited by the lack of current data on food intakes by individuals.

Description of Responses: Individuals or households.

Number of Respondents: 5,066.

Frequency of Responses: Reporting: Annually.

Total Burden Hours: 17,800.

Farm Service Agency

Title: Farmer Program Account Servicing Policies—7 CFR Part 1951–S.

OMB Control Number: 0560–0161.

Summary of Collection: The Farm Service Agency's (FSA) Farm Loan Program (FLP) provides supervised credit in the form of loans to family farmers and ranchers to purchase land and finance agricultural production. The regulations covering this information collection package describe the policies and procedures the agency will use to service most FLP loans when they become delinquent. These loans include Operating, Farm Ownership, Soil and Water, Softwood Timber Production, Emergency, Economic Emergency, Economic Opportunity, Recreation, and Rural Housing loans for farm service buildings. Servicing of accounts is administered in accordance with the provisions of the Consolidated Farm and Rural Development Act (CONACT) as amended by the Food Security Act of 1985, the Agriculture Credit Act of 1987, the Food Agriculture Conservation and Trade Act of 1990, the Agricultural Credit Improvement Act of 1992, and the Federal Agriculture Improvement and Reform Act of 1996. The Agricultural Credit Act of 1987 was intended to ensure that private individuals who have obtained a loan from the U.S. Treasury through the Department of Agriculture are all treated equally when they default on that loan. FSA will collect information using form FSA–1951–39 and other attachments and exhibits.

Need and Use of the Information: FSA will collect information to determine whether a financially distressed or delinquent borrower's request for loan servicing is warranted. If information is not collected, borrowers may not receive the correct servicing options which could result in the failure of their business and the loss of security property through either voluntary or forced liquidation.

Description of Respondents: Farms; individuals or households; business or other for-profit.

Number of Respondents: 12,013.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 16,116.

Animal and Plant Health Inspection Service

Title: Animal Welfare—Guinea Pigs, Hamsters, and Rabbits.

OMB Control Number: 0579—0092.

Summary of Collection: The Laboratory Animal Welfare Act (AWA) enacted in 1966 and amended in 1970 and 1990 requires the U.S. Department of Agriculture to regulate the humane care and handling of most warm-blooded animals used for research or exhibition purposes, sold as pets, or transported in commerce. The Animal and Plant Health Inspection Service (APHIS) has the responsibility for enforcing the Animal Welfare Act and its provisions. APHIS collects information and requires certain recordkeeping in order to review and evaluate program compliance by regulated facilities and ensure a workable enforcement system to carry out the requirements of the AWA. Specific information collection requirements relate to certifications of shipping containers used to transport guinea pigs, hamsters, and rabbits as well as the conditions (*e.g.*, temperature) necessary during transport, and acclimation certificates.

Need and Use of the Information: APHIS collects information from regulated facilities including dealers, exhibitors, and research facilities, intermediate handlers and carriers, and from accredited veterinarians to ensure proper handling and care for guinea pigs, hamsters, and rabbits. Without this information, APHIS would be unable to detect violations and take appropriate actions consistent with the AWA.

Description of Respondents: Business or other for-profit.

Number of Respondents: 1,470.

Frequency of Responses: Recordkeeping; Reporting: On occasion.

Total Burden Hours: 260.

Food and Nutrition Service

Title: Report of School Program Operations.

OMB Control Number: 0584–0002.

Summary of Collection: The Food and Nutrition Service (FNS) administers the National School Lunch Program, the School Breakfast Program, and the Special Milk Program as mandated by the National School Lunch Act, as amended, and the Child Nutrition Act of 1996, as amended. Information on school program operations is collected from State agencies on a monthly basis to monitor and make adjustments to State agency funding requirements. FNS uses form FNS–10 to collect data, although 95 percent of the information is collected through electronic means.

Need and Use of the Information: FNS collects quantity information from State agencies on the number of meals served under the various food programs. Information is categorized in a number of areas and States are asked to provide their estimates along with actual data. FNS uses the information collected on school operations to assess the progress of the various programs and to make monthly adjustments to State agency funding requirements. If the information was not collected, FNS would be unable to monitor the proper use of program funds.

Description of Respondents: State, Local, or Tribal Government.

Number of Respondents: 62.

Frequency of Responses: Reporting: Monthly; annually.

Total Burden Hours: 95,232.

Animal and Plant Health Inspection Service

Title: 9 CFR 160–162, Veterinary Accreditation Program.

OMB Control Number: 0579–0032.

Summary of Collection: Title 21, U.S.C. authorizes sections 111, 114, 114a, 114–1, 115, 120, 121, 125, 126, 134a, 134c, 134f, and 134g, of 21 U.S.C. These authorities permit the Secretary to prevent, control and eliminate domestic diseases such as brucellosis and tuberculosis, as well as to take actions to prevent and to manage exotic diseases such as foot-and-mouth and rinderpest. Disease prevention is the most effective method for maintaining a healthy animal population and enhancing the Animal and Plant Health Inspection Service's (APHIS) ability to compete in exporting animals and animal products. Because APHIS does not have sufficient numbers of Federal personnel to perform all of the disease prevention work that must be done, APHIS relies heavily on assistance from veterinarians in the private sector. Regulations governing the Veterinary Accreditation Program are found in Title 9 of the Code of Federal Regulations, parts 160, 161, and 162. Operating this important program requires APHIS to engage in a number of information collection activities in the form of applications for veterinary accreditation, veterinary accreditation orientation and training, paperwork associated with tasks performed by our accredited veterinarians (such as completing certificates, applying and removing official seals, and completing test reports); reviewing applications for veterinary accreditation and re-accreditation, recordkeeping, and updating information on accredited veterinarians. APHIS will collect information using several forms.

Need and Use of the Information: APHIS will collect information to determine that a veterinarian has met the requirements for being accredited, or for obtaining re-accreditation. APHIS will also collect information to ensure that accredited veterinarians are knowledgeable of current Federal and State animal health regulations, objectives and programs and they are

competent in their application. If information is not collected it would significantly destroy APHIS' ability to operate the Veterinary Accreditation Program.

Description of Respondents: Business or other for-profit; State, Local or Tribal Government.

Number of Respondents: 56,024.

Frequency of Responses: Recordkeeping; Reporting: On occasion; annually.

Total Burden Hours: 52,190.

Rural Utilities Service

Title: 7 CFR Part 1789, Use of Consultants Funded.

OMB Control Number: 0572–0115.

Summary of Collection: The Rural Utilities Service (RUS) is a credit agency of the U.S. Department of Agriculture. It makes mortgage loans and loan guarantees to finance electric, telecommunications, and water and waste water facilities in rural areas. The RUS loan portfolio totals nearly $42 billion. Loan programs are managed in accordance with the Rural Electrification Act (RE Act) of 1936, 7 U.S.C. 901 *et seq.*, as amended, and as prescribed by Office of Management and Budget Circular A–129, Policies for Federal Credit Programs and Non-Tax Receivable. RUS will collect information through the use of consultants.

Need and Use of the Information: RUS will collect information to determine whether it is appropriate to use a consultant voluntarily funded by the borrower to expedite a particular borrower application.

Description of Respondents: Business or other for-profit.

Number of Respondents: 6.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 12.

Food and Nutrition Service

Title: Report of the Child and Adult Care Food Program.

OMB Control Number: 0584–0078.

Summary of Collection: The Child and Adult Care Food Program is mandated by Section 17 of the National School Lunch Act, as amended. Program implementation is contained in 7 CFR Part 226. The Food and Nutrition Service (FNS) collection information using Form FNS–44 to use in managing the Child and Adult Care Food Program. This report is vital since it is the only means by which FNS can obtain current information necessary to make payments to State agencies and to plan for future levels of program funding.

Need and Use of the Information: FNS will collect information in order to analyze progress in the program and to make monthly adjustments to State agency funding requirements. If data is not collected FNS would be unable to monitor the proper use of program funds.

Description of Respondents: State, Local or Tribal Government.

Number of Respondents: 53.

Frequency of Responses: Reporting: Quarterly; semi-annually; Monthly.

Total Burden Hours: 5,724.

Animal and Plant Health Inspection Service

Title: Importation of Gypsy Moth Host Materials from Canada.

OMB Control Number: 0579–0142.

Summary of Collection: Section 5 of the Plant Quarantine Act (7 U.S.C. 159) authorizes the Secretary of Agriculture to determine whether the unrestricted importation of any plants, fruits, vegetables, roots, bulbs, seeds, or other plant products not included by the term ''nursery stock'' will result in the introduction of plant diseases or insect pests into the United States, and to then specify which of these products will be subject to the provisions of Section 1 of the Plant Quarantine Act. Section 105 and 106 of the Federal Plant Pest Act (7 U.S.C. 150dd, 150ee) authorizes the Secretary to require inspection and treatment of any product when the Secretary deems it necessary to prevent a plant pest from being introduced into the United States. Until now the Animal and Plant Health Inspection Service (APHIS) did not specifically regulate the importation of gypsy moth host materials from foreign countries into the United States. APHIS has determined that the gypsy moth population is growing in certain parts of Canada, and that steps must be taken to prevent the introduction of gypsy moth from Canada into non-infested areas of the United States. APHIS will collect information using phytosanitary certificates, certificates of origin, and signed statements from individuals both within and outside the United States.

Need and Use of the Information: APHIS will collect information to ensure that importing foreign logs, trees, shrubs, and other articles do not harbor plant or insect pests such as the gypsy moth. If the information is not collected it would cripple APHIS' ability to ensure that trees, shrubs, logs, and a variety of other items imported from Canada do not harbor gypsy moths.

Description of Respondents: Business or other for-profit; individuals or households; not-for-profit institutions; farms; State, Local or Tribal Government.

Number of Respondents: 2,120.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 183.

Nancy B. Sternberg,

Departmental Clearance Officer.

[FR Doc. 99–28750 Filed 11–2–99; 8:45 am]

BILLING CODE 3410–01–M

DEPARTMENT OF AGRICULTURE

Office of the Chief Economist; Intent To Establish an Advisory Committee on Small Farms

AGENCY: Office of the Chief Economist, USDA.

ACTION: Notice of intent to establish an Advisory Committee on Small Farms.

SUMMARY: The U.S. Department of Agriculture (USDA) proposes to establish an Advisory Committee on Small Farms (Committee). The purposes of the Committee is to gather and analyze information regarding small U.S. farms and ranches within the United States and its Territories and recommend to the Secretary of Agriculture actions to enhance their viability and economic livelihood. The Committee is in the public interest and within the duties and responsibilities of the Department of Agriculture. Establishment of the Committee also ensures the continued consideration and implementation of the recommendations made by the National Commission on Small Farms in its report, ''A Time to Act''.

FOR FURTHER INFORMATION CONTACT: Alfonzo Drain, 202/720–3238. E-mail address: adrain@nass.usda.gov.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act (5 U.S.C. app. 2), notice is hereby given that the Secretary of Agriculture intends to establish the Advisory Committee on Small Farms, hereinafter referred to as the Committee.

The Committee will monitor government and private sector actions, policy and program proposals that relate to small farms, ranches, and woodlots, including limited-resource farms, ranches, and woodlots; and evaluate the impact such actions and proposals may have upon the viability and growth of small farms, ranches and woodlots; review USDA programs and strategies to implement small farm policy; advise the Secretary on actions to strengthen USDA programs; and evaluate other approaches that the Committee would deem advisable or which the Secretary of Agriculture or the Director of Sustainable Development and Small Farms may request the Committee to consider. The Secretary of Agriculture

shall make all appointments to the Committee and members will serve at the Secretary's discretion. Members will serve two-year terms.

The Committee will have 19 members, one of whom will serve as Chair and be appointed by the Secretary of Agriculture, and one of whom will serve as Vice-Chair as appointed by the Committee. Members will represent small farms, ranches, and woodlot owners and will represent the diverse groups USDA programs serve, including but not limited to, finance, commerce, conservation, cooperatives, nonprofit organizations, rural communities, academia, State and local governments, women and minorities, farmworkers, and other interests as the Secretary determines. USDA will follow equal opportunity practices in making appointments to the Committee. To ensure that recommendations of the Committee take into account the needs of the diverse groups USDA serves, membership will include, to the extent practicable, individuals with demonstrated ability to represent minorities, women, and persons with disabilities.

Dated: October 26, 1999.

Keith Collins,

Chief Economist, Office of the Chief Economist.

[FR Doc. 99–28752 Filed 11–2–99; 8:45 am]

BILLING CODE 3810–01–M

DEPARTMENT OF AGRICULTURE

Agricultural Research Service

Government Owned Inventions Available for Licensing

AGENCY: Agricultural Research Service, USDA.

ACTION: Notice of Government owned inventions available for licensing.

SUMMARY: The inventions listed below are owned by the U.S. Government as represented by the Department of Agriculture, and are available for Licensing in accordance with 35 U.S.C. 207 and 37 CFR part 404 to achieve expeditious commercialization of results of federally funded research and development. Foreign patents are filed on selected inventions to extend market coverage for U.S. companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Technical and licensing information on these inventions may be obtained by writing to June Blalock, Technology Licensing Coordinator, USDA, ARS, Office of Technology Transfer, 5601 Sunnyside Avenue, Room 4–1158, Beltsville, Maryland 20705–5131; telephone: 301–504–5989 or fax: 301–504–5060. Issued patents may be obtained from the Commissioner of Patents, U.S. Patent and Trademark Office, Washington, DC 20231.

SUPPLEMENTARY INFORMATION: The inventions available for licensing are:

S.N. 08/848,146, ''Device and Method for Application of Collars to Animals''

S.N. 08/906,091, ''An Attractant for Social Pest Insects''

S.N. 08/958,475, ''Control of Fire Blight on Pome Fruit Trees with Erwinia Herbicola''

S.N. 09/006,562, ''Noxious Weed Control by Soil Solarization''

S.N. 09/019,155, ''Suppression of Alpha-Amylase Expression Using a Serine/Threonine Protein Kinase''

S.N. 09/033,349, ''Control of Fruit Ripening Through Genetic Control of ACC Synthase Synthesis''

S.N. 09/052,333, ''Transgenic Spacer Target Sequence for Detecting and Distinguishing Chlamydial Stains''

S.N. 09/074,394, ''Method for the Simultaneous and Independent Determination of Moisture Content and Density of Particulate Materials for Radio-Frequency Permittivity Measurements''

S.N. 09/083,852 ''Modification of Cereal Grain Hardness Via Expression of Puroindoline Proteins''

S.N. 09/108,051, ''Species-Specific Genetic Identification of Mycobacterium Paratuberculosis''

S.N. 09/110,132, ''Biological Control of Aflatoxin and Cyclopiazonic Acid Contamination of Crops Using Non-Toxigenic Strain of Asperigillus''

S.N. 09/120,347, ''A Novel Fungal Species for the Biocontrol of the Sugarbeet Root Maggot''

S.N. 09/120,521, ''Attractants for Bactrocera Latiforns (Hendel)''

S.N. 09/122,342, ''Control of Replant Disease of Tree Fruits with Pseudomonas putida''

S.N. 09/126,229, ''Taxane Production from Taxus Species Cell Lines''

S.N. 09/130,788, ''Soluble Hydrocolloid Food Additives and Method of Making''

S.N. 09/131,363, ''Variable-Rate, Digitally-Controlled Fluid Metering Device''

S.N. 09/135,999, ''Starch Microcapsules for Delivery of Active Agents''

S.N. 09/156,348, ''Chemical Attractants for Moths''

S.N. 09/156,625, ''Chemical Attractants for Frugivorous Pest Insects''

S.N. 09/166,655, ''Feeding Attractant and Stimulant for Adult Control of Noctuid and/or Other Lepidopteran Species''

S.N. 09/191,906, ''Mimetic Insect Allatostatin Analogs for Insect Control''

S.N. 09/201,449, ''Stabilization of Pet Operon Plasmids and Ethanol Production in Bacterial Strains Lacking Lactate Dehydrogenase and Pyruvate-Formate Lyase Activities''

S.N. 09/204,864, ''Determination of Concentration of a Compound in a Multiple Component Fluid''

S.N. 09/208,449, ''Apparatus and Process for the Rapid Tenderization of Meat''

S.N. 09/211,017, ''Method for the Development of Delta-Lactones and Hydroxy Acids from Unsaturated Fatty Acids and Their Glycerides''

S.N. 09/233,761, ''Paper Coated with Polymerized Vegetable Oils for Use as Biodegradable Mulch''

S.N. 09/252,945, ''Release Rate Modulator and Method for Producing and Using Same''

S.N. 09/257,730, ''Biological Control of Sprouting in Stored Potatoes''

S.N. 09/258,304, ''Sex Pheromone Synergist''

S.N. 09/266,950, ''Ferritin Formation as a Predictor of Iron Availability in Foods''

S.N. 09/281,276, ''Edible Food Coatings Containing Polyvinyl Acetate''

S.N. 09/302,962, ''Extraction of Pectin by Microwave Heating Under Pressure''

S.N. 09/330,365, ''Fruit and Vegetable Based Edible Film Wraps and Methods to Improve the Quality and Extend Shelf Life of Foods''

S.N. 09/336,220, ''Real Time Trash Measurement System for Seed Cotton or Lint for Use in Cotton Gins''

S.N. 09/345,236, ''A Baculovirus for the Biocontrol Control of Larval Mosquitoes''

S.N. 09/347,907, ''Aggregation Pheromone for the Asian Longhorned Beetle''

S.N. 09/353,087, ''Composition and Method for the Control of Diabroticite Insects''

S.N. 09/353,348, ''Monoclonal Antibodies and Antibody Cocktail for Detection of Prion Protein as an Indication of Transmissible Spongiform Encephalopathies''

S.N. 09/353,643, ''Ant Bait Attractive to Multiple Species of Ants''

S.N.09/353,713, ''An Autonomous Animal Control System Without Ground Based Fencing''

S.N. 09/354,446, ''Use of Indigenous Bacterial Enzymatic and Regulatory Processes to Control Enteropathogens Associated with Food Producing Animals''

S.N. 09/360,083, ''Novel System for the Sequential, Directional Cloning of Multiple DNA Sequences''
S.N. 09/364,447, ''Recombinant Bacteria Which Produce Lipase and Poly (B-Hydroxyalkanoates)''
S.N. 09/366,603, ''Vaccines for the Protection of Cattle from Psoroptic Scabies''
S.N. 09/376,755, ''Process for the Enzymatic Conversion of Podophyllotoxin Beta-Glucopyranosides and other Podophyllum Blycosides to Their Corresponding Aglycons''
S.N. 09/377,513, ''Novel Cytoplasm for Maize''
S.N. 09/378,441, ''Biodegradable Films from Agricultural Polymers''
S.N. 09/395,565, ''Insulin Potentiating Compounds in Cinnamon''
S.N. 09/400,799, ''Process for the Production of Fatty Acid Esters''

June Blalock,

Technology Licensing Coordinator.

[FR Doc. 99–28753 Filed 11–2–99; 8:45 am]

BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Forest Service

Gunflint Corridor Fuels Reduction Environmental Impact Statement

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an Environmental Impact Statement.

SUMMARY: On August 24, 1999, the Council on Environmental Quality granted alternative arrangements for the immediate actions needed to address public safety concerns within the Gunflint Trail Corridor as a result of the 4th of July Blowdown Event. These alternative arrangements are effective until close of business on Friday, December 24, 1999. Subsequent actions which the Agency (Forest Service) proposed to take over the ''longer term'' were to be addressed through the normal NEPA process. Therefore, the Department of Agriculture, Forest Service, will prepare an Environmental Impact Statement (EIS) to reduce the fire hazard and restore damaged components of the ecosystem within the Gunflint Corridor. The objectives of the project are to: (1) Reduce fuel and fire hazard, (2) Provide and improve land-based infrastructure needs for fire suppression or public evacuation, (3) Increase the acreage and component of longer lived species, particularly pine, (4) Improve long term visual quality, and (5) Reforest blown-down areas. The Record of Decision will disclose how the Forest Service has decided to treat more than 11,000 acres of blowdown fuels. The proposed action is to treat an estimated 8400 acres with mechanical means such as commercial timber sales or service contract for piling and burning; treat 3000 acres with prescribed fire; and treat 100 acres with service contracts for hand treatment. A range of alternatives responsive to significant issues will be developed, including a no-action alternative. The proposed project is located on the Gunflint Ranger District, Grand Marais, MN, Superior National Forest. The Gunflint Ranger District is requesting the project be considered an emergency under CFR 215.10(d)(1).

DATES: Comments concerning the scope of this project should be received by December 6, 1999.

ADDRESSES: Please send written comments to: Gunflint Ranger District, Superior National Forest, Attn.: Gunflint Corridor Fuels Reduction EIS, P.O. Box 790, Grand Marais, MN 55604.

FOR FURTHER INFORMATION CONTACT: Jo Barnier, District Ranger, or Becky Bartol, Team Leader, Gunflint Ranger District, Superior National Forest, P.O. Box 790, Grand Marais, MN 55604, telephone (218) 387–1750.

SUPPLEMENTARY INFORMATION: Public participation will be an integral component of the study process and will be especially important at several points during the analysis. The first is during the scoping process. The Forest Service will be seeking information, comments, and assistance from Federal, State and local agencies, individuals, and organizations that may be interested in, or affected by, the proposed activities. The scoping process will include: (1) Identification of potential issues, (2) identification of issues to be analyzed in depth, and (3) elimination of insignificant issues or those which have been covered by a previous environmental review. Written scoping comments will be solicited through a scoping package that will be sent to the project mailing list and to the local newspaper. For the Forest Service to best use the scoping input, comments should be received by December 6, 1999. Issues identified for analysis in the EIS include the potential effects of the project on and the relationship of the project to: Fuel hazard reduction, riparian areas and Shipstead Newton Nolan areas, reforestation, temporary roads, inventoried candidate special management complexes, roadless areas, and others.

Based on the results of scoping and the resource capabilities within the Project Area, alternatives, including a no-action alternative, will be developed for the Draft EIS. The Draft EIS is projected to be filed with the Environmental Protection Agency (EPA) in February 2000. The Final EIS is anticipated in May 2000.

The comment period on the Draft EIS will be a minimum of 45 days from the date the EPA publishes the Notice of Availability in the **Federal Register**.

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of Draft EISs must structure their participation in the environmental review of the proposal, so that it is meaningful and alerts an agency to the reviewer's position and contentions (*Vermont Yankee Nuclear Power Corp.* v. *NRDC,* 435 U.S. 519, 553, (1978)). Environmental objections that could have been raised at the Draft EIS stage may be waived or dismissed by the courts (*City of Angoon* v. *Hodel,* 803 F.2nd 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc.* v. *Harris,* 490 F. Supp. 1334, 1338 (E.D. Wis. 1980)). Because of these court rulings, it is very important that those interested in this Proposed Action, participate by the close of the 45-day comment period, so that substantive comments and objections are made available to the Forest Service at a time when they can be meaningfully considered and responded to in the Final EIS.

To assist the Forest Service in identifying and considering issues and concerns of the Proposed Action, comments during scoping and on the Draft EIS should be as specific as possible and refer to specific pages or chapters. Comments may address the adequacy of the Draft EIS or the merits of the alternatives formulated and discussed. In addressing these points reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act in 40 CFR 1503.3. Comments received in response to this solicitation, including names and addresses of those who comment, will be considered part of the public record on this Proposed Action and will be available for public inspection. Comments submitted anonymously will be accepted and considered. Pursuant to 7 CFR 1.27(d), any person may request the agency to withhold a submission, from the public record, by showing how the Freedom of Information Act (FOIA) permits such confidentiality. Requesters should be aware that, under FOIA, confidentiality may be granted in only very limited circumstances, such as to

protect trade secrets. The Forest Service will inform the requester of the agency's decision regarding the request for confidentiality. If the request is denied, the agency will return the submission and notify the requester that the comments may be resubmitted with or without name and address within seven days.

Permits/Authorizations

The proposed action includes prescribed burning in the Boundary Waters Canoe Area Wilderness. An amendment to the Superior National Forest Land and Resource Management Plan would be needed for such burns. James W. Sanders, Forest Supervisor, Superior National Forest, would be the responsible official for the plan amendment.

Responsible Official

Jo Barnier, Gunflint District Ranger, Superior National Forest, is the responsible official. In making the decision, the responsible official will consider the comments, responses, disclosure of environmental consequences, and applicable laws, regulations, and policies. The responsible official will state the rationale for the chosen alternative in the Record of Decision.

Dated: October 27, 1999.

Jo Barnier,

District Ranger.

[FR Doc. 99–28699 Filed 11–2–99; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

John Day/Snake Resource Advisory Council, Hells Canyon Subgroup

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Hells Canyon Subgroup of the John Day/Snake Resource Advisory Council will meet on November 22 and 23, 1999 at the Baker Ranger District of the Wallowa-Whitman National Forest, 3165 10th Street, Baker City, Oregon. The meeting will begin at 9:00 a.m. and continue until 5:00 p.m. the first day and will begin at 9:00 a.m. and continue until 4:00 p.m. on the second day. Agenda items to be covered include: (1) Review draft CMP alternatives and, (2) Open public forum. All meetings are open to the public. Public comments will be received at 1:00 p.m. on November 22.

FOR FURTHER INFORMATION CONTACT: Direct questions regarding this meeting to Kendall Clark, Area Ranger, USDA, Hells Canyon National Recreation Area, 88401 Highway 82, Enterprise, OR 97828, 541–426–5501.

Dated: October 28, 1999.

Kurt R. Wiedenmann,

Acting Deputy Forest Supervisor.

[FR Doc. 99–28701 Filed 11–2–99; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Sunshine Act Meeting; Notice

AGENCY: Rural Telephone Bank, USDA.

ACTION: Staff briefing for the Board of Directors.

TIME AND DATE: 2:00 p.m., Monday, November 8, 1999.

PLACE: Room 5030, South Building, Department of Agriculture, 1400 Independence Avenue, SW, Washington, DC.

STATUS: Open.

MATTERS TO BE DISCUSSED:

1. Current telecommunications industry issues.
2. Fiscal year 2000 agency budget.
3. Status of PBO planning and general discussion on privatization of the Bank.
4. Options relating to the conversion of B stock to C stock.
5. Current method for allocating patronage refunds to class B stockholders.
6. Administrative issues.

ACTION: Board of Directors Meeting.

TIME AND DATE: 9:00 a.m., Tuesday, November 9, 1999.

PLACE: The Williamsburg Room, Room 104–A, Jamie L. Whitten Building, Department of Agriculture, 1400 Independence Avenue, SW, Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED: The following matters have been placed on the agenda for the Board of Directors meeting:

1. Call to order.
2. Action on Minutes of the August 6, 1999, board meeting.
3. Report on loans approved in FY 1999.
4. Summary of financial activity for FY 1999.
5. Privatization committee report.
6. Consideration of resolution of appreciation for former Governor Wally Beyer.
7. Establish dates and locations for Year 2000 board meetings.
8. Adjournment.

CONTACT PERSON FOR MORE INFORMATION: Roberta D. Purcell, Assistant Governor, Rural Telephone Bank, (202) 720–9554.

Dated: October 27, 1999.

Christopher A. McLean,

Acting Governor, Rural Telephone Bank.

[FR Doc. 99–28841 Filed 11–1–99; 9:50 am]

BILLING CODE 3410–15–P

DEPARTMENT OF COMMERCE

International Trade Administration

August 1999 Sunset Reviews: Termination of Review, Final Results of Reviews and Revocation and Termination

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of termination of five-year (''Sunset'') review of the antidumping duty order on kiwifruit from New Zealand (A–614–801); Final Results of Sunset Reviews: Revocation of Antidumping Duty Order on Tungsten Ore Concentrates from the People's Republic of China (A–570–811) and termination of the suspended antidumping duty investigation on uranium from Krygyzstan (A–835–802).

SUMMARY: On August 2, 1999, the Department of Commerce (''the Department'') initiated sunset reviews of the antidumping duty orders on kiwifruit from New Zealand and tungsten ore concentrates from the People's Republic of China (''PRC''), and of the suspended antidumping duty investigation of uranium from Krygyzstan. The Department is terminating the sunset review of the order on kiwifruit from New Zealand on the basis that, on September 17, 1999, the Department issued the final results of a changed circumstances review and revoked this order. Further, because no domestic party responded to the sunset review notice of initiation by the applicable deadline, the Department is revoking the order on tungsten ore concentrates from the PRC and terminating the suspended investigation on uranium from Krygyzstan.

EFFECTIVE DATE: January 1, 2000.

FOR FURTHER INFORMATION CONTACT: Martha V. Douthit or Melissa G. Skinner, Office of Policy, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, D.C. 20230; telephone: (202) 482–5050 or (202) 482–1560, respectively.

SUPPLEMENTARY INFORMATION:

Background

The Department issued antidumping duty orders on kiwifruit from New

Zealand (57 FR 23203 (June 2, 1992)) and tungsten ore concentrates from the People's Republic of China (56 FR 58681 (November 21, 1991)). Further, the Department suspended the antidumping duty investigation on uranium from Krygyzstan (57 FR 49220 (October 30, 1992)). Pursuant to section 751(c) of the Tariff Act of 1930, as amended (''the Act''), the Department initiated sunset reviews of these orders and suspended investigation by publishing notice of the initiation in the **Federal Register** (64 FR 41915 (August 2, 1999)). In addition, as a courtesy to interested parties, the Department sent letters, via certified and registered mail, to each party listed on the Department's most current service list for these proceedings to inform them of the automatic initiation of the sunset reviews on these orders and suspended investigation.

No domestic interested party in the sunset reviews on these orders responded to the notice of initiation by the August 17, 1999 deadline (*see* section 351.218(d)(1)(i) of *Procedures for Conducting Five-year (''Sunset'') Reviews of Antidumping and Countervailing Duty Orders,* 63 FR 13520 (March 20, 1998) (''*Sunset Regulations*'')).

In the sunset review of the suspended antidumping investigation on uranium from Kyrgyzstan, we received notices of intent to participate from domestic interested parties: USEC Inc. and its subsidiary, United States Enrichment Corporation (collectively ''USEC''), the Paper, Allied-Industrial, Chemical & Energy Workers International Union, AFL-CIO (''PACE''), and the Ad Hoc Committee of Domestic Uranium Producers (the ''Ad Hoc Committee''). However, the Ad Hoc Committee, PACE, and USEC withdrew their notices of intent to participate on August 17, August 18, and August 23, 1999, respectively. Further, the Department did not receive a complete substantive response from any domestic interested party (in this case no response) by the September 1, 1999, deadline. (*See* § 351.218(d)(1)(i)). Therefore, the Department has determined that no domestic interested party intends to participate in the sunset review of this suspended investigation.

Determination

Pursuant to section 751(c)(3)(A) of the Act and § 351.218(d)(1)(iii)(B)(3) of the *Sunset Regulations,* if no domestic interested party responds to the notice of initiation, the Department shall issue a final determination, within 90 days after the initiation of the review, revoking the order or terminating the suspended investigation. Because no domestic interested party in the sunset review of tungsten ore concentrates from the PRC responded to the notice of initiation by the applicable deadline, August 17, 1999, we are revoking this antidumping duty order. Additionally, because USEC, PACE and Ad Hoc Committee of Domestic Uranium withdrew their notices of intent to participate and no other domestic interested party filed a substantive response (*see* § § 351.218(d)(1)(i) and 351.218(d)(3) of the *Sunset Regulations*), we are terminating the suspended antidumping duty investigation on uranium from Kyrgyzstan.

Further, the Department revoked the antidumping duty order on kiwifruit from New Zealand on September 17, 1999, effective June 1, 1997. Pursuant to the Department's *Final Results of Changed Circumstances Review; Revocation of the Order on Kiwifruit from New Zealand,* the Department has instructed the United States Customs Service to terminate the liquidation of merchandise subject to the antidumping duty order on kiwifruit from New Zealand effective June 1, 1997 (*see Fresh Kiwifruit From New Zealand: Final Results of Changed Circumstances Review; Revocation of Order,* 64 FR 50486). Because the antidumping duty order on kiwifruit from New Zealand was revoked as a result of a changed circumstances review, we are terminating the sunset review of this order.

Effective Date of Revocation and Termination

Pursuant to section 751(c)(6)(A)(iv) of the Act, the Department will instruct the United States Customs Service to terminate the suspension of liquidation of the merchandise subject to the antidumping duty order on tungsten ore concentrates from the PRC entered, or withdrawn from warehouse, on or after January 1, 2000. Entries of subject merchandise prior to the effective date of revocation will continue to be subject to suspension of liquidation and antidumping duty deposit requirements. The suspension agreement on uranium from Kyrgzystan will remain in effect until January 1, 2000. The Department will complete any pending administrative reviews of the order and this suspension agreement and will conduct administrative reviews of all entries prior to the effective date of revocation or termination in response to appropriately filed requests for review.

Dated: October 28, 1999.

Richard W. Moreland,

Acting Assistant Secretary for Import Administration.

[FR Doc. 99–28763 Filed 11–2–99; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–815 & A–580–816]

Certain Cold-Rolled and Corrosion-Resistant Carbon Steel Flat Products From Korea: Extension of Time Limit for Final Results of the Antidumping Duty Administrative Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of extension of time limit for final results of antidumping duty administrative reviews.

SUMMARY: The Department of Commerce (''the Department'') is extending the time limit for the final results for the fifth reviews of certain cold-rolled and corrosion-resistant carbon steel flat products from Korea. These reviews cover the period August 1, 1997 through July 31, 1998. The extension is made pursuant to section 751(a)(3)(A) of the Tariff Act of 1930, as amended.

EFFECTIVE DATE: November 3, 1999.

FOR FURTHER INFORMATION CONTACT: Becky Hagen at (202) 482–3362 or Robert Bolling at (202) 482–3434; Office of AD/CVD Enforcement, Group III, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW, Washington, DC 20230.

The Applicable Statute

Unless otherwise indicated, all citations to the Tariff Act of 1930 (''the Act'') are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Rounds Agreements Act.

Postponement of Final Results

On September 8, 1999, the Department published the preliminary results for this review. *See* 64 FR 48767. Section 751(a)(3)(A) of the Act requires the Department to complete an administrative review within 120 days of publication of the preliminary results. However, if it is not practicable to complete the review within the 120-day time limit, section 751(a)(3)(A) of the Act allows the Department to extend the time limit to180 days from the date of

publication of the preliminary results. The Department has determined that it is not practicable to issue its final results within the original 120-day time limit (*See* Decision Memorandum from Joseph A. Spetrini to Robert LaRussa dated October 21, 1999). We are therefore extending the deadline for the final results in this review to 180 days from the date on which the notice of preliminary results was published. The fully extended deadline for the final results is March 6, 2000.

Dated: October 28, 1999.

Joseph A. Spetrini,

Deputy Assistant Secretary Enforcement Group III.

[FR Doc. 99–28766 Filed 11–2–99; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–848]

Notice of Extension of Time Limit for Preliminary Results of New-Shipper Antidumping Review: Freshwater Crawfish Tail Meat From the People's Republic of China

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: November 3, 1999.

FOR FURTHER INFORMATION CONTACT: Sarah Ellerman or Maureen Flannery, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–4106 and (202) 482–3020, respectively.

The Applicable Statute

Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended (the Act) are to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act. In addition, unless otherwise indicated, all citations to the Department's regulations are to 19 CFR part 351 (1998).

Background

On March 30, 1999, the Department of Commerce received a request from Yancheng Haiteng Aquatic Products & Foods Co., Ltd., to conduct a new shipper review of the antidumping duty order on freshwater crawfish tail meat from the People's Republic of China. On April 30, 1999, the Department initiated this new shipper antidumping review covering the period September 1, 1998, through February 28, 1999 (64 FR 24328, published May 6, 1999).

Extension of Time Limits for Preliminary Results

The Department has determined that the issues are extraordinarily complicated and it is not practicable to complete this review within the time limits mandated by section 751(a)(2)(B)(iv) of the Act and 19 CFR 351.214 (i)(2) of the Department's regulations. Therefore, in accordance with these sections, the Department is extending the time limits for the preliminary results to February 24, 2000. The final results continue to be due 90 days after the issuance of the preliminary results. This extension of time limits is in accordance with section 751(a)(2)(B)(iv) of the Act, and 19 CFR 351.214(i)(2) of the Department's regulations.

Dated: October 25, 1999.

Joseph A Spetrini,

Deputy Assistant Secretary for AD/CVD Enforcement III.

[FR Doc. 99–28765 Filed 11–2–99; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–837]

Large Newspaper Printing Presses and Components Thereof, Whether Assembled or Unassembled, From Japan: Preliminary Results of Changed Circumstances Antidumping Duty Administrative Review and Intent To Revoke Antidumping Order, In Part

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of preliminary results of changed circumstances and intent to revoke antidumping duty order, in part.

SUMMARY: At the request of Goss Graphic Systems, Inc., the petitioner and a U.S. producer of the subject merchandise, the Department of Commerce is conducting a changed circumstances administrative review of the antidumping duty order on large newspaper printing presses and components thereof, whether assembled or unassembled, from Japan to determine whether to revoke in part the order with respect to large newspaper printing presses and components thereof, whether assembled or unassembled. Goss states that it has no interest in maintaining the antidumping duty order on subject merchandise from Japan with respect to the specific category of large newspaper printing presses and components thereof, whether assembled or unassembled, identified in its request. We preliminarily determine to revoke the order, in part, with respect to these specific systems, as described below under ''Scope of Review.'' We invite interested parties to comment on these preliminary results.

EFFECTIVE DATE: November 3, 1999.

FOR FURTHER INFORMATION CONTACT: David J. Goldberger or Dinah McDougall, Office 2, AD/CVD Enforcement Group I, Import Administration, Room B099, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington D.C. 20230; telephone (202) 482–4136 or (202) 482–3773, respectively.

The Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930 (the Act) by the Uruguay Round Agreements Act. In addition, unless otherwise indicated, all citations to the Department of Commerce's (''Department's'') regulations are to the regulations at 19 CFR Part 351 (1999).

SUPPLEMENTARY INFORMATION:

Background

On September 4, 1996, the Department published in the **Federal Register** (61 FR 46621) the antidumping duty order on large newspaper printing presses (''LNPP'') and components thereof, whether assembled or unassembled, from Japan. On May 28, 1999, Goss Graphic Systems, Inc. (''Goss'') requested that the Department conduct a changed circumstances administrative review to determine, pursuant to 19 CFR 351.216(b), whether to revoke in part the antidumping duty order on LNPPs from Japan with regard to imports of the elements and components of LNPP systems, and additions thereto, imported to fulfill a contract for one or more complete LNPP systems, as described in detail below under ''Scope of Review.'' Goss states that it is no longer interested in maintaining the order as applied to the category of merchandise described in the request.

KBA North America (''KBA''), a U.S. producer and an affiliate of the German respondent Koenig & Bauer-Albert AG in the German less-than-fair-value (''LTFV'') investigation of LNPP from Germany, Tokyo Kikai Seisakusho, Ltd.

(''TKS''), a respondent in the current administrative review of the order on LNPPs from Japan, and MAN Roland, Inc. (''MAN Roland''), a U.S. producer and an affiliate of the other respondent in the German LTFV investigation, MAN Roland Druckmaschinen AG, submitted comments in opposition to Goss' request, which they note, among other things, is limited to a very specific product covered by the antidumping duty order. KBA has also questioned Goss' claim that it represents ''substantially all'' of the U.S. industry. Mitsubishi Heavy Industries, Ltd. (''MHI''), the other respondent in the current administrative review of the order on LNPPs from Japan, supports Goss' request.

Scope of Review

The products covered by this changed circumstances review are elements and components of LNPP systems, and additions thereto, imported to fulfill a contract for one or more complete LNPP systems which feature a 22 inch cut-off, 50 inch web width and a rated speed no greater than 75,000 copies per hour. In addition to the specifications set out in this paragraph, all of which must be met in order for the product to fall within this changed circumstances review, the product must also possess all of the specifications detailed in the five (5) numbered sections following this paragraph and in any figures referenced below. If one or more of these criteria is not fulfilled, the product is not within the scope of this changed circumstances review:

1. *Printing Unit:* A printing unit which is a color keyless blanket-to-blanket tower unit with a fixed gain infeed and fixed gain outfeed, with a rated speed no greater than 75,000 copies per hour, which includes the following features:

- Each tower consisting of four levels, one or more of which must be populated.
- Plate cylinders which contain slot lock-ups and blanket cylinders which contain reel rod lock-ups both of which are of solid carbon steel with nickel plating and with bearers at both ends which are configured in-line with bearers of other cylinders.
- Keyless inking system which consists of a passive feed ink delivery system, an eight roller ink train, and a non-anilox and non-porous metering roller.
- The dampener system which consists of a two nozzle per page spraybar and two roller dampener with one chrome drum and one form roller.
- The equipment contained in the color keyless ink delivery system is designed to achieve a constant, uniform feed of ink film across the cylinder without ink keys. This system requires use of keyless ink which accepts greater water content.

2. *Folder:* A module which is a double 3:2 rotary folder with 160 pages collect capability and double (over and under) delivery, with a cut-off length of 22 inches. The upper section consists of three-high double formers (total of 6) with six sets of nipping rollers.

3. *RTP:* A component which is of the two-arm design with core drives and core brakes, designed for 50 inch diameter rolls; and arranged in the press line in the back-to-back configuration (left and right hand load pairs).

4. *Conveyance and Access Apparatus:* Conveyance and access apparatus capable of manipulating a roll of paper more than two newspaper broadsheets across through the production process, and a drive system which is of conventional shafted design.

5. *Computerized Control System:* A computerized control system, which is any computer equipment and/or software designed specifically to control, monitor, adjust, and coordinate the functions and operations of large newspaper printing presses or press components.

The order with regard to imports of other LNPPs is not affected by this request.

Preliminary Results of Changed Circumstances Antidumping Duty Administrative Review

Pursuant to section 751(d) of the Act, the Department may partially revoke an antidumping duty order based on a review under section 751(b) of the Act. Section 782(h)(2) of the Act and § 351.222(g)(1)(i) of the Department's regulations provide that the Department may revoke an order (in whole or in part) if it determines that producers accounting for substantially all of the production of the domestic like product have no further interest in the order, in whole or in part. The Department interprets ''substantially all'' production to mean at least 85 percent of production of the domestic like product (*i.e.*, the merchandise produced in the United States that corresponds to the scope of the proceeding) (*see, e.g., Preliminary Results of Changed Circumstances Antidumping Duty Administrative Review : Oil Country Tubular Goods From Mexico*, 64 FR 14213–14214, March 24, 1999).

In order to determine whether ''substantially all'' of the domestic producers supported revocation in part of the order, the Department requested domestic production information from Goss and KBA (MAN Roland did not identify any domestic production). Based on their responses, we have preliminarily determined that Goss represents at least 85 percent of the domestic production of the domestic like product and thus accounts for ''substantially all'' of the production of the domestic like product. This lack of interest by the domestic industry constitutes sufficient changed circumstances to warrant partial revocation of the order (*see, e.g., Final Results of Changed Circumstances Antidumping Duty and Countervailing Duty Reviews, and Revocation of Orders in Part: Certain Cut-To-Length Carbon Steel Plate from Finland, Germany and the United Kingdom*, 64 FR 46343, August 25, 1999). The objections raised by other interested parties do not provide a basis for rejecting Goss' request. Therefore, the Department is notifying the public of its intent to revoke in part the antidumping duty order on LNPP from Japan with respect to the import of the elements and components of LNPP systems and additions thereto as described above.

If final revocation in part occurs, we intend to instruct the U.S. Customs Service (Customs) to liquidate without regard to antidumping duties, and to refund any estimated antidumping duties collected for all entries, of the merchandise described above, made on or after September 4, 1996, as requested by the petitioner. Further, we intend to issue instructions to Customs requiring that a party importing the merchandise described above submit a certification to Customs certifying that the imported merchandise meets the specifications of the merchandise covered by the revocation in part. The current requirement for a cash deposit of estimated antidumping duties on LNPP from Japan with regard to the specified merchandise will continue unless and until we publish a final determination to revoke in part.

Public Comment

Interested parties are invited to comment on these preliminary results. Parties who submit argument in this proceeding are requested to submit with the argument (1) a statement of the issue, and (2) a brief summary of the argument. Any interested party may request a hearing within 10 days of the date of publication of this notice. Any hearing, if requested, will be held no later than 25 days after the date of publication of this notice, or the first workday thereafter. Case briefs may be submitted by interested parties not later than 15 days after the date of publication of this notice. Rebuttal

briefs, limited to the issues raised in the case briefs, may be filed not later than 20 days after the date of publication of this notice. All written comments shall be submitted in accordance with 19 CFR 351.303 and shall be served on all interested parties on the Department's service list in accordance with 19 CFR 351.303. Persons interested in attending the hearing should contact the Department for the date and time of the hearing. The Department will publish the final results of this changed circumstances review, including the results of its analysis of issues raised in any written comments.

This notice is in accordance with sections 751(b)(1) and 777(i)(1) of the Act and 19 CFR 351.216 and 351.222.

Dated: October 28, 1999.

Richard Moreland,

Acting Assistant Secretary for Import Administration.

[FR Doc. 99–28762 Filed 11–2–99; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–501]

Notice of Extension of Time Limit for Preliminary Results of Antidumping Administrative Review: Natural Bristle Paint Brushes and Brush Heads From the People's Republic of China

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of extension of time limit for preliminary results of antidumping administrative review.

EFFECTIVE DATE: November 3, 1999.

FOR FURTHER INFORMATION CONTACT: Andrew Nulman or Maureen Flannery, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–4052 and (202) 482–3020, respectively.

The Applicable Statute

Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended (''the Act'') are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act.

Background

On February 23, 1999, the Department of Commerce (the Department) received a request from Hebei Animal By-Products Import and Export Corporation (HACO) to conduct an administrative review of the antidumping duty order on natural bristle paint brushes and brush heads from the People's Republic of China (PRC). On February 26, 1999, the Department received a request from petitioner, the Paint Applicator Division of the American Brush Manufacturers Association, to conduct an administrative review of Hunan Provincial Native Produce and Animal By-Products Import and Export Corporation. On March 19, 1999, the Department initiated an antidumping administrative review of these firms covering the period February 1, 1998 through January 31, 1999 (64 FR 14860, published March 29, 1999).

Extension of Time Limit for Preliminary Results

Under Section 751(a)(3)(A) of the Act, the Department may extend the deadline for completion of an administrative review if it determines that it is not practicable to complete the review within the statutory time limit. Due to the complexity of certain issues in this case, the Department has determined that it is not practicable to complete this review within the time limits mandated by section 751(a)(3)(A) of the Act. See Memorandum from Joseph A. Spetrini to Robert S. LaRussa, *Extension of Time Limit for the Preliminary Results of the Antidumping Duty Administrative Review of Natural Bristle Paint Brushes and Brush Heads from the PRC,* dated October 27, 1999, on file in Room B–099 of the main Commerce building. Therefore, the Department is extending the time limit for the preliminary results of this review to February 28, 2000. This extension of the time limit is in accordance with Section 751(a)(3)(A) of the Act.

Dated: October 27, 1999.

Joseph A. Spetrini,

Deputy Assistant Secretary for AD/CVD Enforcement III.

[FR Doc. 99–28764 Filed 11–2–99; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Commerce Advisory Committee on Africa: Membership

AGENCY: International Trade Administration, Commerce.

ACTION: Notice of committee establishment and membership opportunity.

SUMMARY: A committee comprised of U.S. businesses active in Sub-Saharan Africa is to be established to advise the Secretary on issues of U.S. commercial policy in Africa. This action is taken to ensure regular consultation with the U.S. business community and to reflect its views in the Clinton Administration's Africa Initiative. The Advisory Committee will meet quarterly, or more often as determined by the Secretary.

DATES: In order to receive full consideration, requests must be received no later than November 31, 1999.

ADDRESSES: Please send your requests for consideration to Mrs. S.K. Miller, Director, Office of Africa by fax on 202/482–5198 or by mail at Room 2037, U.S. Department of Commerce, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Mrs. S.K. Miller, Director, Office of Africa, Room 2037, U.S. Department of Commerce, Washington, DC 20230; telephone: 202/482–4227.

Notice of Committee Establishment

In accordance with the provisions of the Federal Advisory Committee Act, 5 U.S.C. App. 2, and the General Services Administration (GSA) rule on Federal Advisory Committee Management, 41 CFR Part 101–6, and, after consultation with GSA, the Secretary of Commerce has determined that the establishment of the Advisory Committee on Africa is in the public interest in connection with the performance of duties imposed on the Department by law.

In furtherance of the President's Africa Initiative, the Committee will advise the Secretary, through the Under Secretary for International Trade, on U.S. commercial policy on trade with Sub-Saharan Africa.

The ACA will be composed of not more than 21 individuals representing companies, and will be chaired by Secretary of Commerce William M. Daley. To assure a balanced representation of interests, members will be selected based on the criteria set forth below, to obtain a balance in industry sectors, company size, location, gender and ethnic representation.

The Committee will function solely as an advisory body, and in compliance with the provisions of the Federal Advisory Committee Act. The Charter will be filed under the Act, fifteen days from the publication of this notice.

The inaugural meeting of the ACA is expected to take place during the first quarter of the year 2000. Meetings will be scheduled quarterly throughout the year at the Department's headquarters. Additional meetings may be called as determined by the Secretary.

Notice of Opportunity To Apply for Membership

Membership Obligations

Members will be expected to serve a term of two years. However, to set up a staggered membership renewal, one-third of the private sector members from this initial appointment will serve for a two year term; a second third will serve for a three year term and a final third for a four year term. Each year, a third of the ACA membership will be replaced.

Nominations are now being sought for private sector members to serve for a two, three, or four year period from January 1, 2000 until December 31, 2001–2004, respectively. Members will serve at the discretion of the Secretary and shall serve as representatives of the business community and, specifically, the industry in which their business is engaged. They are expected to participate fully in implementing the Committee's work program. It is expected that private sector individuals chosen for ACA membership will attend not less than 75% of the ACA meetings each year.

Private sector members are fully responsible for travel, per diem, and personal expenses associated with their participation on the ACA.

The ACA will work on issues of common interest to encourage trade and investment, including the following:

—Resolving obstacles to trade and investment between the United States and Africa;
—Expanding commercial activity between the United States and Africa and identifying commercial opportunities;
—Developing sectoral or project-oriented approaches to expand business opportunities;
—Identifying further steps to facilitate and encourage the development of commercial expansion between the United States and Africa; and
—Taking any other appropriate steps for fostering commercial relations between the U.S. and Africa.

Criteria

In order to be eligible for membership in the U.S. section, potential candidates must be:

(1) U.S. citizens or permanent residents;

(2) CEOs or other senior management level employees of a U.S. company or organization with demonstrated involvement in trade with and/or investment in Sub-Saharan Africa who will participate in not less than 75% of the meetings, which will be held in the United States. Representative nominated should be the individual who will actively participate in the ACA;

(3) Not a Registered Foreign Agent; and

(4) Actively doing business in Sub-Saharan Africa or actively developing entry plans for doing business in Sub-Saharan Africa.

To the extent possible, the Department of Commerce will strive to achieve membership composition that reflects U.S. entrepreneurial diversity. Therefore, in reviewing eligible candidates, the Department of Commerce will consider such selection factors as:

(1) Depth of experience in the Sub-Saharan African market;

(2) Export/investment experience;

(3) Representation of industry or service sectors of importance to our commercial relationship with Sub-Saharan Africa;

(4) Company size or, if an organization, size and number of member companies;

(5) Location of company or organization; and

(6) Contribution to the Committee's ethnic and gender diversity.

To apply for membership, please provide a company information sheet and a personal resume and any other pertinent information which demonstrate how the applicant satisfies the selection criteria identified.

Authority: 15 U.S.C. 1501 *et seq.*; Reorganization Plan No. 3 of 1979, 19 U.S.C. 2171 Note, 5 U.S.C. App.2.

Edward Casselle,

Deputy Assistant Secretary for Africa.

[FR Doc. 99–28694 Filed 11–2–99; 8:45 am]

BILLING CODE 3510–DA–M

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meeting

TIME AND DATE: 2:00 p.m., Wednesday, November 17, 1999.

PLACE: 1155 21st St., N.W., Washington, D.C., 9th Floor Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Enforcement Matters.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 202–418–5100.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 99–28963 Filed 11–1–99; 3:55 pm]

BILLING CODE 6351–01–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Title, Form Number, and OMB Number: Validation of Public or Community Service Employment Performed by Retired Personnel Retired Under the Temporary Early Retirement Authority for Increased Retirement Compensation; DD form 2676; OMB Number 0704–0357.

Type of Request: Revision.

Number of Respondents: 1,775.

Responses per Respondent: 1.

Annual Responses: 1,775.

Average Burden per Response: 10 minutes.

Annual Burden Hours: 296.

Needs and Uses: Public Law 102–484, section 4464, required the Department of Defense to develop policy and procedures to validate and credit increased compensation for qualifying public and community service employment performed by retired personnel of the Armed Forces under the ''Temporary Early Retirement Authority Program.'' Public Law 103–337, section 542, extended this program to the Coast Guard. This information, which uses DD Form 2676, will allow DoD and Coast Guard to collect necessary information to recompute retired pay when the participating member qualifies under this program. Respondents to this program will be registered public or community service employers. The data are submitted by the Defense Manpower Data Center to either the Defense Finance and Accounting Service (DFAS) or the Coast Guard Finance Center for update of final pay information files. When a member reaches age 62, the Finance Centers will recompute retirement pay, adding whatever public or community service employment was validated during the enhanced retirement qualification period.

Affected Public: Business or Other For-Profit; Not-For-Profit Institutions; Federal Government; State, Local, or Tribal Government.

Frequency: On occasion; Annually.

Respondents Obligation: Required to Obtain or Retain Benefits.

OMB Desk Officer: Mr. Edward C. Springer.

Written comments and recommendations on the proposed information collection should be sent to Mr. Springer at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Mr. Robert Cushing.

Written requests for copies of the information collection proposal should be sent to Mr. Cushing, WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202–4302.

Dated: October 28, 1999.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 99–28667 Filed 11–2–99; 8:45 am]

BILLING CODE 5001–10–M

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0130]

Proposed Collection; Comment Request Entitled Buy American Act—North American Free Trade Agreement Implementation Act—Balance of Payments Program Certificate

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for an extension to an existing OMB clearance (9000–0130).

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning Buy American Act—North American Free Trade Agreement Implementation Act—Balance of Payments Program Certificate. The clearance currently expires on February 28, 2000.

DATES: Comments may be submitted on or before January 3, 2000.

ADDRESSES: Comments regarding this burden estimate or any other aspect of the collection of information, including suggestions for reducing this burden, should be submitted to: FAR Desk Officer, OMB, Room 10102, NEOB, Washington, DC 20503, and a copy to the General Services Administration, FAR Secretariat (MVRS), 1800 F Street, NW, Room 4035, Washington, DC 20405.

FOR FURTHER INFORMATION CONTACT: Paul Linfield, Federal Acquisition Policy Division, GSA, (202) 501–1757.

SUPPLEMENTARY INFORMATION:

A. Purpose

Under the North American Free Trade Agreement (NAFTA) Implementation Act, unless specifically exempted by statute or regulation, agencies are required to evaluate offers over a certain dollar limitation to supply an eligible product without regard to the restrictions of the Buy American Act or the Balance of Payments program. Offerors identify excluded end products and NAFTA end products on this certificate.

The contracting officer uses the information to identify the offered items which are domestic and NAFTA country end products so as to give these products a preference during the evaluation of offers. Items having components of unknown origin are considered to have been mined, produced, or manufactured outside the United States.

B. Annual Reporting Burden

Public reporting burden for this collection of information is estimated to average .167 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The annual reporting burden is estimated as follows: *Respondents,* 1,140; *responses per respondent,* 5; *total annual responses,* 5,700; *preparation hours per response,* .167; and *total response burden hours,* 952.

Obtaining Copies of Proposals

Requester may obtain a copy of the justification from the General Services Administration, FAR Secretariat (MVRS), Room 4035, Washington, DC 20405, telephone (202) 208–7312. Please cite OMB Control No. 9000–0130, Buy American Act—North American Free Trade Agreement Implementation Act—Balance of Payments Program Certificate, in all correspondence.

Dated: October 29, 1999.

Edward C. Loeb,

Director, Federal Acquisition Policy Division.

[FR Doc. 99–28718 Filed 11–2–99; 8:45 am]

BILLING CODE 6820–34–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Intelligence Agency, Science and Technology Advisory Board; Closed Panel Meeting

AGENCY: Defense Intelligence Agency, Department of Defense.

ACTION: Notice.

SUMMARY: Pursuant to the provisions of subsection (d) of Section 10 of Public Law 92–463, as amended by Section 5 of Public Law 94–409, notice is hereby given that a closed meeting of the DIA Science and Technology Advisory Board has been scheduled as follows:

DATES: 9–10 November, (800 am to 1600 pm).

ADDRESSES: The Defense Intelligence Agency, Bolling AFB, Washington, DC 20340.

FOR FURTHER INFORMATION CONTACT: Maj. Donald R. Culp, Jr., USAF, Executive Secretary, DIA Science and Technology Advisory Board, Washington, D.C. 20340–1328 (202) 231–4930.

SUPPLEMENTARY INFORMATION: The entire meeting is devoted to the discussion of classified information as defined in Section 552b(c)(I), Title 5 of the U.S. Code, and therefore will be closed to the public. The Board will receive briefings on and discuss several current critical intelligence issues and advise the Director, DIA, on related scientific and technical matters.

Dated: October 28, 1999.

L.M. Bynum,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 99–28668 Filed 11–2–99; 8:45 am]

BILLING CODE 5001–10–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Science Board Task Force on DoD Frequency Spectrum Issues

ACTION: Notice of Advisory Committee meetings.

SUMMARY: The Defense Science Board Task Force on DoD Frequency Spectrum Issues will meet in closed session on November 9–10, December 10, 1999, January 20–21, February 24–25, March 29–30, April 20–21, May 24–25, 2000 at SAIC, 4001 N. Fairfax Drive, Arlington, Virginia (except for the 10 December meeting which will be held at the Joint Spectrum Center, Annapolis, MD.) In order for the Task Force to obtain time sensitive classified briefings, critical to the understanding of the issues, the

meeting to be held on November 9–10, 1999, is scheduled on short notice. The mission of the Defense Science Board is to advise the Secretary of Defense through the Under Secretary of Defense for Acquisition, Technology and Logistics on scientific and technical matters as they affect the perceived needs of the Department of Defense. At these meetings the Task Force will examine the competing interest in, and access to, the RF frequency spectrum and its impact on military readiness and national security in the 21st century. This study will review and evaluate DoD user frequency spectrum requirements and related advances in technology to improve utilization of this finite resource.

In accordance with Section 10(d) of the Federal Advisory Committee Act, Pub. L. No. 92–463, as amended (5 U.S.C. App. II, (1994)), it has been determined that these DSB Task Force meetings concern matters listed in 5 U.S.C. 552b(c)(1) (1994), and that accordingly these meetings will be closed to the public.

Dated: October 27, 1999.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 99–28670 Filed 11–2–99; 8:45 am]

BILLING CODE 5001–10–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Threat Reduction Advisory Committee

AGENCY: Office of the Under Secretary of Defense (Acquisition and Technology) Department of Defense.

ACTION: Notice of Advisory Committee meeting.

SUMMARY: The Threat Reduction Advisory Committee will meet in closed session on Tuesday December 7, 1999, at the Pentagon.

The mission of the Committee is to advise the Under Secretary of Defense (Acquisition and Technology) on technology security, counterproliferation, chemical and biological defense, sustainment of the nuclear weapons stockpile, and other matters related to the Defense Threat Reduction Agency's mission.

In accordance with Section 10(d) of the Federal Advisory Committee Act, Public Law 92–463, as amended (5 U.S.C. Appendix II, (1994), it has been determined that this Committee meeting concerns matters listed in 5 U.S.C. 552b(c)(1) (1994), and that accordingly the meeting will be closed to the public.

DATES: Tuesday, December 7, 1999, (8:00 a.m. to 5:30 p.m.)

ADDRESSES: Room 3E869, The Pentagon, Washington, DC 20301.

FOR FURTHER INFORMATION CONTACT: Ms. Eileen Giglio, Defense Threat Reduction Agency/AS, 45045 Aviation Drive, Dulles, VA 20166–7517. Phone: (703) 326–8789.

Dated: October 27, 1999.

L.M. Bynum,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 99–28669 Filed 11–2–99; 8:45 am]

BILLING CODE 5001–10–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Revised Non-Foreign Overseas Per Diem Rates

AGENCY: Per Diem, Travel and Transportation Allowance Committee, DoD.

ACTION: Notice of revised non-foreign overseas per diem rates.

SUMMARY: The Per Diem, Travel and Transportation Allowance Committee is publishing Civilian Personnel Per Diem Bulletin Number 211. This bulletin lists revisions in the per diem rates prescribed for U.S. Government employees for official travel in Alaska, Hawaii, Puerto Rico, the Northern Mariana Islands and Possessions of the United States. AEA changes announced in Bulletin Number 194 remain in effect. Bulletin Number 211 is being published in the **Federal Register** to assure that travelers are paid per diem at the most current rates.

EFFECTIVE DATE: November 1, 1999.

SUPPLEMENTARY INFORMATION: This document gives notice of revisions in per diem rates prescribed by the Per Diem Travel and Transportation Allowance Committee for non-foreign areas outside the continental United States. It supersedes Civilian Personnel Per Diem Bulletin Number 210. Distribution of Civilian Personnel Per Diem Bulletins by mail was discontinued. Per Diem Bulletins published periodically in the **Federal Register** now constitute the only notification of revisions in per diem rates to agencies and establishments outside the Department of Defense. For more information or questions about per diem rates, please contact your local travel office. The text of the Bulletin follows:

Dated: October 27, 1999.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, DoD.

BILLING CODE 5001–10–M

Maximum Per Diem Rates for official travel in Alaska, Hawaii, the Commonwealths of Puerto Rico and the Northern Mariana Islands and Possessions of the United States by Federal Government civilian employees.

LOCALITY	MAXIMUM LODGING AMOUNT (A) +	M&IE RATE (B) =	MAXIMUM PER DIEM RATE (C)	EFFECTIVE DATE
THE ONLY CHANGE IN CIVILIAN BULLETIN 211 UPDATES RATES FOR PUERTO RICO.				
ALASKA				
ANCHORAGE [INCL NAV RES]				
05/01 - 09/30	161	63	224	03/01/1999
10/01 - 04/30	89	56	145	03/01/1999
BARROW	115	73	188	03/01/1999
BETHEL	105	60	165	03/01/1999
CLEAR AB	80	57	137	03/01/1999
COLD BAY	110	68	178	03/01/1999
COLDFOOT	135	71	206	10/01/1999
CORDOVA	85	62	147	03/01/1998
CRAIG				
05/01 - 08/31	95	66	161	10/01/1998
09/01 - 04/30	79	64	143	10/01/1998
DEADHORSE	80	67	147	03/01/1999
DENALI NATIONAL PARK				
06/01 - 08/31	115	52	167	03/01/1998
09/01 - 05/31	90	50	140	03/01/1998
DILLINGHAM	95	59	154	10/01/1998
DUTCH HARBOR-UNALASKA	110	71	181	03/01/1999
EARECKSON AIR STATION	80	57	137	03/01/1999
EIELSON AFB				
05/15 - 09/15	118	58	176	03/01/1999
09/16 - 05/14	81	54	135	03/01/1999
ELMENDORF AFB				
05/01 - 09/30	161	63	224	03/01/1999
10/01 - 04/30	89	56	145	03/01/1999
FAIRBANKS				
05/15 - 09/15	118	58	176	03/01/1999
09/16 - 05/14	81	54	135	03/01/1999
FT. RICHARDSON				
05/01 - 09/30	161	63	224	03/01/1999
10/01 - 04/30	89	56	145	03/01/1999
FT. WAINWRIGHT				
05/15 - 09/15	118	58	176	03/01/1999
09/16 - 05/14	81	54	135	03/01/1999
GLENNALLEN	90	52	142	10/01/1998
HEALY				
06/01 - 08/31	115	52	167	03/01/1998
09/01 - 05/31	90	50	140	03/01/1998

Maximum Per Diem Rates for official travel in Alaska, Hawaii, the Commonwealths of Puerto Rico and the Northern Mariana Islands and Possessions of the United States by Federal Government civilian employees.

LOCALITY	MAXIMUM LODGING AMOUNT (A) +	M&IE RATE (B) =	MAXIMUM PER DIEM RATE (C)	EFFECTIVE DATE
HOMER				
05/15 - 09/15	115	58	173	03/01/1999
09/16 - 05/14	98	57	155	03/01/1999
JUNEAU	105	68	173	03/01/1999
KAKTOVIK	175	74	249	03/01/1999
KAVIK CAMP	125	69	194	03/01/1999
KENAI-SOLDOTNA				
05/01 - 09/30	114	63	177	03/01/1999
10/01 - 04/30	76	59	135	03/01/1999
KENNICOTT	149	68	217	10/01/1998
KETCHIKAN				
05/01 - 09/30	110	74	184	03/01/1999
10/01 - 04/30	88	73	161	03/01/1999
KING SALMON	101	70	171	03/01/1999
KLAWOCK				
05/01 - 08/31	95	66	161	10/01/1998
09/01 - 04/30	79	64	143	10/01/1998
KODIAK	99	67	166	03/01/1999
KOTZEBUE				
05/01 - 08/31	137	75	212	03/01/1999
09/01 - 04/30	73	61	134	03/01/1999
KULIS AGS				
05/01 - 09/30	161	63	224	03/01/1999
10/01 - 04/30	89	56	145	03/01/1999
MCCARTHY	149	68	217	10/01/1998
METLAKATLA				
05/30 - 10/01	85	52	137	03/01/1999
10/02 - 05/29	78	51	129	03/01/1999
MURPHY DOME				
05/15 - 09/15	118	58	176	03/01/1999
09/16 - 05/14	81	54	135	03/01/1999
NOME				
03/01 - 03/31	117	58	175	03/01/1999
04/01 - 02/29	92	56	148	03/01/1999
NUIQSUT	120	69	189	03/01/1999
PETERSBURG	87	57	144	03/01/1999
POINT HOPE	130	70	200	03/01/1999
POINT LAY	105	67	172	03/01/1999
PRUDHOE BAY	80	67	147	03/01/1999
SEWARD				
05/01 - 09/30	122	65	187	03/01/1999
10/01 - 04/30	86	61	147	03/01/1999

Maximum Per Diem Rates for official travel in Alaska, Hawaii, the Commonwealths of Puerto Rico and the Northern Mariana Islands and Possessions of the United States by Federal Government civilian employees.

LOCALITY	MAXIMUM LODGING AMOUNT (A) +	M&IE RATE (B) =	MAXIMUM PER DIEM RATE (C)	EFFECTIVE DATE
SITKA-MT. EDGECOMBE				
09/05 - 03/31	83	59	142	10/01/1998
04/01 - 09/04	101	60	161	03/01/1998
SKAGWAY				
05/01 - 09/30	110	74	184	03/01/1999
10/01 - 04/30	88	73	161	03/01/1999
SPRUCE CAPE	99	67	166	03/01/1999
TANANA				
03/01 - 03/31	117	58	175	03/01/1999
04/01 - 02/29	92	56	148	03/01/1999
UMIAT	107	33	140	03/01/1999
VALDEZ				
05/15 - 10/01	110	63	173	03/01/1999
10/02 - 05/14	84	60	144	03/01/1999
WAINWRIGHT	127	82	209	03/01/1999
WRANGELL				
05/01 - 09/30	110	74	184	03/01/1999
10/01 - 04/30	88	73	161	03/01/1999
YAKUTAT	110	68	178	03/01/1999
[OTHER]	80	57	137	03/01/1999
AMERICAN SAMOA				
AMERICAN SAMOA	73	53	126	03/01/1997
GUAM				
GUAM (INCL ALL MIL INSTAL)	150	79	229	10/01/1998
HAWAII				
CAMP H M SMITH	110	61	171	10/01/1998
EASTPAC NAVAL COMP TELE AREA	110	61	171	10/01/1998
FT. DERUSSEY	110	61	171	10/01/1998
FT. SHAFTER	110	61	171	10/01/1998
HICKAM AFB	110	61	171	10/01/1998
HONOLULU (INCL NAV & MC RES CTR)	110	61	171	10/01/1998
ISLE OF HAWAII: HILO	80	52	132	06/01/1998
ISLE OF HAWAII: OTHER	100	54	154	10/01/1998
ISLE OF KAUAI				
12/01 - 04/30	145	64	209	06/01/1999
05/01 - 11/30	115	62	177	06/01/1998
ISLE OF KURE	65	41	106	05/01/1999
ISLE OF MAUI	112	64	176	10/01/1998
ISLE OF OAHU	110	61	171	10/01/1998
KANEOHE BAY MC BASE	110	61	171	10/01/1998
KEKAHA PACIFIC MISSILE RANGE FAC				
12/01 - 04/30	145	64	209	06/01/1999
05/01 - 11/30	115	62	177	06/01/1998

Maximum Per Diem Rates for official travel in Alaska, Hawaii, the Commonwealths of Puerto Rico and the Northern Mariana Islands and Possessions of the United States by Federal Government civilian employees.

LOCALITY	MAXIMUM LODGING AMOUNT (A) +	M&IE RATE (B) =	MAXIMUM PER DIEM RATE (C)	EFFECTIVE DATE
KILAUEA MILITARY CAMP	80	52	132	06/01/1998
LUALUALEI NAVAL MAGAZINE	110	61	171	10/01/1998
NAS BARBERS POINT	110	61	171	10/01/1998
PEARL HARBOR [INCL ALL MILITARY]	110	61	171	10/01/1998
SCHOFIELD BARRACKS	110	61	171	10/01/1998
WHEELER ARMY AIRFIELD	110	61	171	10/01/1998
[OTHER]	79	62	141	06/01/1993
JOHNSTON ATOLL				
JOHNSTON ATOLL	13	9	22	10/01/1998
MIDWAY ISLANDS				
MIDWAY ISLANDS [INCL ALL MILITAR	65	41	106	05/01/1999
NORTHERN MARIANA ISLANDS				
ROTA	88	69	157	06/01/1999
SAIPAN	154	88	242	06/01/1999
[OTHER]	61	62	123	06/01/1999
PUERTO RICO				
BAYAMON				
04/11 - 12/23	169	73	242	11/01/1999
12/24 - 04/10	216	77	293	11/01/1999
CAROLINA				
04/11 - 12/23	169	73	242	11/01/1999
12/24 - 04/10	216	77	293	11/01/1999
FAJARDO [INCL CEIBA & LUQUILLO]	90	55	145	11/01/1999
FT. BUCHANAN [INCL GSA SVC CTR,				
04/11 - 12/23	169	73	242	11/01/1999
12/24 - 04/10	216	77	293	11/01/1999
HUMACAO	90	55	145	11/01/1999
LUIS MUNOZ MARIN IAP AGS				
04/11 - 12/23	169	73	242	11/01/1999
12/24 - 04/10	216	77	293	11/01/1999
MAYAGUEZ	94	60	154	06/01/1998
PONCE	107	70	177	11/01/1999
ROOSEVELT RDS & NAV STA	90	55	145	11/01/1999
SABANA SECA [INCL ALL MILITARY]				
04/11 - 12/23	169	73	242	11/01/1999
12/24 - 04/10	216	77	293	11/01/1999
SAN JUAN & NAV RES STA				
04/11 - 12/23	169	73	242	11/01/1999
12/24 - 04/10	216	77	293	11/01/1999
[OTHER]	66	57	123	09/01/1998

Maximum Per Diem Rates for official travel in Alaska, Hawaii, the Commonwealths of Puerto Rico and the Northern Mariana Islands and Possessions of the United States by Federal Government civilian employees.

LOCALITY	MAXIMUM LODGING AMOUNT (A) +	M&IE RATE (B) =	MAXIMUM PER DIEM RATE (C)	EFFECTIVE DATE
VIRGIN ISLANDS (U.S.)				
ST. CROIX				
04/15 - 12/14	100	73	173	08/01/1999
12/15 - 04/14	140	77	217	08/01/1999
ST. JOHN				
04/15 - 12/14	236	85	321	08/01/1999
12/15 - 04/14	413	103	516	08/01/1999
ST. THOMAS				
04/15 - 12/14	176	74	250	08/01/1999
12/15 - 04/14	311	88	399	08/01/1999
WAKE ISLAND				
WAKE ISLAND	60	32	92	09/01/1998

[FR Doc. 99–28671 Filed 11–2–99; 8:45 am]
BILLING CODE 5001–10–C

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Availability of Inventions for Licensing; Government-Owned Inventions

AGENCY: Department of the Navy, DOD.

ACTION: Notice.

SUMMARY: The inventions listed below are assigned to the United States Government as represented by the Secretary of the Navy and are available for licensing by the Department of the Navy.

U.S. Patent No. 5,259,061 entitled ''Fabrication and Phase Tuning of an Optical Waveguide Device,'' Navy Case No. 75,085.

U.S. Patent No. 5,195,163 entitled ''Fabrication and Phase Tuning of an Optical Waveguide Device,'' Navy Case No. 73,281.

ADDRESSES: Requests for copies of the patents cited should be directed to the Naval Research Laboratory, Code 3008.2, 4555 Overlook Avenue, SW, Washington, DC 20375–5320, and must include the Navy Case number.

FOR FURTHER INFORMATION CONTACT: Catherine M. Cotell, Head, Technology Transfer Office, NRL Code 1004, 4555 Overlook Avenue, SW, Washington, DC 20375–5320, telephone (202) 767–7230.

(Authority: 35 U.S.C. 207, 37 CFR Part 404)

Dated: October 26, 1999.

J.L. Roth,

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 99–28783 Filed 11–2–99; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The Leader, Information Management Group, Office of the Chief Information Officer, 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 January 3, 2000.

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 Leader, Information Management Group, Office of the Chief Information Officer, 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: October 27, 1999.

William Burrow,

Leader, Information Management Group, Office of the Chief Information Officer.

Office of Student Financial Assistance Programs

Type of Review: Reinstatement.

Title: Directory of Designated Low-Income Schools for Teacher Loan Cancellation Benefits.

Frequency: Annually.

Affected Public: Federal Government; State; local or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Burden: Responses: 57. Burden Hours: 570.

Abstract: Under the Federal Perkins and National Direct Student Loan Programs, a borrower may have a portion of his/her loan cancelled, if they teach at a school that appears in the Directory.

Requests for copies of the proposed information collection (1845–New) request should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW, Room 5624, Regional Office Building 3, Washington, D.C. 20202–4651, or should be electronically mailed to the internet address OCIO__IMG__Issues@ed.gov, or should be faxed to 202–708–9346.

Written comments or questions regarding burden and/or the collection activity requirements should be directed to Joseph Schubart at 202–708–9266 or by e-mail at joe__schubart@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. 99–28577 Filed 11–2–99; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The Leader, Information Management Group, Office of the Chief Information Officer, 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 January 3, 2000.

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 Leader, Information Management Group, Office of the Chief Information Officer, 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: October 29, 1999.

William Burrow,

Leader, Information Management Group, Office of the Chief Information Officer.

Office of Educational Research and Improvement

Type of Review: New.

Title: School Survey on Crime and Safety.

Frequency: Intended to be biennial; clearance is being sought for year 2000 only.

Affected Public: State, local or Tribal Gov't; SEAs or LEAs (schools).

Reporting and Recordkeeping Hour Burden:

Responses: 3,000.

Burden Hours: 3,000.

Abstract: This survey of 3,000 public elementary and secondary schools is intended to be the first of a biennial series. It collects data on the frequency of crime and disciplinary problems, the characteristics of school policies and programs to prevent or reduce crime, and school disciplinary actions.

Requests for copies of the proposed information collection request should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW, Room 5624, Regional Office Building 3, Washington, D.C. 20202–4651,or should be electronically mailed to the internet address *OCIO__IMG__Issues@ed.gov*.

Written comments or questions regarding burden and/or the collection activity requirements should be directed to Kathy Axt at 703–426–9692. 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. 99–28709 Filed 11–2–99; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Paducah

AGENCY: Department of Energy (DOE).

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Paducah. The 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: Thursday, November 18, 1999: 6 p.m.–9:30 p.m.

ADDRESSES: Metropolis Junior High School Auditorium, 1004 Catherine Street (Eleventh Street Entrance), Metropolis, Illinois.

OTHER INFORMATION CONTACT: John D. Sheppard, Site Specific Advisory Board Coordinator, Department of Energy Paducah Site Office, Post Office Box 1410, MS–103, Paducah, Kentucky 42001, (270) 441–6804.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE and its regulators in the areas of environmental restoration and waste management activities.

Tentative Agenda

6:00 p.m.	Call to order/Discussion
6:05 p.m.	Approve Meeting Minutes
6:15 p.m.	Public Comments/Questions
6:30 p.m.	Presentations
8:30 p.m.	Sub Committee Reports
9:00 p.m.	Administrative Issues
9:30 p.m.	Adjourn

Public Participation: The meeting is open to the public. Written statements may be filed with the Committee either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact John D. Sheppard at the address or telephone number listed above. Requests must be received 5 days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Official is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of 5 minutes to present their comments at the end of the meeting.

Minutes: The minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC 20585 between 9:00 a.m. and 4 p.m., Monday–Friday, except Federal holidays. Minutes will also be available at the Department of Energy's Environmental Information Center and Reading Room at 175 Freedom Boulevard, Highway 60, Kevil, Kentucky between 8:00 a.m. and 5:00 p.m. on Monday thru Friday or by writing to John D. Sheppard, Department of Energy Paducah Site Office, Post Office Box 1410, MS–103, Paducah, Kentucky 42001 or by calling him at (270) 441–6804.

Issued at Washington, DC on October 29, 1999.

Rachel M. Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 99–28710 Filed 11–2–99; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Los Alamos

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Los Alamos. The 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: Wednesday, November 17, 1999, 6 p.m.–9 p.m.

ADDRESSES: San Juan Pueblo, Bureau of Indian Affairs Conference Room, Route 68, New Mexico.

FOR FURTHER INFORMATION CONTACT: Ann DuBois, Northern New Mexico Citizens' Advisory Board, 1640 Old Pecos Trail, Suite H, Santa Fe, NM 87505. Phone: 505–989–1662; Fax: 505–989–1752; E-mail: *adubois@doeal.gov;* or Internet http:www.nmcab.org.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE and its regulators in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

1. Public Comment, 6:30 p.m.–7 p.m.
2. Committee Reports:
   Environmental Restoration
   Monitoring and Surveillance
   Waste Management
   Community Outreach
   Budget
3. Election of Officers for FY 2000
4. Other Board business will be conducted as necessary.

Public Participation: The meeting is open to the public. Written statements may be filed with the Committee either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Ann DuBois at the address or telephone number listed above. Requests must be received 5 days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of 5 minutes to present their comments at the beginning of the meeting.

Minutes: The minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC 20585 between 9 a.m. and 4 p.m., Monday–Friday, except Federal holidays. Minutes will also be available at the Public Reading Room located at the Board's office at 528 35th Street, Los Alamos, NM 87544. Hours of operation for the Public Reading Room are 9 a.m. and 4 p.m. on Monday through Friday. Minutes will also be made available by writing or calling Ann DuBois at the Board's office address or telephone number listed above.

Issued at Washington, DC on October 28, 1999.

Rachel M. Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 99–28711 Filed 11–2–99; 8:45 am]

BILLING CODE 6405–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Pantex Plant

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Pantex Plant, Amarillo, Texas. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

Date and Time: Tuesday, November 16, 1999: 10 a.m.–2:30 p.m.

Address: Amarillo Senior Citizens' Center, 1217 Tyler Street, Amarillo, TX.

FOR FURTHER INFORMATION CONTACT: Jerry S. Johnson, Assistant Area Manager, Department of Energy, Amarillo Area Office, P.O. Box 30030, Amarillo, TX 79120, (806) 477–3125.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to advise the Department of Energy and its regulators in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

10:00 Welcome—Agenda Review—Approval of Minutes
10:15 Co-Chair Comments
10:30 Task Force/Subcommittee Reports
11:00 Breakdown of Technical Terms on Groundwater Issues
11:15 Updates—Occurrence Reports—DOE
11:30 Lunch
12:30 Texas Risk Reduction Program Rule Update
1:00 E-Officios Reports
1:30 Public Comments
2:00 Closing Comments
2:15 Adjourn

Public Participation: The meeting is open to the public. Written statements may be filed with the Committee either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Jerry Johnson's office at the address or telephone number listed above. Requests must be received 5 days prior to the meeting and every reasonable provision will be made to accommodate the request in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of 5 minutes to present their comments.

Minutes: The minutes of this meeting will be available for public review and copying at the Pantex Public Reading Rooms located at the Amarillo College Lynn Library and Learning Center, 2201 South Washington, Amarillo, TX, phone (806) 371–5400. Hours of operation are from 7:45 a.m. to 10 p.m. Monday through Thursday; 7:45 a.m. to 5 p.m. on Friday; 8:30 a.m. to 12 noon on Saturday; and 2 p.m. to 6 p.m. on Sunday, except for Federal holidays. Additionally, there is a Public Reading Room located at the Carson County Public Library, 401 Main Street, Panhandle, TX, phone (806) 537–3742. Hours of operation are from 9 a.m. to 7 p.m. on Monday; 9 a.m. to 5 p.m. Tuesday through Friday; and closed Saturday and Sunday as well as Federal Holidays. Minutes will also be available by writing or calling Jerry S. Johnson at the address or telephone number listed above.

Issued at Washington, DC on October 28, 1999.

Rachel M. Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 99–28713 Filed 11–2–99; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Science; DOE/NSF Nuclear Science Advisory Committee

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the DOE/NSF Nuclear Science Advisory Committee (NSAC). 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: Monday, November 22, 1999; 9 a.m. to 6 p.m. and Tuesday, November 23, 1999; 9 a.m. to 5 p.m.

ADDRESSES: National Science Foundation, 4201 Wilson Boulevard, National Science Board Room 1235, Arlington, Virginia 22230.

FOR FURTHER INFORMATION CONTACT: Cathy A. Hanlin, U.S. Department of Energy; 19901 Germantown Road; Germantown, Maryland 20874–1290; Telephone: 301–903–3613.

SUPPLEMENTARY INFORMATION:

Purpose of Meeting: To provide advice and guidance on a continuing basis to the Department of Energy and the National Science Foundation on scientific priorities within the field of basic nuclear science research.

Tentative Agenda

Monday, November 22, 1999, and Tuesday, November 23, 1999

- Presentation of Rare Isotope Accelerator (RIA) Task Force Report;
- Briefing on DOE Office of Science; Office of High Energy and Nuclear Physics; and Division of Nuclear Physics Activities and Budget Outlook;
- Briefing on NSF Mathematical and Physical Sciences Directorate; Physics Division; and Nuclear Physics Program Activities and Budget Outlook;
- Discussion of RIA Task Force Report, and Draft and Formulation of NSAC Response;
- Public Comment (10-minute rule).

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 these items on the agenda, you should contact Cathy A. Hanlin at 301–903–3613. You must make your request for an oral statement at least 5 business days before 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 the meeting will be available for public review and copying within 30 days at the Freedom of Information Public Reading Room, Room 1E–190, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

Issued at Washington, DC on October 29, 1999.

Rachel M. Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 99–28712 Filed 11–2–99; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC00–597–000]

Proposed Information Collection and Request for Comments

October 27, 1999.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of proposed information collection and request for comments.

SUMMARY: In compliance with the requirements of Section 3506(c)(2)(a) of the Paperwork Reduction Act of 1995 (Pub. L. No. 104–13), the Federal Energy Regulatory Commission (Commission) is soliciting public comment on the specific aspects of the information collection described below.

DATES: Consideration will be given to comments submitted on or before January 3, 2000.

ADDRESSES: Written comments on the proposed collection of information may be submitted to the Federal Energy Regulatory Commission, Attn: Michael Miller, Office of the Chief Information Officer, CI–1, 888 First Street NE., Washington, D.C. 20426.

FOR FURTHER INFORMATION CONTACT: Michael Miller may be reached by telephone at (202) 208–1415, by fax at (202) 208–2425 and by E-mail at mike.*miller@ferc.fed.us.*

SUPPLEMENTARY INFORMATION: *Abstract:* The FERC–597, ''Customer Satisfaction Survey'' (OMB No. 1902–0163) is used by the Commission to evaluate the services performed in the Public Reference Room for the public. The Public Reference Room is the Commission's repository and reference center for most of the documents filed with the Commission. Official file copies of all public records of the Commission are accessible through the Public Reference Room. Duplicate copies of those documents and reports in greatest demand are available on open shelves or in labeled file cabinets in the public area of the reference room. Other documents, historical records, indexes and publications are available but mut be retrieved by Commission staff. The Public Reference room staff respond to both oral, written and electronic inquiries regarding the Commission's official records and documents. The customer survey is conducted on an annual basis and responses to the survey are voluntary. The Commission uses the survey to assess the performance of its staff and to determine how best to serve the public.

Action: The Commission is requesting a three-year extension of the current expiration date, with no changes to the existing collection of data.

Burden Statement: Public reporting burden for this collection is estimated as:

Number of respondents (1)	Annual responses per response (2)	Average burden Hours per response (3)	Total annual burden hours (1)×(2)×(3)
100	1	.15 Hours	15 Hours

Estimated cost burden to respondents: Because of the minimal amount of time to conduct this survey (15 minutes), and the voluntary nature of response to this survey, the commission estimates that the cost to respondents will be minimal.

The reporting burden includes the total time, effort, or financial resources expended to generate, maintain, retain, or disclose or provide the information including (*as applicable):* (1) reviewing instructions; (2) developing, acquiring, installing, and utilizing technology and systems for the purposes of collecting, validating, verifying, processing, maintaining, disclosing and providing information; (3) adjusting the existing ways to comply with any previously applicable instructions and requirements; (4) training personnel to respond to a collection of information; (5) searching data sources; (6) completing and reviewing the collection of information; and (7) transmitting, or otherwise disclosing the information.

The estimate of cost for respondents is based upon salaries for professional and clerical support, as well as direct and indirect overhead costs. Direct costs include all costs directly attributable to providing this information, such as administrative costs and the cost for information technology. Indirect or overhead costs are costs incurred by an organization in support of its mission. These costs apply to activities which benefit the whole organization rather than any one particular function or activity.

Comments are invited on: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology

e.g., permitting electronic submission of responses.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–28569 Filed 11–2–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP00–30–000]

ANR Pipeline Company; Notice of Proposed Changes in FERC Gas Tariff

October 27, 1999.

Take notice that on October 21, 1999, ANR Pipeline Company (ANR) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the revised tariff sheets as listed in Appendix A to the filing, to be effective December 1, 1999.

ANR states that this filing, made on a limited basis in accordance with the provisions of Section 4 of the Natural Gas Act and Section 154 of the Commission's regulations, is to implement new Rate Schedules FTS–3 and ITS–3, which will enable firm and interruptible transportation shippers, respectively, to obtain service at variable hourly flow rates. Accordingly, this filing includes revised tariff sheets for these two new rate schedules, as well as certain conforming revisions to the General Terms and Conditions of ANR's tariff.

ANR states that copies of the filing have been mailed to all affected customers and state regulatory commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–28568 Filed 11–2–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER00–41–000]

Entergy Services, Inc.; Notice of Filing

October 28, 1999.

Take notice that on October 5, 1999, Entergy Services, Inc. (Entergy Services), on behalf of Entergy Gulf States, Inc. (Entergy Gulf States), tendered for filing a Letter Amendment to the Interconnection and Operating Agreement between Entergy Gulf States and PPG Industries, Inc.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.11 and 385.214). All such motions and protests should be filed on or before November 8, 1999. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 99–28714 Filed 11–2–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP99–274–003]

Kern River Gas Transmission Company; Notice of Compliance Filing

October 28, 1999.

Take notice that on October 20, 1999, Kern River Gas Transmission Company (Kern River) tendered for filing information and documentation (including work papers) supporting the proposed settlement and rates contained in its filing of March 31, 1999 during which Kern River's rates as established in Docket No. RP99–274 are applicable.

Kern River states that the purpose of this filing is to comply with the Commission's September 20, 1999 Order in Docket No. RP99–274–001. Kern River states that its compliance filing is consistent with the Commission's orders and directives that have been issued with respect to Docket No. RP99–274–001.

Kern River states that a copy of this filing has been served upon each person designated on the official service lists compiled by the Secretary in this proceeding.

Any person desiring to protest this filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed as provided in Section 154.210 of the Commission's Rules and Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance.)

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–28682 Filed 11–2–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP00–12–000]

Questar Pipeline Company; Notice of Application

October 28, 1999.

Take notice that on October 25, 1999, Questar Pipeline Company (Questar), P.O. Box 45360, Salt Lake City, Utah 84145–0360, filed in Docket No. CP00–12–000 an application pursuant to Section 7(b) of the Natural Gas Act for permission and approval to abandon natural gas transportation service provided to Northwest Pipeline Corporation (Northwest) under individually certificated agreements, all as more fully set forth in the application which is on file with the Commission and open to public inspection. This

filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Questar proposes to abandon natural gas transportation service provided to Northwest Pipeline Corporation under Questar's Rate Schedules X–29, X–30, X–36, X–37, X–38, and X–39 contained in its respective FERC Gas Tariff, Original Volume No. 3. Questar states that these service agreements have been inactive for several years and will never be re-activated. Questar declares that a letter notifying Northwest of Questar's intent to terminate these agreements was received and signed by Northwest, evidencing its agreement with the proposed terminations. Questar requests that authority to abandon the rate schedules be made effective September 1, 1999. Questar states that it does not propose to abandon or modify any existing facilities pursuant to the instant application.

Any person desiring to be heard or to make any protest with reference to said Application should on or before November 18, 1999, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 383.211 or 18 CFR 385.214) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that pursuant to the authority contained in and subject to the jurisdiction conferred upon the Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this Application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the abandonment is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission, on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–28679 Filed 11–2–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. RP97–28–004 and CP99–102–001]

Wyoming Interstate Company, Ltd.; Notice of Tariff Filing

October 27, 1999.

Take notice that on October 20, 1999, Wyoming Interstate Company, Ltd. (WIC), P.O. Box 1087, Colorado Springs, Colorado 80944, tendered for filing to become part of its FERC Gas Tariff, Second Revised Volume No. 2, the tariff sheets listed in Appendix A to be effective November 20, 1999.

WIC states it was granted authority to construct the Medicine Bowl Lateral in an Order Issuing Certificate that issued July 28, 1999 in Docket No. CP99–102.

WIC further states it is making this filing in compliance with Ordering Paragraph H of the Preliminary Determination on Non-Environmental Issues in Docket No. CP99–102 (''PD'') which issued April 28, 1999. The tariff sheets filed herein are consistent with both the pro forma tariff sheets contained in the application and revisions as required in the PD.

WIC states it is also filing tariff sheets as required in Article 33 of its General Terms and Conditions for the negotiated rate agreements supporting the Medicine Bow project.

Any person desiring to protest this filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed as provided in section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–28567 Filed 11–2–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EC96–19–032, et al.]

California Power Exchange Corporation, et al.; Electric Rate and Corporate Regulation Filings

October 25, 1999.

Take notice that the following filings have been made with the Commission:

1. California Power Exchange Corporation

[Docket Nos. EC96–19–032 and ER96–1663–033]

Take notice that on October 18, 1999, the California Power Exchange Corporation (CalPX) submitted a compliance filing in the above-referenced dockets. The compliance filing states how CalPX intends to implement the resolution of settlement and billing issues once they are resolved through the California stakeholder process.

Comment date: November 17, 1999, in accordance with Standard Paragraph E at the end of this notice.

2. TECO EnergySource, Inc.; Poco Petroleum, Inc.; Poco Marketing Ltd.; Kamps Propane, Inc.; Conoco Power Marketing Inc.

[Docket Nos. ER96–1563–015; ER97–2197–008; ER97–2198–009; ER98–1148–005; and ER95–1441–019]

Take notice that on October 18, 1999, the above-mentioned power marketers filed quarterly reports with the Commission in the above-mentioned proceedings for information only.

3. Florida Power Corporation and Progress Power Marketing

[Docket Nos. ER97–2846–001 and ER96–1618–014]

Take notice that on October 19, 1999, Florida Power Corporation (FPC) and Progress Power Marketing, Inc. (PPM) tendered for filing a Notification of Change in Status. The Notification of Change in Status is intended to inform the Commission that Florida Progress Corporation (parent of FPC and PPM), and Carolina Power & Light Company (CP&L) announced a share exchange whereby FPC would become an affiliate of CP&L upon consummation of the

proposed exchange. In addition, the filing makes certain commitments, consistent with Commission precedent, regarding sales of power and the pricing of non-power goods and services.

Comment date: November 8, 1999, in accordance with Standard Paragraph E at the end of this notice.

4. NYSEG Solutions, Inc.; The Furst Group, Inc.; The Mack Services Group; Unicom Power Marketing, Inc.; Bangor Energy Resale, Inc.; Monterey Consulting Associates, Incorporated; Thicksten Grimm Burgum, Incorporated; Cargill-Alliant, LLC

[Docket Nos. ER99–220–003; ER98–2423–004; ER99–1750–003; ER97–3954–009; ER98–459–007; ER96–2143–012; ER96–2241–013; and ER97–4273–009]

Take notice that on October 20, 1999, the above-mentioned power marketers filed quarterly reports with the Commission in the above-mentioned proceedings for information only.

5. e prime, inc.; Energy Atlantic, LLC; Southwood 2000, Inc.; Burlington Resources Trading Inc.

[Docket Nos. ER99–1610–004; ER98–4381–004; ER98–2603–002; and ER96–3112–012]

Take notice that on October 19, 1999, the above-mentioned power marketers filed quarterly reports with the Commission in the above-mentioned proceedings for information only.

6. Williams Energy Marketing & Trading Company

[Docket No. ER99–1722–003]

Take notice that on October 13, 1999, Williams Energy Marketing & Trading Company filed its second revised first quarter 1999 Power Marketer Report for information only.

7. Maine Public Service Company; Kansas City Power & Light Company

[Docket Nos. ER00–158–000 and ER00–156–000]

Take notice that on October 19, 1999, the above-mentioned affiliated power producers and/or public utilities filed their quarterly reports for the quarter ending September 30, 1999.

Comment date: November 8, 1999, in accordance with Standard Paragraph E at the end of this notice.

8. Wisvest-Connecticut, LLC; Commonwealth Edison Company; PacifiCorp; Westchester RESCO Company, L.P.; Bangor Hydro-Electric Company; Florida Power Corporation; Carthage Energy, LLC; South Glens Falls Energy, LLC

[Docket Nos. ER00–159–000; ER00–160–000; ER00–161–000; ER00–162–000; ER00–163–000; ER00–164–000; ER00–165–000; and ER00–166–000]

Take notice that on October 20, 1999, the above-mentioned affiliated power producers and/or public utilities filed their quarterly reports for the quarter ending September 30, 1999.

Comment date: November 9, 1999, in accordance with Standard Paragraph E at the end of this notice.

9. PJM Interconnection, L.L.C.

[Docket No. ES00–2–000]

Take notice that on October 15, 1999, PJM Interconnection, L.L.C. (PJM), submitted for filing an application under Section 204 of the Federal Power Act. PJM is seeking authorization for the issuance of an unsecured promissory note for a revolving line of credit of up to $15 million.

Comment date: November 15, 1999, in accordance with Standard Paragraph E at the end of this notice.

10. The Detroit Edison Company

[Docket No. OA96–78–005]

Take notice that on October 15, 1999, The Detroit Edison Company made a compliance filing in the above-referenced docket.

Comment date: November 15, 1999, in accordance with Standard Paragraph E at the end of this notice.

11. New England Power Company; Massachusetts Electric Company; The Narragansett Electric Company; New England Electric Transmission Corporation; New England Hydro-Transmission Corporation; New England Hydro-Transmission Electric Company, Inc.; AllEnergy Marketing Company, L.L.C.; Montaup Electric Company; Blackstone Valley Electric Company; Eastern Edison Company; Newport Electric Corporation and Research Drive LLC; New England Power Company; Montaup Electric Company

[Docket No. OA00–1–000]

Take notice that on October 14, 1999, New England Power Company, et al. and Montaup Electric Company, et al. submitted for filing revised standards of conduct in compliance with the Federal Energy Regulatory Commission's September 29, 1999, order (88 FERC ¶ 61,292 (1999) in the above captioned proceeding.

Copies of the filing have been served on all parties to the proceedings, as well as the relevant state commissions.

Comment date: November 15, 1999, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of these filings are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at http://www.ferc.fed.us/ online/rims.htm (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 99–28566 Filed 11–2–99; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EG00–11–000, et al.]

Oswego Harbor Power LLC, et al.; Electric Rate and Corporate Regulation Filings

October 27, 1999.

Take notice that the following filings have been made with the Commission:

1. Oswego Harbor Power LLC

[Docket No. EG00–11–000]

Take notice that on October 22, 1999, Oswego Harbor Power LLC filed with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to Section 32(a)(1) of the Public Utility Holding Company Act of 1935 (PUHCA). The applicant is a limited liability company organized under the laws of the State of Delaware that will be engaged directly and exclusively in owning and operating the Oswego generating station in Oswego, New York (Facility) and

selling electric energy at wholesale. The Facility consists of two oil-fired 850 MW units, four retired units, and associated interconnection components. The applicant intends to purchase the Facility from Niagara Mohawk Power Corporation and Rochester Gas and Electric Company.

Comment date: November 17, 1999, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

2. Stand Energy Corporation, Griffin Energy Marketing, L.L.C., Shell Energy Services Company, L.L.C., PacifiCorp Power Marketing and IGI Resources, Inc.

[Docket Nos. ER95–362–019, ER97–4168–008, ER99–2109–002, ER95–1096–020, ER95–1034–017]

Take notice that on October 22, 1999, the above-mentioned power marketers filed quarterly reports with the Commission in the above-mentioned proceedings for information only.

3. Lowell Cogeneration Company, L.P.

[Docket No. ER97–2414–002]

Take notice that on October 21, 1999 Lowell Cogeneration Company, L.P. (LCCLP) tendered for filing a Notification of Change in Status. LCCLP seeks to notify the Commission that it has become affiliated with the Duke Power Company and Nantahala Power and Light Company divisions of Duke Energy Corporation. Due to its new affiliation with these regulated utilities, LCCLP is filing with the Commission an amended Rate Schedule No. 1 as well as a Code of Conduct (Supplement No. 1 to Rate Schedule No. 1).

Comment date: November 10, 1999, in accordance with Standard Paragraph E at the end of this notice.

4. PPM One LLC, PPM Two LLC, PPM Three LLC, PPM Four LLC, PPM Five LLC, and PPM Six LLC.

[Docket Nos. ER97–3926–003, ER97–3927–003, ER97–3928–003, ER97–3929–003, ER97–3930–003, and ER97–3931–003]

Take notice that on October 19, 1999, the above-mentioned power marketers filed quarterly reports with the Commission in the above-mentioned proceedings for information only.

5. TransCanada Power Marketing Ltd., MEG Marketing, LLC, NGTS Energy Services, Sparc, L.L.C., El Paso Power Services Company, Superior Electric Power Corporation, and Strategic Energy L.L.C.

[Docket No. ER98–564–005, ER98–2284–006, ER96–2892–011, ER98–2671–003, ER95–428–022, ER95–1747–017 and ER96–3107–012]

Take notice that on October 21, 1999, the above-mentioned power marketers filed quarterly reports with the Commission in the above-mentioned proceedings for information only.

6. Commonwealth Edison Company and Unicom Power Marketing, Inc.

[Docket Nos. ER98–1734–001 and ER97–3954–010]

Take notice that on October 21, 1999, Commonwealth Edison Company (ComEd) and its affiliate Unicom Power Marketing, Inc. (UPMI) filed their report of change in status to reflect a departure from the facts relied upon by the Federal Energy Regulatory Commission (Commission) in its grant of market-based rate authority to ComEd and UPMI in the above-referenced proceedings.

7. PowerSource Corp.

[Docket No. ER98–3052–005]

Take notice that on October 25, 1999, PowerSource Corp. filed its quarterly report for the quarter ending September 30, 1999 for information only.

8. The United Illuminating Company

[Docket No. ER00–143–000]

Take notice that on October 18, 1999, The United Illuminating Company (UI) tendered for filing a Service Agreement dated September 12, 1999, between UI and Entergy Power Marketing Corp. (Entergy) for non-firm point-to-point transmission service under UI'S Open Access Transmission Tariff, FERC Electric Tariff, Original Volume No. 4, as amended. The Service Agreement adds Entergy as a transmission customer under the Tariff.

UI requests an effective date of September 12, 1999 and has therefore requested that the Commission waive its 60-day prior notice requirement.

Copies of the filing were served upon the Contract Administrator, Entergy Power Marketing, Corp, and Robert J. Murphy, Executive Secretary, Connecticut Department of Public Utility Control.

Comment date: November 5, 1999, in accordance with Standard Paragraph E at the end of this notice.

9. Strategic Energy Management Corp.

[Docket No. ER00–167–000]

Take notice that on October 20, 1999, Strategic Energy Management Corp., petitioned the Commission for acceptance of Strategic Energy Management Corp., Rate Schedule FERC No. 1; the granting of certain blanket approvals, including the authority to sell electricity at market-based rates; and the waiver of certain Commission Regulations.

Strategic Energy Management Corp., intends to engage in wholesale electric power and energy purchases and sales as a marketer. Strategic Energy Management Corp., is not in the business of generating or transmitting electric power. Strategic Energy Management Corp., has no affiliates and is independently owned.

Comment date: November 9, 1999, in accordance with Standard Paragraph E at the end of this notice.

10. Reliant Energy HL&P

[Docket No. ER00–168–000]

Take notice that on October 20, 1999, Reliant Energy HL&P (Reliant), tendered for filing a notice of cancellation of a transmission service agreement with NP Energy, Inc., under Reliant's tariff for transmission service ''to, from and over'' certain HVDC Interconnections.

Reliant states that a copy of the filing has been served on the affected customer.

Comment date: November 9, 1999, in accordance with Standard Paragraph E at the end of this notice.

11. Southern California Edison Company

[Docket No. ER00–169–000]

Take notice that on October 20, 1999, Southern California Edison Company (SCE), tendered for filing a Notice of Cancellation of the Harborgen Substation Service Agreement with Harbor Cogeneration Company.

Copies of this filing were served upon the Public Utilities Commission of the State of California and all interested parties.

Comment date: November 9, 1999, in accordance with Standard Paragraph E at the end of this notice.

12. Avista Corporation

[Docket No. ER00–170–000]

Take notice that on October 20, 1999, Avista Corporation (AVA), tendered for filing with the Federal Energy Regulatory Commission pursuant to 18 CFR Section 35.13, an executed Settlement Procedures Agreement allowing for arrangements of amounts which become due and owing to one

Party to be set off against amounts which are due and owing to the other Party with Citizens Power Sales.

Avista Corporation requests waiver of the prior notice requirement and requests an effective date of October 1, 1999.

Comment date: November 9, 1999, in accordance with Standard Paragraph E at the end of this notice.

13. PP&L, Inc.

[Docket No. ER00–171–000]

Take Notice that on October 20, 1999, PP&L, Inc. (PP&L), tendered for filing a Service Agreement dated September 27, 1999 with TransCanada Power Marketing Ltd. (TCPM) under PP&L's Market-Based Rate and Resale of Transmission Rights Tariff, FERC Electric Tariff, Revised Volume No. 5. The Service Agreement adds TCPM as an eligible customer under the Tariff.

PP&L requests an effective date of October 20, 1999, for the Service Agreement.

PP&L states that copies of this filing have been supplied to TCPM and to the Pennsylvania Public Utility Commission.

Comment date: November 9, 1999, in accordance with Standard Paragraph E at the end of this notice.

14. American Electric Power Service Corporation

[Docket No. ER00–172–000]

Take notice that on October 21, 1999, the American Electric Power Service Corporation (AEPSC), on behalf of Columbus Southern Power Company (CSP), tendered for filing with the Commission a Facilities, Operations, Maintenance And Repair Agreement dated September 27, 1999, between CSP and The City of Columbus, Ohio.

AEPSC requests an effective date of November 1, 1999, for the tendered agreement.

A copy of the filing was served upon The City of Columbus, Ohio and the Public Utilities Commission of Ohio.

Comment date: November 9, 1999, in accordance with Standard Paragraph E at the end of this notice.

15. Duquesne Light Company

[Docket No. ER00–173–000]

Take notice that on October 21, 1999, Duquesne Light Company (DLC), tendered for filing a Service Agreement for Retail Network Integration Transmission Service and a Network Operating Agreement for Retail Network Integration Transmission Service dated October 11, 1999, Utility.com under DLC's Open Access Transmission Tariff (Tariff). The Service Agreement and Network Operating Agreement adds Utility.com as a customer under the Tariff.

DLC requests an effective date of October 11, 1999, for the Service Agreement.

Comment date: November 10, 1999, in accordance with Standard Paragraph E at the end of this notice.

16. Niagara Mohawk Power Corporation

[Docket No. ER00–174–000]

Take notice that on October 21, 1999, Niagara Mohawk (Niagara Mohawk), tendered for filing with the Federal Energy Regulatory Commission an executed Transmission Service Agreement between Niagara Mohawk and Virginia Electric & Power Co. This Transmission Service Agreement specifies that Virginia Electric & Power Co., has signed on to and has agreed to the terms and conditions of Niagara Mohawk's Open Access Transmission Tariff as filed in Docket No. OA96–194–000. This Tariff filed with FERC on July 9, 1996, will allow Niagara Mohawk and Virginia Electric & Power Co., to enter into separately scheduled transactions under which Niagara Mohawk will provide firm transmission service for Virginia Electric & Power Co., as the parties may mutually agree.

Niagara Mohawk requests an effective date of September 24, 1999. Niagara Mohawk has requested waiver of the notice requirements for good cause shown.

Niagara Mohawk has served copies of the filing upon the New York State Public Service Commission and Virginia Electric & Power Co.

Comment date: November 10, 1999, in accordance with Standard Paragraph E at the end of this notice.

17. UtiliCorp United Inc.

[Docket No. ER00–175–000]

Take notice that on October 21, 1999, UtiliCorp United Inc. filed the following three rate schedules (Rate Schedules): (1) Missouri Public Service Purchases of Electricity from Non-QF Small Independent Power Producers; (2) WestPlains Energy-Kansas Purchases of Electricity from Non-QF Small Independent Power Producers; and (3) WestPlains Energy-Colorado Purchases of Electricity from Non-QF Small Independent Power Producers. Under the three respective Rate Schedules, UtiliCorp's Missouri Public Service, WestPlains Energy-Kansas, and WestPlains Energy-Colorado operating divisions may purchase electricity from certain non-QF small-scale independent power producers.

Comment date: November 10, 1999, in accordance with Standard Paragraph E at the end of this notice.

18. PP&L, Inc., Wisconsin Electric Power Company, Jersey Central Power & Light Company, Metropolitan Edison Company and Pennsylvania Electric Company

[Docket Nos. ER00–178–000, ER00–179–000, ER00–200–000]

Take notice that on October 21, 1999, the above-mentioned affiliated power producers and/or public utilities filed their quarterly reports for the quarter ending September 30, 1999.

19. Avista Corporation

[Docket No. ER00–177–000]

Take notice that on October 21, 1999, Avista Corporation, tendered for filing with the Federal Energy Regulatory Commission pursuant to 18 CFR Part 35 of the Commission Rules and Regulations, an executed Service Agreement under Avista Corporation's FERC Electric Tariff First Revised Volume No. 9., replacing a previously filed unsigned Service Agreement with MIECO, Inc., under Docket No. ER98–3482–000, Service Agreement No. 157, effective July 1, 1998.

Notice of the filing has been served upon MIECO, Inc.

Comment date: November 10, 1999, in accordance with Standard Paragraph E at the end of this notice.

20. Tampa Electric Company

[Docket No. ER00–181–000]

Take notice that on October 21, 1999, Tampa Electric Company (Tampa Electric), tendered for filing a service agreement with City of Homestead Utilities (Homestead) under Tampa Electric's market-based sales tariff.

Tampa Electric proposes that the service agreement be made effective on September 27, 1999.

Copies of the filing have been served on Homestead and the Florida Public Service Commission.

Comment date: November 10, 1999, in accordance with Standard Paragraph E at the end of this notice.

21. Commonwealth Edison Company and Commonwealth Edison Company of Indiana

[Docket No. ER00–182–000]

Take notice that on October 21, 1999, Commonwealth Edison Company tendered for filing an amended service agreement between Commonwealth Edison Company and PECO Energy Company to put into effect a market index rate cap for sales from Commonwealth Edison Company to

PECO Energy Company in light of their announced intention to merge.

Comment date: November 10, 1999, in accordance with Standard Paragraph E at the end of this notice.

22. Entergy Services, Inc.

[Docket No. ER00–183–000]

Take notice that on October 21, 1999, Entergy Services, Inc., on behalf of Entergy Arkansas, Inc. (EAI), tendered for filing a Settlement Agreement between Entergy Services, Inc. as agent for EAI, and Associated Electric Cooperative, Inc.

Comment date: November 10, 1999, in accordance with Standard Paragraph E at the end of this notice.

23. American Electric Power Service Corporation

[Docket No. ER00–184–000]

Take notice that on October 21, 1999, the American Electric Power Service Corporation (AEPSC), on behalf of Ohio Power Company (OPCo), tendered for filing with the Commission a Facilities, Operation and Maintenance Agreement dated September 21, 1999, between OPCo and American Municipal Power—Ohio (AMP-Ohio) as agent for The Ohio Municipal Joint Venture 5 (OMEGA–JV5).

AEPSC requests an effective date of October 1, 1999, for the tendered agreement citing cause for waiver of the usual notice requirements.

A copy of the filing was served upon AMP-Ohio and the Public Utilities Commission of Ohio.

Comment date: November 10, 1999, in accordance with Standard Paragraph E at the end of this notice.

24. Hardee Power Partners Limited

[Docket No. ER00–185–000]

Take notice that on October 21, 1999, Hardee Power Partners Limited (HPP), tendered for filing an unexecuted service agreement with Reedy Creek Energy Services, Inc. (RCES) under HPP's market-based sales tariff.

HPP proposes that the service agreement be made effective on September 23, 1999.

Copies of the filing have been served on RCES and the Florida Public Service Commission.

Comment date: November 10, 1999, in accordance with Standard Paragraph E at the end of this notice.

25. Central Illinois Light Company, Rochester Gas and Electric Corporation, Monmouth Energy, Inc., Carolina Power & Light Company, Oklahoma Gas and Electric Co., Great Bay Power Corporation and Little Bay Power Corporation

[Docket Nos. ER00–189–000, ER00–190–000, ER00–191–000, ER00–196–000, ER00–197–000, ER00–201–000 and ER00–202–000

Take notice that on October 22, 1999, the above-mentioned affiliated power producers and/or public utilities filed their quarterly reports for the quarter ending September 30, 1999.

Comment date: November 10, 1999, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of these filings are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 99–28715 Filed 11–2–99; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2170–010, Alaska]

Chugach Electric Association, Inc.; Notice of Availability of Final Environmental Assessment

October 28, 1999.

A final environmental assessment (FEA) is available for public review. the FEA is for an application to amend the license for the Cooper Lake Project (FERC No. 2170) for a 4.3 megawatt increase in the rated generating capacity. The increase would be achieved by rewinding the stator coils of the generators and by replacing the runners of the turbines. The hydraulic capacity of each of the two generating units would increase from 165.5 cubic feet per second (cfs) to 190 cfs, a total project increase from 331 cfs to 380 cfs. Cooper Lake, the project reservoir would be drawn down to facilitate the upgrades of the generating units. The Cooper Lake Project is located on Cooper Lake, Cooper Creek and Kenai Lake Near Cooper Landing on the Kenai Peninsula, Alaska. The FEA finds that approval of the application would not constitute a major federal action significantly affecting the quality of the human environment.

The FEA was written by staff in the Office of Hydropower Licensing, Federal Energy Regulatory Commission. Copies of the FEA are available for review in the Commission's Public Reference Branch, Room 2A, 888 First Street, N.E., Washington, D.C. 20426 or by calling (202) 208–1371. The FEA may be viewed on the web at *httP://www.ferc.fed.us./online/rims.htm*. Please call (202) 208–2222 for assistance. For further information, please contact John K. Novak at (202) 219–2828.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–28681 Filed 11–2–99; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Intent To File Application for New License

October 28, 1999.

a. *Type of filing*: Notice of Intent to File Application for New License.

b. *Project No.*: 2105.

c. *Date filed*: October 19, 1999.

d. *Submitted By*: Pacific Gas and Electric Company.

e. *Name of Project*: Upper North Fork Feather River Hydroelectric Project.

f. *Location*: On the North Fork Feather River and Butt Creek in Plumas County, California.

g. *Filed Pursuant to*: Section 15 of the Federal Power Act, 18 CFR 16.6 of the Commission's regulations.

h. *Effective date of original license*: November 1, 1954.

i. *Expiration date of original license*: October 31, 2004.

j. The project consists of the Butt Valley powerhouse with an installed capacity of 41 megawatts (MW), the Caribou No. 1 powerhouse with an installed capacity of 75 MW, the

Caribou No. 2 powerhouse with an installed capacity of 120 MW, the Oak Flat powerhouse with an installed capacity of 1.3 MW, and the Belden powerhouse with an installed capacity of 125 MW.

k. Pursuant to 18 CFR 16.7, information on the project is available contacting John Gourley at Pacific Gas and Electric Company, 245 Market Street, Room 1137, San Francisco, CA 94105, (415) 972–5772.

l. *FERC contact*: Sergiu Serban (202) 501–6935.

m. Pursuant to 18 CFR 16.9(b)(l) each application for a new license and any competing license applications must be filed with the Commission at least 24 months prior to the expiration of the existing license. All applications for license for this project must be filed by October 31, 2002.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 99–28680 Filed 11–2–99; 8:45 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6469–2]

Adequacy Status of Milwaukee, Wisconsin Submitted 9% Rate of Progress Plan for Transportation Conformity Purposes

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of adequacy.

SUMMARY: In this document, EPA is notifying the public that EPA has found that the Milwaukee, Wisconsin 9% Rate of Progress (ROP) plan does contain adequate mobile source emission budgets. On March 2, 1999, the D.C. Circuit Court ruled that submitted State Implementation Plans (SIPs) cannot be used for conformity determinations until EPA has affirmatively found them adequate. Since the December 11, 1997, submittal does contain adequate budgets, this attainment demonstration can be used for future conformity determinations.

FOR FURTHER INFORMATION CONTACT: The finding and the response to comments will be available at EPA's conformity website: *http://www.epa.gov/oms/traq*, (once there, click on the ''Conformity'' button, then look for ''Adequacy Review of SIP Submissions for Conformity'').

Michael G. Leslie, Regulation Development Section (AR–18J), Air Programs Branch, Air and Radiation Division, United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard., Chicago, Illinois, 60604, (312) 353–6680, leslie.michael@epa.gov.

SUPPLEMENTARY INFORMATION:

Background

Throughout this document, whenever ''we'', ''us'' or ''our'' is used, we mean EPA. This notice is simply an announcement of a finding that we have already made. EPA Region 5 sent a letter to the Wisconsin Department of Natural Resources on October 7, 1999, stating that the Milwaukee, Wisconsin submitted 9% ROP does contain adequate mobile source emission budgets. This finding will also be announced on EPA's conformity website: http://www.epa.gov/oms/traq, (once there, click on the ''Conformity'' button, then look for ''Adequacy Review of SIP Submissions for Conformity'').

Transportation conformity is required by section 176(c) of the Clean Air Act. EPA's conformity rule requires that transportation plans, programs, and projects conform to state air quality implementation plans and establishes the criteria and procedures for determining whether or not they do. Conformity to a SIP means that transportation activities will not produce new air quality violations, worsen existing violations, or delay timely attainment of the national ambient air quality standards.

The criteria by which we determine whether a SIP's motor vehicle emission budgets are adequate for conformity purposes are outlined in 40 CFR 93.118(e)(4). Please note that an adequacy review is separate from EPA's completeness review, and it also should not be used to prejudge EPA's ultimate approval of the SIP. Even if we find a budget adequate, the SIP could later be disapproved.

We've described our process for determining the adequacy of submitted SIP budgets in guidance (May 14, 1999 memo titled ''Conformity Guidance on Implementation of March 2, 1999 Conformity Court Decision''). We followed this guidance in making our adequacy determination.

Authority: 42 U.S.C. 7401–7671q.

Dated: October 22, 1999.

David A. Ullrich,

Acting Regional Administrator, Region 5.

[FR Doc. 99–28724 Filed 11–2–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–100150; FRL–6386–2]

Oracle Corporation; Transfer of Data

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces that pesticide related information submitted to EPA's Office of Pesticide Programs (OPP) pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), including information that may have been claimed as Confidential Business Information (CBI) by the submitter, will be transferred to Oracle Corporation in accordance with 40 CFR 2.307(h)(3) and 2.308(i)(2). Oracle Corporation has been awarded a contract to perform work for OPP, and access to this information will enable Oracle Corporation to fulfill the obligations of the contract.

DATES: Oracle Corporation will be given access to this information on or before November 8, 1999.

FOR FURTHER INFORMATION CONTACT: By mail: Erik R. Johnson, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: 703–305–7248; e-mail address: johnson.erik@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

This action applies to the public in general. As such, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person under ''FOR FURTHER INFORMATION CONTACT.''

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**--Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

II. Contractor Requirements

Under this contract number, the contractor will perform the following:

Under Contract No. 68-W2-0033, this project will deal with the analysis, design, development, installation, and maintenance of OPP applications developed in Oracle as the RDBMS with Graphical User Interface. The requirements may consist of detailed system requirements/specifications, screen layouts, navigation and interface among screens, data validation rules, and detailed storage and processing requirements. The contractor will complete the work to meet the requirements of the assignment, complete initial alpha testing, and document the completed work.

This contract involves no subcontractors.

The OPP has determined that the contract described in this document involves work that is being conducted in connection with FIFRA, in that pesticide chemicals will be the subject of certain evaluations to be made under this contract. These evaluations may be used in subsequent regulatory decisions under FIFRA.

Some of this information may be entitled to confidential treatment. The information has been submitted to EPA under sections 3, 4, 6, and 7 of FIFRA and under sections 408 and 409 of the FFDCA.

In accordance with the requirements of 40 CFR 2.307(h)(3), the contract with Oracle Corporation, prohibits use of the information for any purpose not specified in this contract; prohibits disclosure of the information to a third party without prior written approval from the Agency; and requires that each official and employee of the contractor sign an agreement to protect the information from unauthorized release and to handle it in accordance with the FIFRA Information Security Manual. In addition, Oracle Corporation is required to submit for EPA approval a security plan under which any CBI will be secured and protected against unauthorized release or compromise. No information will be provided to Oracle Corporation until the requirements in this document have been fully satisfied. Records of information provided to Oracle Corporation will be maintained by EPA Project Officers for this contract. All information supplied to Oracle Corporation by EPA for use in connection with this contract will be returned to EPA when Oracle Corporation has completed its work.

List of Subjects

Environmental protection, Business and industry, Government contracts, Government property, Security measures.

Dated: September 30, 1999.

Richard D. Schmitt

Acting Director, Information Resources and Services Division, Office of Pesticide Programs.

[FR Doc. 99–28727 Filed 11–2–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6468–9]

Guam: Adequacy Determination of State Municipal Solid Waste Permit Program

AGENCY: Environmental Protection Agency.

ACTION: Notice; extension of comment period for tentative determination to fully approve the adequacy of the Guam Municipal Solid Waste Permitting Program.

SUMMARY: Section 4005(c)(1)(B) of the Resource Conservation and Recovery Act (RCRA), as amended by the Hazardous and Solid Waste Amendments (HSWA) of 1984, 42 U.S.C. 6945(1)(B), requires states to develop and implement permit programs to ensure that municipal solid waste landfills (MSWLFs), which may receive hazardous household waste or small quantity generator hazardous waste will comply with the revised Federal MSWLF Criteria (40 CFR part 258). RCRA section 4005(c)(1)(C), 42 U.S.C. 6945(c)(1)(C), requires the Environmental Protection Agency (EPA) to determine whether states have adequate ''permit'' programs for MSWLFs, but does not mandate issuance of a rule for such determinations. Approved State permit programs provide for interaction between the State and the Owner/Operator regarding site-specific permit conditions. Only those owners/operators located in States with approved permit programs can use the site specific flexibilities provided by 40 CFR part 258 to the extent the State permit program allows such flexibility. EPA notes that, regardless of the approval status of any facility, the federal landfill criteria shall apply to all permitted and unpermitted MSWLF facilities.

Guam is defined as a ''State'' in 40 CFR 258.2. Guam has applied for a determination of adequacy under section 4005(c)(1)(C) of RCRA, 42 U.S.C. 6945(c)(1)(C). EPA Region IX has reviewed Guam's MSWLF permit program application and has made a tentative determination that all portions of Guam's MSWLF permit program are adequate to assure compliance with the revised MSWLF Criteria. Guam's application for program adequacy determination is available for public review and comment at the place(s) listed in the **ADDRESSES** section below during regular office hours.

RCRA does not require EPA to hold a public hearing on a determination to approve any State's MSWLF permit. However, if a sufficient number of persons express interest in participating in a hearing by writing to the Region IX Solid Waste Program or calling the contact given below by November 22, 1999 the Region will hold a hearing in Tiyan, Guam. The Region will notify all persons who submit comments on this notice if it appears that there is sufficient public interest to warrant a hearing. In addition, anyone who wishes to learn whether the hearing will be held may call the person listed in the **FOR FURTHER INFORMATION CONTACT** section below.

DATES: The Public Comment Period for Guam's application for a determination of adequacy has been extended to November 22, 1999. All comments on Guam's application for a determination of adequacy must be received by the close of business on November 22, 1999. If there is sufficient interest, a public hearing will be held in Tiyan, Guam at least 45 days from the date of notice that such a hearing will be held. Guam's Environmental Protection Agency will participate in the public hearing, if held by EPA on this subject.

ADDRESSES: Written comments should be sent to Ms. Heidi Hall, Chief, Solid Waste Program, mail code WST–7, EPA Region IX, 75 Hawthorne Street, San Francisco, California 94105. The public hearing, if held, will be held at the Guam Environmental Protection Agency's Main Conference Room, Building 15–6101 Mariner Avenue, Tiyan, Guam. Copies of Guam's application for adequacy determination are available at the following address for inspection and copying: Guam Environmental Protection Agency, Calibration Laboratory Building, 15–6101 Mariner Ave. Tiyan, Barrigada, Guam between the hours of 8:00 a.m. and 5:00 p.m.

FOR FURTHER INFORMATION CONTACT: EPA Region IX, 75 Hawthorne Street, San Francisco, California 94105 attention Ms. Beth Godfrey, mail code WST–7, telephone 415 744–2095.

Compliance With Executive Order 12866

The Office of Management and Budget has exempted this document from the requirements of section 6 of Executive Order 12866.

Certification Under the Regulatory Flexibility Act

Pursuant to the provisions of 5 U.S.C. 605(b), I hereby certify that this approval will not have a significant economic impact on a substantial number of small entities. It does not impose any mew burdens on small entities. This document, therefore, does not require a regulatory flexibility analysis.

Authority: This document is issued under the authority of section 4005 of the Solid Waste Disposal Act, as amended, 42 U.S.C. 6946.

Dated: October 20, 1999.

Laura Yoshi,

Acting Regional Administrator, Region 9.

[FR Doc. 99–28721 Filed 11–2–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–00622; FRL–6387–3]

Pesticide Data Submitters List; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of an updated version of the Pesticide Data Submitters List which supersedes and replaces all previous versions. The Pesticide Data Submitters List is a compilation of names and addresses of registrants who wish to be notified and offered compensation for use of their data. It was developed to assist pesticide applicants in fulfilling their obligation as required by sections 3(c)(1)(f) and 3(c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and 40 CFR part 152, subpart E regarding ownership of data used to support registration.

DATES: Comments regarding additions, deletions, and changes to the Data Submitters List must be received on or before March 15, 2000 to be included in the next edition of the Data Submitters List which is scheduled for publication on March 31, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the ''SUPPLEMENTARY INFORMATION.'' To ensure proper receipt by EPA it is imperative that you identify docket control number OPP-00622 in the subject line on the front page of your response.

FOR FURTHER INFORMATION CONTACT: John Jamula, Information Resources and Services Division, mail code (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305–6426.; fax number: (703) 305–7670; e-mail address: jamula.john @epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to those persons who plan to apply for registration of pesticide products under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under ''FOR FURTHER INFORMATION CONTACT.''

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**- -Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

You may access an electronic copy of the Data Submitters List from the EPA Internet Home Page at http://www.epa.gov. To access the Data Submitters List by searching for the keyword 'DataSubmittersList'. You can also access the Data Submitters List directly at http://www.epa.gov/opppmsd1/DataSubmittersList/index.html. Note that this address is case sensitive.

2. *In person.* The Data Submitters List is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *On Microfiche.* The Data Submitters List is available on microfiche from the National Technical Information Service (NTIS) ATTN: Order Desk, 5285 Port Royal Road, Springfield, VA 22161. Telephone: 1–800–553–6847. When requesting a document from NTIS, please provide its name and publication number (PB). The NTIS publication number for this version of the Data Submitters List is PB–99–171670.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically.

1. *By mail.* Submit your comments regarding additions, changes and deletions to: Information Services Branch (7504C) (DSL), Information Resources and Services Division Office of Pesticide Programs, U.S. Environmental Protection Agency, Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Document Processing Desk, Information Services Branch (ISB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 226, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Document Processing Desk is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

D. How Should I Handle CBI That I Want To Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under ''FOR FURTHER INFORMATION CONTACT.''

II. What Action Is the Agency Taking?

The Office of Pesticide Programs announces the availability of an updated version of the Pesticide Data Submitters List which supersedes and replaces all previous versions. The Pesticide Data Submitters List is a compilation of names and addresses of registrants who wish to be notified and offered compensation for use of their data. It was developed to assist pesticide applicants in fulfilling their obligation as required by sections 3(c)(1)(f) and 3(c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and 40 CFR part 152 subpart E regarding ownership of data used to support registration.

List of Subjects

Environmental protection, Data Submitters List

Dated: October 4, 1999.

Richard D. Schmitt,

Acting Director, Information Resources and Services Division, Office of Pesticide Programs.

[FR Doc. 99–28730 Filed 11–2–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENT PROTECTION AGENCY

[OPP–66271; FRL–6383–9]

Notice of Receipt of Requests To Voluntarily Cancel Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with Section 6(f)(1) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, EPA is issuing a notice of receipt of requests by registrants to voluntarily cancel certain pesticide registrations.

DATE: Unless a request is withdrawn the Agency will approve these use deletions and the deletions will become effective on May 1, 2000.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Hollins, Office of Pesticide Programs (7502C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location for commercial courier delivery and telephone number: Room, 224, Crystal Mall No. 2, 1921 Jefferson Davis Highway, Arlington, VA 22202, e-mail: hollins.james@epa.gov.(703) 305–5761.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to persons who produce or use pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the information in this notice, consult the person listed in the ''FOR FURTHER INFORMATION CONTACT'' section.

B. How Can I Get Additional Information or Copies of Support Documents?

1. *Electronically.* You may obtain electronic copies of this document and various support documents are available from the EPA Home Page at the **Federal Register**- Environmental Documents entry for this document under ''Laws and Regulations'' (http://www.epa.gov/fedrgstr/).

2. *In person.* The Agency has established an official record for this action under docket control number [insert appropriate docket #]. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4:00 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. What Action Is the Agency Taking?

This notice announces receipt by the Agency of applications from registrants to cancel some 45 pesticide products registered under Section 3 or 24 of FIFRA. These registrations are listed in sequence by registration number (or company number and 24 number) in the following Table 1:

TABLE 1.—REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION

Registration no.	Product Name	Chemical Name
000402–00132	Aerochem General Purpose Spray	*o*-Isopropoxyphenyl methylcarbamate
N/A	N/A	*N*-Octyl bicycloheptene dicarboximide
N/A	N/A	(Butylcarbityl)(6-propylpiperonyl)ether 80% and related compounds 20%
N/A	N/A	Pyrethrins
000707–00204	Kelthane EC Agricultural Miticide	1,1-Bis(chlorophenyl)-2,2,2-trichloroethanol
001459–00027	Ack-Ack Residual Insect Spray	*o*-Isopropoxyphenyl methylcarbamate
002517–00065	Sergeant's Flea & Tick Killer and Coat Conditioning Spray	*o*-Isopropoxyphenyl methylcarbamate
002781–00003	Happy Jack Kennel Dip	Lindane (Gamma isomer of benzene hexachloride)(99% pure gamma isomer
002781–00047	Sardex	*O,O*-Diethyl *O*-(3,5,6-trichloro-2-pyridyl)phosphorothioate
002935 WA–88–0003.	Dupont Karmex Df Herbicide	3-(3,4-Dichlorophenyl)-1,1-dimethylurea
002935 WA–97–0018.	Methyl Parathion 5 Spray	*O,O*-Dimethyl *O*-*p*-nitrophenyl phosphorothioate
004758–00078	Holiday Double Strength Fly Relief Insect Repellant	Butoxypolypropylene glycol
N/A	N/A	*N,N*-Diethyl-meta-toluamide and other isomers

TABLE 1.—REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION—Continued

Registration no.	Product Name	Chemical Name
004758–00081	Holiday Outdoorsman Insect Repellent	*N,N*-Diethyl-meta-toluamide and other isomers
006959–00089	Cessco Accudose Residual Spray II	*o*-Isopropoxyphenyl methylcarbamate
N/A	N/A	(Butylcarbityl)(6-propylpiperonyl)ether 80% and related compounds 20%
N/A	N/A	Pyrethrins
N/A	N/A	Rotenone
007401–00315	Ferti-Lome Lindane Borer, Leaf Miner & Bark Beetle Spray	Lindane (Gamma isomer of benzene hexachloride)99% pure gamma isomer
007401–00321	Hi-Yield Lindane Spray	Lindane (Gamma isomer of benzene hexachloride)99% pure gamma isomer
010370–00182	Bendiocarb 20% Wettable Powder	Bendiocarb (2,2-dimethyl-1,3-benzoldioxol-4-yl methylcarbamate)
010370–00183	Bendiocarb 76% Wettable Powder	Bendiocarb (2,2-dimethyl-1,3-benzoldioxol-4-yl methylcarbamate)
010370–00185	Bendiocarb Technical 95.0%	Bendiocarb (2,2-dimethyl-1,3-benzoldioxol-4-yl methylcarbamate)
011715–00012	Speer Fast Knockdown Wasp & Hornet Spray	*o*-Isopropoxyphenyl methylcarbamate
N/A	N/A	*N*-Octyl bicycloheptene dicarboximide
N/A	N/A	(Butylcarbityl)(6-propylpiperonyl)ether 80% and related compounds 20%
N/A	N/A	Pyrethrins
011715–00022	Speer Insect Repellent	*N,N*-Diethyl-meta-toluamide and other isomers
011715–00086	Speer Insect Repellent for Fisherman, Hunters, and Camp	Dipropyl isocinchomeronate
N/A	N/A	*N*-Octyl bicycloheptene dicarboximide
N/A	N/A	*N,N*-Diethyl-meta-toluamide and other isomers
011715–00129	Magic Guard Residual Insecticide	*o*-Isopropoxyphenyl methylcarbamate
N/A	N/A	*N*-Octyl bicycloheptene dicarboximide
N/A	N/A	(Butylcarbityl)(6-propylpiperonyl)ether 80% and related compounds 20%
N/A	N/A	Pyrethrins
011715–00185	Speer Repellent 100	*N,N*-Diethyl-meta-toluamide and other isomers
011715–00242	SPI Personal Insect Repellent Towelette	Dipropyl isocinchomeronate
N/A	N/A	*N*-Octyl bicycloheptene dicarboximide
N/A	N/A	*N,N*-Diethyl-meta-toluamide and other isomers
011715–00301	Speer Cyfluthrin Ant and Roach Killer II	*o*-Isopropoxyphenyl methylcarbamate
N/A	N/A	(Butylcarbityl)(6-propylpiperonyl)ether 80% and related compounds 20%
N/A	N/A	Pyrethrins
N/A	N/A	CYANO(4-FLUORO-3-PHENOXYPHENYL)METHYL 3-(2,2-DICHLOROETHENYL)-2,2-
019713–00220	Dylox 5% Granular Insecticide	Dimethyl (2,2,2-trichloro-1-hydroxyethyl)phosphonate
019713–00314	Drexel Shoo Insect Repellent Lotion	*N,N*-Diethyl-meta-toluamide and other isomers
032802–00051	Sevin Brand 5% Carbaryl Insecticide	1-Naphthyl-*N*-methylcarbamate
032802–00058	Carbaryl 390 Insecticide/Fertilizer	1-Naphthyl-*N*-methylcarbamate
032802–00059	Carbaryl 143 Insecticide/fertilizer	1-Naphthyl-*N*-methylcarbamate
033355–00012	Selcide 901	5-Chloro-2-methyl-3(2H)-isothiazolone
N/A	N/A	2-Methyl-3(2H)-isothiazolone
045639–00001	Ficam W	Bendiocarb (2,2-dimethyl-1,3-benzoldioxol-4-yl methylcarbamate)
045639–00002	Bendiocarb WP	Bendiocarb (2,2-dimethyl-1,3-benzoldioxol-4-yl methylcarbamate)
045639–00003	Ficam D	Bendiocarb (2,2-dimethyl-1,3-benzoldioxol-4-yl methylcarbamate)
045639–00006	Bendiocarb Technical	Bendiocarb (2,2-dimethyl-1,3-benzoldioxol-4-yl methylcarbamate)
045639–00009	Bendiocarb 1% Dust	Bendiocarb (2,2-dimethyl-1,3-benzoldioxol-4-yl methylcarbamate)
045639–00010	Bendiocarb 1% Homeowner Dust	Bendiocarb (2,2-dimethyl-1,3-benzoldioxol-4-yl methylcarbamate)
045639–00059	Turcam	Bendiocarb (2,2-dimethyl-1,3-benzoldioxol-4-yl methylcarbamate)
045639–00066	Ficam Plus	(Butylcarbityl)(6-propylpiperonyl)ether 80% and related compounds 20%
N/A	N/A	Pyrethrins
N/A	N/A	Bendiocarb (2,2-dimethyl-1,3-benzoldioxol-4-yl methylcarbamate)
045639–00100	Turcam 2 1/2 G	Bendiocarb (2,2-dimethyl-1,3-benzoldioxol-4-yl methylcarbamate)
045639–00148	Turcam Fertilizer	Bendiocarb (2,2-dimethyl-1,3-benzoldioxol-4-yl methylcarbamate)
045639–00150	Ficam 2 1/2 G	Bendiocarb (2,2-dimethyl-1,3-benzoldioxol-4-yl methylcarbamate)
067517–00050	Tick and Mange Dip for Dogs	Lindane (Gamma isomer of benzene hexachloride)99% pure gamma isomer

TABLE 1.—REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION—Continued

Registration no.	Product Name	Chemical Name
067760–00021	Chlorpyrifos 4E-AG	*O,O*-Diethyl *O*-(3,5,6-trichloro-2-pyridyl)phosphorothioate
068688–00020	Elite Insect Repellent 100	*N,N*-Diethyl-meta-toluamide and other isomers
068688–00042	Elite Insect Repellent Spray-R70	Dipropyl isocinchomeronate
N/A	N/A	*N*-Octyl bicycloheptene dicarboximide
N/A	N/A	*N,N*-Diethyl-meta-toluamide and other isomers
070051–00038	Anagrapha Falcifera MNPV PIB's	Anagrapha falcifera multi-nuclear polyhedrosis virus polyhedral inclusion

Unless a request is withdrawn by the registrant within 180 days (30 days when requested by registrant) of publication of this notice, orders will be issued canceling all of these registrations. (A 30-day comment period applies to EPA Registrations 002781-00003. 002781-00047 and 067517-00050).

Users of these pesticides or anyone else desiring the retention of a registration should contact the applicable registrant during this comment period.

The following Table 2 includes the names and addresses of record for all registrants of the products in Table 1, in sequence by EPA company number:

Table 2—Registrants Requesting Voluntary Cancellation

EPA Company no.	Company Name and Address
000402	Hill Mfg. Co., Inc., 1500 Jonesboro Rd Se, Atlanta, GA 30315.
000707	Rohm & Haas Co, Attn: Robert H. Larkin, 100 Independence Mall W., Philadelphia, PA 19106.
001459	Bullen Companies, Box 37, Folcroft, PA 19032.
002517	Sergeant's Pet Products, Box 18993, Memphis, TN 38181.
002781	Happy Jack Inc., Box 475, Snow Hill, NC 28580.
002935	Wilbur Ellis Co., 191 W. Shaw Ave, #107, Fresno, CA 93704.
004758	Pet Chemicals, 4242 BF Goodrich Blvd, Box 18993, Memphis, TN 38181.
006959	Cessco Inc., 3609A River Rd, Johns Island, SC 29455.
007401	Brazos Associates, Inc., Agent For: Voluntary Purchasing Group Inc≤, c/o Voluntary Purchasing Groups, Inc. Box 460, Bonham, TX 75418.
010370	Agrevo Environmental Health, 95 Chestnut Ridge Rd, Montvale, NJ 07645.

Table 2—Registrants Requesting Voluntary Cancellation—Continued

EPA Company no.	Company Name and Address
011715	Speer Products Inc., 4242 B.F. Goodrich Blvd., Memphis, TN 38181.
019713	Drexel Chemical Co, 1700 Channel Ave., Box 13327, Memphis, TN 38113.
032802	Howard Johnson's Enterprises Inc., 700 W. Virginia St., Ste 222, Milwaukee, WI 53204.
033355	Southeastern Laboratories, Inc., Box 10189, Goldsboro, NC 27532.
045639	Agrevo USA Co, Little Falls Centre One, 2711 Centerville Rd, Wilmington, DE 19808.
067517	PM Resources Inc., 13001 St. Charles Rock Rd, Bridgeton, MO 63044.
067760	Cheminova Inc., Oak Hill Park 1700 Route 23 - Ste 210, Wayne, NJ 07470.
068688	Speer Products Inc., 4242 B.F. Goodrich Blvd., , Memphis, TN 38181.
070051	Thermo Trilogy Corp., 9145 Guilford Rd., Suite 175, Columbia, MD 21046.

III. Loss of Active Ingredients

Unless the request for cancellation is withdrawn, one pesticide active ingredient will no longer appear in any registered products. Those who are concerned about the potential loss of this active ingredient for pesticidal use are encouraged to work directly with the registrant(s) to explore the possibility of withdrawing their request for cancellation. The active ingredient is listed in the following Table 3, with the CAS Number and EPA Company Number.

TABLE 3.—ACTIVE INGREDIENTS WHICH WOULD DISAPPEAR AS A RESULT OF REGISTRANT'S REQUEST TO CANCEL

CAS No.	Chemical Name	EPA Co. Number
None Assigned.	Anagrapha falcifera MNPV PIB's in aqueous suspension	070051

IV. What Is the Agency's Authority for Taking This Action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be amended to delete one or more uses. The Act further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, the Administrator may approve such a request.

V. Procedures for Withdrawal of Request

Registrants who choose to withdraw a request for cancellation must submit such withdrawal in writing to James A. Hollins, at the address given above, postmarked before May 1, 2000. This written withdrawal of the request for cancellation will apply only to the applicable 6(f)(1) request listed in this notice. If the product(s) have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling. The withdrawal request must also include a commitment to pay any reregistration fees due, and to fulfill any applicable unsatisfied data requirements.

VI. Provisions for Disposition of Existing Stocks

The effective date of cancellation will be the date of the cancellation order. The orders effecting these requested cancellations will generally permit a registrant to sell or distribute existing

stocks for one year after the date the cancellation request was received by the Agency. This policy is in accordance with the Agency's statement of policy as prescribed in **Federal Register** dated June 26, 1991 (56 FR 29362) (FRL–3846–4). Exception to this general rule will be made if a product poses a risk concern, or is in noncompliance with reregistration requirements, or is subject to a data call-in. In all cases, product-specific disposition dates will be given in the cancellation orders.

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the cancellation action. Unless the provisions of an earlier order apply, existing stocks already in the hands of dealers or users can be distributed, sold or used legally until they are exhausted, provided that such further sale and use comply with the EPA- approved label and labeling of the affected product(s). Exceptions to these general rules will be made in specific cases when more stringent restrictions on sale, distribution, or use of the products or their ingredients have already been imposed, as in Special Review actions, or where the Agency has identified significant potential risk concerns associated with a particular chemical.

Dated: September 29, 1999.

Richard D. Schmitt,

Acting Director, Information Resources & Services Division, Office of Pesticide Programs.

[FR Doc. 99–28729 Filed 11–2–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[OPP–30468A; FRL–6387–1]

Pesticide Product Registrations; Conditional Approval

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces Agency approval of applications submitted by Tomen Agro Inc., to conditionally register the pesticide products Fenhexamid Technical and Elevate 50 WDG Fungicide products containing a new active ingredient not included in any previously registered products pursuant to the provisions of section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

FOR FURTHER INFORMATION CONTACT: By mail: Mary Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: 703–308–9354; and e-mail address: waller.mary@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

ategories

Cat-egories	NAICS codes	Examples of poten-tially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufac-turing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the ''FOR FURTHER INFORMATION CONTACT.''

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**--Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

To access a fact sheet which provides more detail on this registration, go to the home page for the Office of Pesticide Programs at http://www.epa.gov/pesticides/, and select ''factsheet.''

2. *In person*. The Agency has established an official record for this action under docket control number OPP–30468A. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

In accordance with section 3(c)(2) of FIFRA, a copy of the approved label, the list of data references, the data and other scientific information used to support registration, except for material specifically protected by section 10 of FIFRA, are available for public inspection in the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Rm. 119, Crystal Mall #2, Arlington, VA ((703) 305–5805). Requests for data must be made in accordance with the provisions of the Freedom of Information Act and must be addressed to the Freedom of Information Office (A–101), 401 M St., SW., Washington, DC 20460. Such requests should: Identify the product name and registration number and specify the data or information desired.

A paper copy of the fact sheet, which provides more detail on this registration, may be obtained from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

II. Did EPA Conditionally Approve the Application(s)?

A conditional registration may be granted under section 3(c)(7)(C) of FIFRA for a new active ingredient where certain data are lacking, on condition that such data are received by the end of the conditional registration period and do not meet or exceed the risk criteria set forth in 40 CFR 154.7; that

use of the pesticide during the conditional registration period will not cause unreasonable adverse effects; and that use of the pesticide is in the public interest. The Agency has considered the available data on the risks associated with the proposed use of *N*-(2,3-dichloro-4-hydroxyphenyl)-1-methyl cyclohexanecarboxamide, and information on social, economic, and environmental benefits to be derived from such use. Specifically, the Agency has considered the nature and its pattern of use, application methods and rates, and level and extent of potential exposure. Based on these reviews, the Agency was able to make basic health and safety determinations which show that use of *N*-(2,3-dichloro-4-hydroxyphenyl)-1-methyl cyclohexanecarboxamide during the period of conditional registration will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is, in the public interest.

Consistent with section 3(c)(7)(C) of FIFRA, the Agency has determined that these conditional registrations are in the public interest. Use of the pesticides are of significance to the user community, and appropriate labeling, use directions, and other measures have been taken to ensure that use of the pesticides will not result in unreasonable adverse effects to man and the environment.

III. Conditionally Approved Registrations

EPA issued a notice, published in the **Federal Register** of February 23, 1999 (64 FR 8815)(FRL–6062–1), which announced that Tomen Agro Inc., 100 First St., Suite 1610, San Francisco, CA 94105, had submitted applications to register the products Fenhexamid Technical and Elevate 50 WDG Fungicide (EPA File Symbols 66330–GA and 66330–GL) containing the active ingredient *N*-(2,3-dichloro-4-hydroxyphenyl)-1-methyl cyclohexanecarboxamide at 97.8% and 50% respectively. These products were not previously registered.

The applications were approved on May 21, 1999, for one technical and one end-use product:

1.Fenhexamid Technical for manufacturing use only; for disease control in grapes, strawberries, and ornamentals (EPA Registration Number 66330–36.

2. Elevate 50 WDG Fungicide for agricultural and horticultural use only; for use to control *Botrytis* diseases of grapes, strawberries, and ornamentals (EPA Registration Number 66330–35).

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: October 13, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 99–28638 Filed 11–2–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–897; FRL–6389–1]

Notice of Filing a Pesticide Petition To Establish a Tolerance for Certain Pesticide Chemicals in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by docket control number PF–897, must be received on or before December 3, 1999.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the ''SUPPLEMENTARY INFORMATION'' section. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–897 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: James Tompkins, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305–5697; and e-mail address: tompkins.james@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of potentially affected entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the ''FOR FURTHER INFORMATION CONTACT'' section.

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**--Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number PF–897. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway,

Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–897 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically.* You may submit your comments electronically by E-mail to: ''*opp-docket@epa.gov*,'' or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–897. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want To Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the ''FOR FURTHER INFORMATION CONTACT'' section.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action Is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 26, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

The petitioner summary of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the views of the petitioner. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

E.I. DuPont de Nemours & Company

PP 7F4849 and 9F6039

EPA has received pesticide petitions (9F6039 and an amended petition 7F4849) from E.I. DuPont de Nemours and Company, Barley Mill Plaza, P.O. Box 80083, Wilmington, DE 19880-0038 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of azafenidin, 2-[2,4-dichloro-5-(2-propynyloxy)phenyl]-5,6,7,8-tetrahydro-1,2,4-triazolo[4,3-a]pyridin-3(2H)-one] in or on the raw agricultural commodities (RAC) crop groupings of pome fruits at 0.02 ppm, the crop grouping stone fruits at 0.02 ppm, the crop grouping of tree nuts including pistachios at 0.02 ppm, and almond hulls at 0.5 ppm 9F6039. On December 3, 1997 (62 FR 63942) (FRL–5756–1), EPA issued a notice proposing to amend 40 CFR part 180 by establishing tolerances for residues of azafendin in or on the raw agricultural commodities (RAC) crop grouping citrus, grapes, sugarcane, and sugarcane molasses (7F4849). DuPont has amended PP 7F4849 by proposing the amend 40 CFR part 180 by establishing tolerances for residues of the herbicide azafenidn, 2-[2,4-dichloro-5-(2-propynyloxy)phenyl]-5,6,7,8-tetrahydro-1,2,4-triazolo[4.3-a]pyridin-3(2H)-one in or on the crop grouping citrus at 0.1 ppm, and the RAC citrus oil at 0.50 ppm, grapes at 0.02 ppm, sugarcane at 0.05 ppm, and sugarcane molasses at 0.5 ppm . EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. The qualitative nature of the residues of azafenidin in pome fruit, stone fruit, and tree nuts is

adequately understood for the purposes of registration. Similar metabolic pathways were previously demonstrated in the three dissimilar crops of grapefruit, grapes, and sugarcane. The primary metabolic pathway begins with rapid O-dealkylation and production of hydroxyl derivatives, with subsequent formation of glucoside conjugates.

2. *Analytical method*. There is an independently validated practical analytical method available using gas chromatography (GC) and mass selective detection (MS) to measure levels of azafenidin in or on pome fruits, stone fruits, and tree nuts, with limits of quantitation (LOQ) that will allow for monitoring of crop residues at or above tolerance levels.

3. *Magnitude of residues*. Crop field trial residue data from pome fruit, stone fruit and tree nut studies show that the proposed tolerances on these commodities will not be exceeded when Milestone* is used as directed. Excessive application rates made to pome fruit and stone fruit in field trial residue studies demonstrated that azafenidin does not concentrate in the processed commodities of these crops.

B. Toxicological Profile

1. *Acute toxicity*. Technical azafenidin has been placed in acute toxicology category III based on overall results from several studies. Results from the following studies indicate toxicology category III: acute dermal toxicity (LD_{50} > 2,000 milligrams/kilograms (mg/kg); rabbits) and eye irritation (effects reversible within 72 hours; rabbits). Acute oral toxicity (LD_{50} > 5,000 mg/kg; rats), acute inhalation toxicity (LC_{50} > 5.4 milligrams per liter (mg/L), rats) and skin irritation (slight effects resolved within 48 hours; rabbits) results were assigned toxicology category IV. Technical azafenidin is not a dermal sensitizer.

An acute neurotoxicity study was conducted in rats administered azafenidin via gavage at 0, 100, 300, or 900 mg/kg. Azafenidin was not neurotoxic at any dose. The systemic no observed adverse effect level (NOAEL) was 100 mg/kg for males and females based on reduced food consumption and body weights at 300 mg/kg and above.

2. *Genotoxicity*. Technical azafenidin was negative for genotoxicity in a battery of *in vitro* and *in vivo* tests. These tests included the following: mutagenicity in bacterial (Ames test) and mammalian Chinese hampster ovary/hypoxanthine guanine phophoribosyl transferase (CHO/HGPRT assay) cells; *in vitro* cytogenetics (chromosomal aberration in human lymphocytes); *in vivo* cytogenetics (bone marrow micronucleus assay in mice); and unscheduled DNA synthesis (UDS) in rat primary hepatocytes.

3. *Reproductive and developmental toxicity*—i. A 2-generation reproduction study was conducted in rats with dietary technical azafenidin concentrations of 0, 5, 30, 180, or 1,080 ppm. The NOAEL was 30 ppm (1.7 to 2.8 mg/kg/day for P_1 and F_1 males and females and their offspring). This was based on the following effects at 180 ppm (10.1 to 17.8 mg/kg/day for P_1 and F_1 males and females and/or their offspring): slight reductions in mean body weights for F_1 males and females; reductions in mean gestation body weight gain and implantation efficiency; slightly increased gestation lengths; decreased offspring survival, body weights and other indices of offspring health; and increased incidence of diarrhea among F_1 parental males.

ii. A developmental study was conducted in rats administered technical azafenidin by gavage at 0, 3, 8, 16, or 24 mg/kg/day. Azafenidin was not teratogenic. The NOAEL was 16 mg/kg/day based on the following observations at 24 mg/kg/day: reduced maternal body weight, increased resorptions, reductions in litter size and fetal weights and increased sternebral variations. The maternal effects consisted of transient body weight reductions; however, the nature of these effects suggested that fetal resorptions contributed to weight reductions.

iii. A developmental study was conducted in rabbits administered technical azafenidin by gavage at 0, 12, 36, 100, or 300 mg/kg/day. Azafenidin was not teratogenic. The NOAELs for maternal and offspring toxicity were 12 and 100 mg/kg/day, respectively. The maternal NOAEL was based on reduced body weight at 36 and 100 mg/kg/day and mortality at higher doses. Excessive maternal toxicity at 300 mg/kg/day precluded assessment of developmental effects at this level. However, the developmental NOAEL was considered to be 100 mg/kg/day since there were no indications of fetal toxicity up to and including this dose level.

iv. A dermal pre-natal developmental toxicity study was conducted in rats administered technical azafenidin. The dose levels were 0, 5, 25, 50, and 100 mg/kg/day. The NOAEL was 5 mg/kg/day based on postimplantation losses with a corresponding decrease in viable litter size and fetal weight, visceral variations and increased skeletal malformations at all other dose levels. The maternal effects consisted of body weight gain reduction.

4. *Subchronic toxicity*—i. A 90-day study in mice was conducted at dietary concentrations of 0, 50, 300, 900, or 1,500 ppm. The NOAEL was 300 ppm (47.2 and 65.8 mg/kg/day for male and female mice, respectively). This was based on reduced body weight gain in males and microcytic and hypochromic anemia in males and females at 900 ppm (or 144 and 192 mg/kg/day for males and females, respectively).

ii. Technical azafenidin was administered in the diets of rats at 0, 50, 300, 900, or 1,500 ppm for 90 days. The NOAEL was 300 ppm (24.2 and 28.2 mg/kg/day for male and female rats, respectively). This was based on methemoglobinemia and microcytic and hypochromic anemia in males and females at 900 ppm (or 71.9 and 83.8 mg/kg/day for male and female rats, respectively).

iii. Dogs were administered technical azafenidin in their diets at 0, 10, 60, 120, or 240 ppm for 90 days. The NOAEL was 10 ppm (0.34 and 0.33 mg/kg/day for males and females, respectively). This was based on enlarged hepatocytes and increased serum alkaline phosphatase and alanine aminotransferase activities at 60 ppm (2.02 and 2.13 mg/kg/day for male and female dogs, respectively).

iv. A 90–day subchronic neurotoxicity study was conducted in rats at 0, 50, 750, or 1,500 ppm. There were no neurological effects observed in this study. The NOAEL for systemic toxicity was 50 ppm (3.0 mg/kg/day) and 750 ppm (54.5 mg/kg/day) for male and female rats, respectively. These were based on reduced food consumption and body weights and increased incidences of clinical signs of toxicity at the higher doses.

v. A 28–day dermal study was conducted in rats at 0, 80, 400, or 1,000 mg/kg/day. There was no dermal irritation or systemic toxicity among males or females at the highest dose tested (HDT). The NOAEL was > 1,000 mg/kg/day.

5. *Chronic toxicity*—i. An 18–month mouse study was conducted with dietary concentrations of 0, 10, 30, 300, or 900 ppm technical azafenidin. This product was not oncogenic in mice. The systemic NOAEL was 300 ppm (39.8 and 54.1 mg/kg/day for males and females, respectively). This was based on hepatotoxicity among males and reduced body weights and food efficiency among females at 900 ppm (or 122 and 163 mg/kg/day for males and females, respectively).

ii. A 2–year chronic toxicity/oncogenicity study was conducted in rats fed diets that contained 0, 5, 15, 30, 300, or 900 ppm technical azafenidin.

This product was not oncogenic in rats. The systemic NOAEL was 300 ppm (12.1 and 16.4 mg/kg/day males and females, respectively). The NOAEL was defined by microcytic, hypochromic and hemolytic anemia and mortality at 900 (or 35.2 and 50.2 mg/kg/day for male and female rats, respectively).

iii. Technical azafenidin was administered for 1–year to dogs at dietary concentrations of 0, 5, 10, 120, and 360 ppm. The NOAEL was 10 ppm (0.30 mg/kg/day for males and females). This was based on observations of altered hepatocyte morphology, hydropic degeneration and elevated alanine aminotransferase and alkaline phosphatase at 30 ppm (0.86 and 0.87 mg/kg/day for male and female dogs, respectively) and above.

6. *Animal metabolism*. The metabolism of azafenidin in animals (rat and goat) is adequately understood and is similar among the species evaluated. Azafenidin was readily absorbed following oral administration, extensively metabolized and rapidly eliminated in the urine and feces. The terminal elimination half-life in plasma was 40 hours in rats. Less than 1% of the administered dose was present in rat tissues at 120 hours. There were no volatile metabolites of azafenidin. The major metabolic pathways in the rat and goat consisted of rapid O-dealkylation and production of hydroxyl derivatives, subsequent formation of glucuronide and sulfate conjugates and elimination of these conjugates in feces and urine. There was no evidence of accumulation of azafenidin or its metabolites in the tissues of either species or in the goat's milk.

7. *Metabolite toxicology*. There is no evidence that the metabolites of azafenidin identified in animal or plant metabolism studies are of any toxicological significance. The existing metabolism studies indicate that the metabolites formed are unlikely to accumulate in humans or in animals that may be exposed to these residues in the diet. The fact that no quantifiable residues were found in edible portions of treated crops further indicates that exposures to and accumulation of metabolites are unlikely.

8. *Endocrine disruption*. No special studies investigating potential estrogenic or other endocrine effects of azafenidin have been conducted. However, the standard battery of toxicology studies required to support product registration has been completed. Studies in this battery included an evaluation of the potential effects on reproduction in the rat over 2-generations and effects on offspring development in two species. Evaluations of the pathology of the endocrine organs in subchronic and chronic studies at doses that far exceed likely human exposures have also been conducted in several species. Based on the results of these studies, the potential for azafenidin to impact the endocrine system has been adequately defined. There is no evidence to suggest that azafenidin has estrogenic properties or mimics the actions of other hormones in the endocrine system.

C. Aggregate Exposure

1. *Dietary exposure*. It is proposed that azafenidin be defined as the residue for enforcement purposes. Monitoring for azafenidin residues in field samples will provide an adequate estimate of this compound in edible portions of treated crops.

i. *Food—Acute dietary exposure*. An acute dietary exposure assessment was made using the dietary exposure evaluation model (DEEM) computer software (version 6.73, Acute Module, Novigen Sciences, Inc, 1999). Acute dietary exposure was based upon the following crop uses: citrus, grapes, pome fruit, stone fruit, sugarcane, and tree nuts. Anticipated residues were estimated based on field trial data and assuming that 30% of every crop was treated. The predicted acute exposure for the U.S. population subgroup was 0.000158 mg/kg body weight day (bw/d). The population subgroup with the highest predicted level of acute exposure was the children age 1-6–year subgroup with an exposure of 0.000273 mg/kg bw/d (99.9th percentile). Based on an acute NOAEL of 16 mg/kg bw/d from an oral developmental toxicity study with rats, and a 100-fold safety factor, the acute reference dose (aRfD) would be 0.16 mg/kg bw/d. For the U.S. population the predicted exposure is equivalent to 0.10% of the aRfD. For the population subgroup children age 1-6–year, the exposure would be equivalent to 0.17% of the aRfD. Because the predicted exposures, expressed as percentages of the aRfD, are well below 100%, there is reasonable certainty that no acute effects would result from dietary exposure to azafenidin.

ii. *Chronic dietary exposure*. A chronic dietary exposure assessment was made using the DEEM computer software (version 6.74, Chronic Module, Novigen Sciences, Inc, 1999). Acute dietary exposure was based upon the following crop uses: citrus, grapes, pome fruit, stone fruit, sugarcane, and tree nuts. Anticipated residues were estimated based on field trial data and assuming that 30% of every crop was treated. The predicted chronic exposure for the U.S. population subgroup was 0.000007 mg/kg bw/d. The population subgroup with the highest predicted level of chronic exposure was the children age 1–6–year subgroup with an exposure of 0.000021 mg/kg bw/d. Based on a chronic NOAEL of 0.3 mg/kg bw/d from a 1-year chronic feeding study in dogs, and a 100-fold safety factor, the chronic reference dose (cRfD) would be 0.003 mg/kg bw/d. For the U.S. population the predicted exposure is equivalent to 0.2% of the cRfD. For the population subgroup children age 1-6–year, the exposure would be equivalent to 0.7% of the cRfD. Because the predicted exposures, expressed as percentages of the cRfD, are well below 100%, there is reasonable certainty that no chronic effects would result from dietary exposure to azafenidin.

iii. *Drinking water*. Surface water exposure was estimated using the PRZM/EXAMS models. Several USEPA standard scenarios were used (Florida citrus, Louisiana sugar cane, and New York grapes) along with standard methods for selecting input data. Ground water exposure was estimated using SCI-GROW. These are screening level models used for determining upper bound concentrations of pesticides in surface and ground water. PRZM/EXAMS and SCI-GROW use the soil/water partition coefficient , hydrolysis half life, and maximum label rate to estimate surface water concentration. The models and accompanying scenarios contain a number of very conservative underlying assumptions. Therefore, the concentrations derived from PRZM/EXAMS and SCI- GROW for drinking water are likely to be great overestimates. The predicted concentration for azafenidin in ground water under worst-case conditions was 2 parts per billion (ppb). The predicted peak concentration for azafenidin in surface water in a small non-flowing pond directly adjacent a treated citrus grove at the maximum rate was 24 ppb. The annual average concentration predicted for the same pond scenario was 4.72 ppb. EPA uses drinking water levels of comparison (DWLOCs) as a surrogate measure to capture risk associated with exposure to pesticides in drinking water. A DWLOC is the concentration of a pesticide in drinking water that would be acceptable as an upper limit in light of total aggregate exposure to that pesticide from food, water, and residential uses. A DWLOC will vary depending on the residue level in foods, the toxicity endpoint and with drinking water consumption patterns and body weights for specific subpopulations. The acute DWLOC for

azafenidin was calculated for the subpopulation of concern, children (ages 1-6 years) to be 1.6 parts per million (ppm). The estimated maximum concentration of azafenidin in surface water (24 ppb) derived from PRZM/EXAMS is much lower than the acute DWLOC. Therefore, one can conclude with reasonable certainty that residues of azafenidin in drinking water do not contribute significantly to the aggregate acute human health risk. The chronic DWLOCs are 0.1 ppm for the U.S. population and 0.03 ppm for the most sensitive subgroup, children (1-6 years). The DWLOCs are substantially higher than the PRZM/EXAMS estimated annual environmental concentration of 4.7 ppb for azafenidin in surface water. Therefore, one can conclude with reasonable certainty that residues of azafenidin in drinking water do not contribute significantly to the aggregate chronic human health risk.

2. *Non-dietary exposure*. Azafenidin is pending registration for use in weed control in selective non-food crop situations including certain temperate woody crops, and in non-crop situations including industrial sites and unimproved turf areas. Azafenidin is not to be used in on residential temperate woody plantings, or on lawns, walkways, driveways, tennis courts, golf courses, athletic fields, commercial sod operations, or other high maintenance fine turf grass areas, or similar areas. Any non-occupational exposure to azafenidin is likely to be negligible.

D. Cumulative Effects

The herbicidal activity of azafenidin is due to its inhibition of an enzyme involved with synthesis of the porphyrin precursors of chlorophyll, protoporphyrinogen oxidase. Mammals utilize this enzyme in the synthesis of heme. Although there are other herbicides that also inhibit this enzyme, there is no reliable information that would indicate or suggest that azafenidin has any toxic effects on mammals that would be cumulative with those of any other chemicals. In addition there is no valid methodology for combining the risks of adverse effects of overexposures to these compounds.

E. Safety Determination

1. *U.S. population*. Based on the completeness and reliability of the azafenidin toxicology database and using the conservative aggregate exposure assumptions presented earlier, it is concluded that azafenidin products may be used with a reasonable certainty of no harm relative to exposures from food and drinking water. The TMRC determined for the combined pending and proposed uses of azafenidin in citrus, grapes, pome fruit, stone fruit, sugar cane and tree nuts utilized only 0.2% of the cRfD (an exposure of 0.000007 mg/kg bw/d). The chronic calculated drinking water level of comparison DWLOCs of 0.1 ppm for the U.S. population is substantially higher than the PRZM/EXAMS estimated annual environmental concentration of 4.7 ppb for azafenidin. Therefore, one can conclude with reasonable certainty that chronic aggregate exposure will not exceed 100% of the cRfD. In a similar analysis of acute risk for the U.S. population, a predicted exposure of 0.000158 mg/kg bw/d, equivalent to 0.10% of the aRfD is determined. The aRfD For the U.S. population is based on an acute NOAEL of 16 mg/kg bw/d from an oral developmental toxicity study with rats, and a 100-fold safety factor. An acute DWLOC for azafenidin, calculated for the subpopulation of children (ages 1-6 yrs), was 1.6 parts per million (ppm). The estimated maximum concentration of azafenidin in water (24 ppb) derived from PRZM/EXAMS is again, much lower than this acute DWLOC. Therefore, one can conclude with reasonable certainty that residues of azafenidin in drinking water would not contribute significantly to the aggregate acute human health risk. In conclusion, there is a reasonable certainty of no harm to the general population resulting from either acute or chronic aggregate exposure to azafenidin.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of azafenidin, data from the previously discussed developmental and multigeneration reproductive toxicity studies were considered. Developmental studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during pre-natal development. Reproduction studies provide information relating to reproductive and other effects on adults and offspring from pre-natal and post-natal exposures to the pesticide. The rat reproduction and developmental studies indicated developmental effects in this species at exposures that produced minimal maternal effects. A clear dose-response and developmental NOAEL has been defined for these effects. FFDCA section 408 provides that EPA may apply an additional uncertainty factor for infants and children in the case of threshold effects to account for pre-natal and post-natal toxicity and the completeness of the database. The additional uncertainty factor may increase the margin of exposure (MOE) from the usual 100- up to 1,000-fold. Based on current toxicological data requirements, the database for azafenidin relative to pre-natal and post-natal effects for children is complete. In addition, the NOAEL of 0.3 mg/kg/day in the 1–year dog study and upon which the RfD is based is much lower than the NOAELs defined in the reproduction and developmental toxicology studies. Conservative assumptions utilized to estimate acute and chronic dietary exposures of infants and children to azafenidin demonstrated that only 0.17% of the aRfD and 0.7% of the cRfD were utilized. Chronic and acute drinking water levels of concern (DWLOC's) of 0.03 ppm and 1.6 ppm calculated for children age 1–6–years, were significantly greater than predicted chronic and acute water concentrations of 4.7 ppb and 24 ppb respectively. Based on these exposure estimates it may be concluded that there is reasonable certainty that no harm will result to infants and children from aggregate exposures to azafenidin.

F. International Tolerances

There are no established Canadian, Mexican or Codex MRLs for azafenidin. Compatibility is not a problem.

[FR Doc. 99–28728 Filed 11–2–99; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL MARITIME COMMISSION

[Docket No. 99–21]

South Carolina Maritime Services, Inc. v. South Carolina State Ports Authority; Notice of Filing of Complaint and Assignment

Notice is given that a complaint was filed by South Carolina Maritime Services, Inc. (''Complainant''), against South Carolina State Ports Authority (''Respondent''). The complaint was served on October 27, 1999. Complainant alleges that Respondent violated sections 10(b)(10) and (d)(4) of the Shipping Act of 1984, 46 U.S.C. app. §§ 1709(b)(10) and (d)(4), by refusing to deal with gaming vessels and refusing to provide berthing space to Complainant for its ''cruises to nowhere'' and cruises to the Bahamas, yet providing berthing space to other vessels providing ''cruises to nowhere'' and cruises to the Bahamas.

This proceeding has been assigned to the office of Administrative Law Judges. Hearing in this matter, if any is held, shall commence within the limitations

prescribed in 46 CFR 502.61, and only after consideration has been given by the parties and the presiding officer to the use of alternative forms of dispute resolution. The hearing shall include oral testimony and cross-examination in the discretion of the presiding officer only upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the presiding officer in this proceeding shall be issued by October 27, 2000, and the final decision of the Commission shall be issued by February 26, 2001.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 99–28734 Filed 11–2–99; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission applications for licenses as Non-Vessel Operating Common Carrier and Ocean Freight Forwarder—Ocean Transportation Intermediaries pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. app. 1718 and 46 CFR 515).

Persons knowing of any reason why any of the following applicants should not receive a license are requested to contact the Office of Freight Forwarders, Federal Maritime Commission, Washington, D.C. 20573.

Non-Vessel-Operating Common Carrier Ocean Transportation Intermediary Applicants:

Uni International, America Corp. d/b/a Unistar Lines, 190 Walker Street S.W., Suite 204, Atlanta, GA 30313, Officers: Joseph Schulte, President, (Qualifying Individual), Eduardo Macaluso, Vice President

General Logistics International Inc., 139 York Drive, Princeton, NJ 08540, Officer: Glenn R. Nudell, President, (Qualifying Individual)

Shipping International, 1161 Mission Street, San Francisco, CA 94103, Hossein Bolourchi, Sole Proprietor

Newmark Shipping Ltd. d/b/a R S Freight, Inc., 4455 Torrance Boulevard, Suite 848, Torrance, CA 90503, Officer: Alfred Yau, President, (Qualifying Individual)

Non-Vessel-Operating Common Carrier and Ocean Freight Forwarder Transportation Intermediary Applicants:

SeaGate Logistics, Inc., 182–11 150th Road, Suite #205, Jamaica, NY 11413, Officers: Vi Hung Vuong, President, (Qualifying Individual), Renbo Lee, Secretary, Secretary

Ocean Freight Forwarders—Ocean Transportation Intermediary Applicants:

All World International Shipping, Inc., 2630 NW 97th Avenue, Miami, FL 33172, Officers: Elizabeth R. Monserrate, (Qualifying Individual), Alexandra Gayraud, President

Arrowpak, Inc., 2240 74th Street, North Bergen, NJ 09047, Officers: Walter J. Kenney, Vice President, (Qualifying Individual), Paul S. Doherty, Jr., President

Dated: October 29, 1999.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 99–28735 Filed 11–2–99; 8:45 am]

BILLING CODE 6730–01–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.

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 November 26, 1999.

A. Federal Reserve Bank of Cleveland (Paul Kaboth, Banking Supervisor) 1455 East Sixth Street, Cleveland, Ohio 44101-2566:

1. Rockhold-Brown Bancshares, Inc., Bainbridge, Ohio; to become a bank holding company by acquiring 100 percent of the voting shares of The Rock-Hold Brown & Company Bank, Bainbridge, Ohio.

2. United Bancshares, Inc., Columbus Grove, Ohio; to acquire 100 percent of the voting shares of The Bank of Leipsic Company, Leipsic, Ohio.

Board of Governors of the Federal Reserve System, October 28, 1999.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 99–28660 Filed 11–2–99; 8:45 am]

BILLING CODE 6210–01–F

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.

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 November 17, 1999.

A. Federal Reserve Bank of San Francisco (Maria Villanueva, Manager of Analytical Support, Consumer

Regulation Group) 101 Market Street, San Francisco, California 94105-1579:

1. Banque Nationale de Paris, and Paribas, both of Paris, France; to acquire Paribas Corporation, New York, New York, and thereby indirectly acquire Paribas Asset Management, Inc., New York, New York, and Paribas Futures, Inc., New York, New York, and thereby engage in underwriting and dealing to a limited extent in all types of equity securities and debt securities that a member bank may not underwrite or deal in, *see First Security Corporation*, 85 Fed Res. Bull. 207 (1999); in acting as investment or financial advisor to any person, pursuant to § 224.28(b)(6) of Regulation Y; in providing securities brokerage services and incidental activities, as agent for the account of customers, pursuant to § 225.28(b)(7)(i) of Regulation Y; in buying and selling in the secondary market all types of securities on the order of customers as a riskless principal, pursuant to § 225.28(b)(7)(ii) of Regulation Y; in acting as agent in the private placement of all types of securities, including providing related advisory services, pursuant to § 225.28(b)(7)(iii) of Regulation Y; in providing to customers as agent transactional services, pursuant to § 225.28(b)(7)(v) of Regulation Y; in engaging as principal in underwriting and dealing in governmental obligations and money market instruments, pursuant to § 225.28(b)(8)(i) of Regulation Y; in investing and trading in: foreign exchange, and forward contracts, options, futures, options on futures, swaps and similar contracts, whether traded on exchanges or not, based on any rate, price, financial asset, nonfinancial asset or group of assets, pursuant to § 225.28(b)(8)(ii) of Regulation Y; in making, acquiring, brokering or servicing loans or other extensions of credit for its own account or for the account of others, pursuant to § 225.28(b)(1) of Regulation Y; in engaging in asset management, servicing and collection of assets of a type that an insured depository institution may originate and own, pursuant to § 225.25(b)(2)(vi) of Regulation Y; in acquiring debt that is in default at the time of acquisition, pursuant to § 225.28(b)(2)(vii) of Regulation Y; in acting as a futures commission merchant in the execution, clearance, or execution and clearance of futures contracts and options on futures contracts, pursuant to § 225.28(b)(7)(iv) of Regulation Y; in engaging as principal in certain forward contracts, options, futures, options on futures, swaps and similar contracts, pursuant to § 225.28(b)(8)(ii)(B) or (C) of Regulation Y; and in serving as the investment advisor to and the general partner of, and holding and placing equity interests in, certain investment funds which invest only in securities and other instruments which Notificant would be permitted to hold directly under the Bank Holding Company Act, including acting as a commodity pool operator for private investment funds organized as commodity pools, *see Dresdner Bank AG*, 84 Fed. Res. Bull. 361 (1998).

Board of Governors of the Federal Reserve System, October 28, 1999.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 99–28659 Filed 11–2–99; 8:45 am]

BILLING CODE 6210–01–F

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 11:00 a.m., Monday, November 8, 1999.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, N.W., Washington, D.C. 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.

CONTACT PERSON FOR MORE INFORMATION: Lynn S. Fox, Assistant to the Board; 202–452–3204.

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.

Dated: October 29, 1999.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 99–28789 Filed 10–29–99; 4:44 pm]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

Notice of Intent To Prepare an Environmental Impact Statement

The United States General Services Administration intends to prepare an Environment Impact Statement (EIS) on the following project:

Federal Building—U.S. Courthouse, San Jose, California

Proposed Action: The United States General Services Administration is planning the construction of a new U.S. Courthouse in the Central Business District of San Jose, California. This construction is intended to accommodate the need of the Courts for expanded courtroom and office space. The building will house the U.S. Courts and other Court related agencies currently located in the Robert F. Peckham Federal Building Courthouse and in leased locations.

Alternatives to the Proposed Action Include

A. Construction of new facility on the site located within the Central Business District of San Jose and comprised of a full city block bounded by East St. James Street, North First Street, North Market Street and Divine Street. This action may entail demolition of existing structures.

B. Construction of a new facility on the site located within the Central Business District of San Jose and comprised of the northeastern half of the block bounded by East Santa Clara Street, North Fourth Street, East St. John Street, and North Third Street. This action may entail demolition of an existing structure.

C. Construction of a new facility on the site located within the Central Business District of San Jose and comprised by a full city block bounded by East San Carlos Street, East San Salvador Street, South First Street, and South Second Street. This site is immediately adjacent to the south of the Robert F. Peckham Federal Building and Courthouse. This action may entail demolition of an existing structure.

D. Construction of a new facility on the site located within the Central Business District of San Jose and comprised of a full city block bounded by West Santa Clara Street, North Market Street, West St. John Street, and North First Street. This action may entail demolition of an existing structure.

E. No action: Space for the U.S. Courts' functions will continue to be provided in the current facilities. The

impact to the community of maintaining the status quo will be analyzed.

The public is cordially invited to participate in the scoping process, review of the draft Environmental Impact Statement, and the public meeting.

The scoping meeting will be held at the Victory Theater on Thursday, November 18, 1999 from 5 p.m. to 8 p.m.

At the scoping meeting, the public will be asked to identify any significant issues that they believe should be analyzed in the Environmental Impact Statement. The Victory Theater is located at 14 South Second Street, between East San Fernando and East Santa Clara Streets in San Jose, California.

Release of the draft EIS for public comment and the public meeting will be announced in the local newspaper, as these dates are established.

FOR FURTHER INFORMATION CONTACT: George F. Doñes, General Services Administration, Portfolio Management Division (9PT), 450 Golden Gate Avenue, San Francisco, California 94102, (415) 522–3497, Fax: (415) 522–3215, Email: *george.dones@gsa.gov*

Approved: October 28, 1999.

Kenn N. Kojima,

Regional Administrator.

[FR Doc. 99–28700 Filed 11–2–99; 8:45 am]

BILLING CODE 6820–JC–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 64 FR 25897, dated May 13, 1999) is amended to reflect the reoganization of the Scientific Resources Program, National Center for Infectious Diseases.

Section C–B, Organization and Functions, is hereby amended as follows:

After the title for the *Scientific Resources Program (CRL)*, delete the functional statement and insert the following:

(1) Provides animals, animal and human blood products, glassware, mammalian tissue cultures, microbiological media, special reagents, and other laboratory materials in support of research and service activities to NCID laboratories and other CDC organizations; (2) installs, fabricates, modifies, services, and maintains laboratory equipment used in the research and service activities of CDC; (3) develops and implements applied research programs to expand and enhance the use of animal models necessary to support research and diagnostic programs and to improve breeding and husbandry procedures; (4) conducts both basic and applied research in cell biology and in the expansion of tissue culture technology as a research and diagnostic tool for infectious disease activities; (5) provides services for NCID investigators in protein and DNA synthesis and sequencing; (6) maintains a bank of serum and other biological specimens of epidemiological and special significance to CDC's research and diagnostic activities; (7) obtains and distributes experimental and orphaned vaccines, drugs, antisera, antitoxins, and immune globulins; (8) manages and distributes the inventory, maintains the computerized system database, and provides general technical service support for dispensing, lyophilizing, capping, and labeling CDC Reference Reagents; (9) provides support for liquid nitrogen freezers; (10) administratively and technically supports the CDC Animal Policy Board and the Atlanta Area Animal Care and Use Committee; (11) provides computer support services for the Program's activities; (12) receives, categorizes, processes and distributes specimens to CDC laboratories for reference diagnostic testing, research studies, and epidemics and reports diagnostic test results to submitting organizations; (13) manages all CDC exports and ensures compliance with regulations and serves as CDC liaison with Department of Commerce for export related issues; (14) maintains the CDC Atlanta laboratory water treatment systems; (15) provides collaborative development and production services to produce high priority reference reagents and specialized diagnostics for internal NCID investigators.

Dated: October 25, 1999.

Jeffrey P. Koplan,

Director.

[FR Doc. 99–28739 Filed 11–2–99; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Form OCSE–396A, Child Support Enforcement Program Financial Report and Form OCSE–34A. Child Support Enforcement Program Quarterly Report of Collections.

OMB No.: 0970–0181.

Description: These forms are used by States to report the administrative costs of operating the Child Support Enforcement Program and to report the collections of child support payments made under Title IV–D of the Social Security Act during each fiscal quarter. These forms also reports the portion of the collected payments distributed to the custodial parent or to the Federal or State governments. The information is used to calculate quarterly grant awards, annual incentive payments to the State, and is published in an Annual Report to Congress.

Respondents: State Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE–396A	54	4	8	1,728
OCSE–34A	54	4	8	1,728

Estimated Total Annual Burden Hours: 3,456.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of

Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, SW.; Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 to 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW, Attn: ACF Desk Officer.

Dated: October 27, 1999.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 99–28677 Filed 11–2–99; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93N–0260]

Agency Information Collection Activities; Submission for OMB review; Comment Request; Medical Devices; Recall Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the information collection by December 3, 1999.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20501, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices; Recall Authority—21 CFR Part 810

Section 518(e) (21 U.S.C. 360h) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 *et seq.*) provides that if FDA finds that there is a reasonable probability that a device intended for human use would cause serious adverse health consequences or death, FDA shall issue an order requiring the appropriate person to immediately cease distribution of such device, immediately notify health professionals and device user facilities of the order, and instruct such professionals and facilities to cease use of the device. Under this statutory authority, FDA issued regulations under part 810 (21 CFR part 810).

The regulation in § 810.10(d) provides that FDA may require the person named in the cease distribution and notification order to submit certain information to the agency. Section 810.11(a) requires that a request for a regulatory hearing regarding the cease distribution and notification order must be submitted in writing to FDA. In lieu of a written request for a regulatory hearing, the person named in the cease distribution and notification order may submit a written request asking that the order be modified or vacated as provided in § 810.12(a). Under § 810.12(b), a written request for review of a cease distribution and notification order must identify each ground upon which the requestor relies in asking that the order be modified or vacated and address an appropriate cease distribution and notification strategy. A written request must also address whether the order should be amended to require a recall of the device that was the subject of the order.

Section 810.14 states that the person named in the cease distribution and notification order or a mandatory recall order must develop a strategy for complying with the order that is appropriate for the individual circumstances and submit the strategy to the agency for review. Section 810.15(a) requires that the person named in the cease distribution and notification order or a mandatory recall order must promptly notify each health professional, user facility, consignee, or individual of the order, and § 810.15(b) through (c) prescribes the contents and implementation of such notification. Section 810.15(d) requires the person named in the order to ensure that followup communications are sent to all who fail to respond to the initial communications. Under § 810.15(e), recipients of such letters must follow instructions in the letter and notify consignees of the order. Section 810.16 requires that the person named in a cease distribution and notification order or a mandatory recall order submit periodic status reports to FDA to enable the agency to assess the person's progress in complying with the order. The frequency of such reports and the agency official to whom such reports must be submitted will be specified in the order. Lastly, § 810.17 provides that the person named in a cease distribution and notification order or a mandatory recall order may request termination of the order by submitting a written request to FDA. The person submitting a request must certify that he or she has complied in full with all the requirements of the order and must include a copy of the most current status report submitted to the agency.

The information collected under the recall authority will be used by FDA to ensure that all devices entering the market are safe and effective, to learn quickly about serious problems with medical devices, and to remove dangerous and defective devices from the market.

In the preamble to the final rule (61 FR 59004 at 59018, November 20, 1996), hereinafter referred to as the November 1996 final rule, the agency requested comments on the information collection provisions of the new regulation. The 60-day comment period closed January 21, 1997. The agency received two comments. The comments stated that: (1) The information collection requirements in this regulation are redundant and time and resource consuming, and (2) FDA should provide for the use of electronic media for complying with this rule.

FDA disagrees with the comment that the information collection requirements for the medical device recall authority are redundant and time and resource consuming. Almost all recalls are carried out under the voluntary recall procedures in part 7 (21 CFR part 7). As discussed in the November 1996 final rule, for cease distribution and notification orders and recall orders, FDA interprets the standard in §§ 810.10(a) and 810.13 to match closely to the elements of a class I voluntary recall under part 7, subpart C, for which the agency has a long record of experiences. FDA will initiate a mandatory recall under section 518(e) of the act when FDA finds that there is a reasonable probability that a device would cause serious, adverse health consequences or death. A firm may initiate a voluntary recall of a violative device without FDA intervention;

however, if FDA determines that such a voluntary recall is not effective in remedying a violation and there remains a reasonable probability that the violative device would cause serious adverse health consequences or death, FDA will invoke the medical device recall authority in addition to the voluntary efforts that the manufacturer has already undertaken. FDA will not order a mandatory recall if a voluntary recall has been effective in addressing the problems.

FDA believes that the November 1996 final rule provides sufficient flexibility so as to minimize the burden on those required to take action consistent with the determination that the device presents a risk of serious adverse health consequences or death. FDA expects that at most one or two recalls per year would be ordered that would not have occurred without this regulation.

In response to the comment regarding the use of electronic media for complying with these provisions, the regulation for electronic records and electronic signatures became effective March 20, 1997. Part 11 (21 CFR part 11) sets forth the criteria under which FDA will accept documents and signatures in electronic form in lieu of paper.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
810.10(d)	2	1	2	8	16
810.11(a)	1	1	1	8	8
810.12(a) and (b)	1	1	1	8	8
810.14	2	1	2	16	32
810.15(a) through (d)	2	1	2	16	32
810.15(e)	10	1	1	1	10
810.16	2	12	24	40	960
810.17	2	1	2	8	16
Total					1,082

[1] There are no operating and maintenance or capital costs associated with this collection of information.

FDA developed these estimates based on its experience with the number of voluntary recalls received in the last 3 years and other similar procedures.

Dated: October 27, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99–28664 Filed 11–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–4614]

Agency Emergency Processing Request Under OMB Review; Guidance for Industry; Changes to an Approved NDA or ANDA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The collection of information is contained in a guidance for industry entitled ''Changes to an Approved NDA or ANDA.'' The guidance is intended to assist applicants in determining how they should report changes to an approved new drug application (NDA) or abbreviated new drug application (ANDA) under section 116 of the Food and Drug Administration Modernization Act (the Modernization Act), which provides requirements for making and reporting manufacturing changes to an approved application and for distributing a drug product made with such changes.

DATES: Submit written comments on the collection of information by November 10, 1999.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm 10235, Washington, DC 20503, Attn: Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: On November 21, 1997, the President signed the Modernization Act (Public Law 105–115) into law. Section 116 of the Modernization Act amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 506A (21 U.S.C. 356a), which describes requirements and procedures for making and reporting manufacturing changes to approved NDA's and ANDA's, to new and abbreviated animal drug applications, and to license applications for biological products.

The guidance for industry entitled ''Changes to an Approved NDA or ANDA'' provides recommendations to holders of NDA's and ANDA's who intend to make postapproval changes in accordance with section 506A of the act. The guidance covers recommended reporting categories for postapproval changes for drugs, other than specified biotechnology and specified synthetic biological products. Recommendations are provided for postapproval changes in: (1) Components and composition, (2) sites, (3) manufacturing process, (4) specification(s), (5) package, (6) labeling, and (7) miscellaneous changes.

With respect to the collection of information described below, FDA invites comment on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques,

when appropriate, and other forms of information technology.

Title: Changes to an Approved NDA or ANDA

Section 116 of the Modernization Act amended the act by adding section 506A, which includes the following provisions:

1. A drug made with a manufacturing change, whether a major manufacturing change or otherwise, may be distributed only after the applicant validates the effects of the change on the identity, strength, quality, purity, and potency of the drug as these factors may relate to the safety or effectiveness of the drug (sections 506A(a)(1) and (b) of the act). This section recognizes that additional testing, beyond testing to ensure that an approved specification is met, is required to ensure unchanged identity, strength, quality, purity, or potency as these factors may relate to the safety or effectiveness of the drug.

A drug made with a major manufacturing change may be distributed only after the applicant submits a supplemental application to FDA and the supplemental application is approved by the agency. The application is required to contain information determined to be appropriate by FDA and include the information developed by the applicant when ''validating the effects of the change'' (section 506A(c)(1) of the act).

3. A major manufacturing change is a manufacturing change determined by FDA to have substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as these factors may relate to the safety or effectiveness of the drug. Such changes include: (1) A change made in the qualitative or quantitative formulation of the drug involved or in the specifications in the approved application or license unless exempted by FDA by regulation or guidance; (2) a change determined by FDA by regulation or guidance to require completion of an appropriate clinical study demonstrating equivalence of the drug to the drug manufactured without the change; and (3) other changes determined by FDA by regulation or guidance to have a substantial potential to adversely affect the safety or effectiveness of the drug (section 506A(c)(2) of the act).

4. FDA may require submission of a supplemental application for drugs made with manufacturing changes that are not major (section 506A(d)(1)(B) of the act) and establish categories of manufacturing changes for which a supplemental application is required (section 506A(d)(1)(C) of the act). In such a case the applicant may begin distribution of the drug 30 days after FDA receives a supplemental application unless the agency notifies the applicant within the 30-day period that prior approval of the application is required (section 506A(d)(3)(B)(i) of the act). FDA may also designate a category of manufacturing changes that permit the applicant to begin distributing a drug made with such changes upon receipt by the agency of a supplemental application for the change (section 506A(d)(3)(B)(ii) of the act). If FDA disapproves a supplemental application, the agency may order the manufacturer to cease the distribution of drugs that have been made with the disapproved change (section 506A(d)(3)(B)(iii) of the act).

5. FDA may authorize applicants to distribute drugs without submitting a supplemental application (section 506A(d)(1)(A) of the act) and may establish categories of manufacturing changes that may be made without submitting a supplemental application (section 506A(d)(1)(C) of the act). The applicant is required to submit a report to FDA on such a change, and the report is required to contain information the agency deems to be appropriate and information developed by the applicant when validating the effects of the change. FDA may also specify the date on which the report is to be submitted (section 506A(d)(2)(A) of the act). If during a single year an applicant makes more than one manufacturing change subject to an annual reporting requirement, FDA may authorize the applicant to submit a single report containing the required information for all the changes made during the year (annual report) (section 506A(d)(2)(B) of the act).

Section 506A of the act provides FDA with considerable flexibility to determine the information and filing mechanism required for the agency to assess the effect of manufacturing changes in the safety and effectiveness of the product. There is a corresponding need to retain such flexibility in the guidance on section 506A of the act to ensure that the least burdensome means for reporting changes are available. FDA believes that such flexibility will allow it to be responsive to increasing knowledge of and experience with certain types of changes and help ensure the efficacy and safety of the products involved. For example, a change that may currently be considered to have a substantial potential to have an adverse effect on the safety or effectiveness of the product may, at a later date, based on new information or advances in technology, be determined to have a lesser potential to have such an adverse effect. Conversely, a change originally considered to have a minimal or moderate potential to have an adverse effect on the safety or effectiveness of the product may later, as a result of new information, be found to have an increased, substantial potential to adversely affect the product. The guidance enables the agency to respond more readily to knowledge gained from manufacturing experience, further research and data collection, and advances in technology. The guidance describes the agency's current interpretation of specific changes falling into the four filing categories. Section 506A of the act explicitly provides FDA the authority to use guidance documents to determine the type of changes that do or do not have a substantial potential to adversely affect the safety or effectiveness of the drug product. The use of guidance documents allows FDA to more easily and quickly modify and update important information.

Description of Respondents: Businesses or other for-profit organizations.

As explained below, FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

Federal Food, Drug, and Cosmetic Act Sections	No. of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
506A(c)(1) 506A(c)(2) Prior approval supplement (supp.) 506A(d)(1)(B) 506A(d)(1)(C)	594	3	1,744	120	209,280

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Federal Food, Drug, and Cosmetic Act Sections	No. of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
506A(d)(3)(B)(i) Changes being effected (CBE) in 30-day supp.	594	5	2,754	80	220,320
506A(d)(1)(B) 506A(d)(1)(C) 506A(d)(3)(B)(ii) CBE supp.	486	1	486	80	38,880
506A(d)(1)(A) 506A(d)(1)(C) 506A(d)(2)(A) 506A(d)(2)(B) Annual Report	704	10	6,929	25	173,225
Total					641,705

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Sections 506A(a)(1) and 506A(b) of the act require the holder of an approved application to validate the effects of a manufacturing change on the identity, strength, quality, purity, or potency of the drug as these factors may relate to the safety or effectiveness of the drug before distributing a drug made with the change. Under section 506A(d)(3)(A), information developed by the applicant to validate the effects of the change regarding identity, strength, quality, purity, and potency is required to be submitted to FDA as part of the supplement or annual report. Thus, no separate estimates are provided for these sections in the Table 1; estimates for validation requirements are included in the estimates for supplements and annual reports. The guidance does not provide recommendations on the specific information that should be developed by the applicant to validate the effect of the change on the identity, strength (e.g., assay, content uniformity), quality (e.g., physical, chemical, and biological properties), purity (e.g., impurities and degradation products), or potency (e.g., biological activity, bioavailability, bioequivalence) of a product as they may relate to the safety or effectiveness of the product.

Sections 506A(c)(1) and 506A(c)(2) of the act set forth requirements for changes requiring supplement submission and approval prior to distribution of the product made using the change (major changes). Under these sections, a supplement must be submitted for any change in the product, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as these factors may relate to the safety or effectiveness of the product. The applicant must obtain approval of a supplement from FDA prior to distribution of a product made using the change.

Based on data concerning the number of supplements received by the agency, FDA estimates that approximately 1,744 supplements will be submitted annually under sections 506A(c)(1) and 506A(c)(2) of the act. FDA estimates that approximately 594 applicants will submit such supplements, and that it will take approximately 120 hours to prepare and submit to FDA each supplement.

Under section 506A(d)(1)(B), 506A(d)(1)(C), and 506A(d)(3)(B)(i) of the act set forth requirements for changes requiring supplement submission at least 30 days prior to distribution of the product made using the change (moderate changes). Under these sections, a supplement must be submitted for any change in the product, production process, quality controls, equipment, or facilities that has a moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as these factors may relate to the safety or effectiveness of the product. Distribution of the product made using the change may begin not less than 30 days after receipt of the supplement by FDA.

Based on data concerning the number of supplements received by the agency, FDA estimates that approximately 2,754 supplements will be submitted annually under sections 506A(d)(1)(B), 506A(d)(1)(C), and 506A(d)(3)(B)(i) of the act. FDA estimates that approximately 594 applicants will submit such supplements, and that it will take approximately 80 hours to prepare and submit to FDA each supplement.

Under section 506A(d)(3)(B)(ii) of the act, FDA may designate a category of changes for the purpose of providing that, in the case of a change in such category, the holder of an approved application may commence distribution of the drug upon receipt by the agency of a supplement for the change. Based on data concerning the number of supplements received by the agency, FDA estimates that approximately 486 supplements will be submitted annually under section 506A(d)(3)(B)(ii) of the act. FDA estimates that approximately 486 applicants will submit such supplements, and that it will take approximately 80 hours to prepare and submit to FDA each supplement.

Sections 506A(d)(1)(A), 506A(d)(1)(C), 506A(d)(2)(A), and 506A(d)(2)(B) of the act set forth requirements for changes to be described in an annual report (minor changes). Under these sections, changes in the product, production process, quality controls, equipment, or facilities that have a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as these factors may relate to the safety or effectiveness of the product must be documented by the applicant in the next annual report.

Based on data concerning the number of supplements and annual reports received by the agency, FDA estimates that approximately 6,929 annual reports will include documentation of certain manufacturing changes as required under sections 506A(d)(1)(A), 506A(d)(1)(C), 506A(d)(2)(A), and 506A(d)(2)(B) of the act. FDA estimates that approximately 704 applicants will submit such information, and that it will take approximately 25 hours to prepare and submit to FDA the information for each annual report.

In the **Federal Register** of June 28, 1999 (64 FR 34608), FDA published a

proposed rule to implement section 116 of the Modernization Act by revising current regulations at 21 CFR 314.70 on supplements and other changes to an approved application. In that same issue of the **Federal Register** (64 FR 34660), FDA published a notice of availability of a draft guidance for industry entitled ''Changes to an Approved NDA or ANDA.'' On August 19, 1999, FDA held a public meeting to discuss and receive comments on the proposed regulations and the draft guidance. (On August 5, 1999, a notice of the meeting was published in the **Federal Register** (64 FR 42625).)

The period for public comment on the proposed regulations closed on September 13, 1999, and FDA is currently reviewing the comments and preparing a final rule. The comment period for the draft guidance closed on August 27, 1999, and FDA has considered these comments when preparing the guidance that is the subject of this request for emergency processing.

FDA is requesting emergency processing of this proposed collection of information under section 3507(j) of the PRA and 5 CFR 1320.13. The information is needed immediately to implement section 506A of the act, which provides requirements for making and reporting manufacturing changes to an approved application and for distributing a drug product made with such changes. The use of normal information clearance procedures would likely result in the prevention or disruption of this collection of information because section 506A takes effect on November 21, 1999. After November 20, 1999, and until final regulations are issued revising 21 CFR 314.70, section 506A of the act will be the sole basis for FDA's regulation of postapproval manufacturing changes for products approved under NDA's or ANDA's. The guidance provides recommendations to holders of approved NDA's and ANDA's who intend to make postapproval changes in accordance with section 506A of the act. Section 506A of the act explicitly provides FDA the authority to use guidance documents to determine the type of changes that do or do not have a substantial potential to adversely affect the safety or effectiveness of the drug product.

Dated: October 29, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–28793 Filed 11–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Training Programs for Regulatory Project Managers; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is initiating of two new training programs: The Regulatory Project Manager Site Tours and the Regulatory Project Manager Shadowing Program. These programs are intended to give the Center for Drug Evaluation and Research's (CDER's) regulatory project managers an opportunity to tour pharmaceutical facilities and shadow their industry counterparts. Both the tour and shadowing programs are intended to enhance review efficiency and quality by providing CDER staff with a better understanding of the pharmaceutical industry and its operations. The purpose of this notice is to invite pharmaceutical companies interested in participating in these programs to contact CDER for more information.

DATES: Pharmaceutical companies may request training program information at any time.

FOR FURTHER INFORMATION CONTACT: Deborah L. Kallgren, Center for Drug Evaluation and Research (HFD–2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5481, FAX 301–827–3132.

SUPPLEMENTARY INFORMATION:

I. Background

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this primary goal, CDER has initiated various training and development programs to promote high performance in its regulatory project management staff. CDER seeks to significantly enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is initiating two new training programs to give regulatory project managers the opportunity to tour pharmaceutical facilities and shadow their industry regulatory/project management counterparts. The goals are: (1) To provide first hand exposure to industry's drug development processes, and (2) to provide a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

II. The Project Manager Site Tours and Regulatory Project Manager Shadowing Program

A. Regulatory Project Management Site Tours

In this program, over a 2-day period, small groups (six or less) of project managers accompanied by a senior level regulatory project manager may observe operations of pharmaceutical manufacturing, packaging facilities and pathology/toxicology laboratories, and regulatory affairs operations. The purpose of this tour, or any part of the program, is meant to improve mutual understanding and to provide an avenue for open dialogue.

B. Regulatory Project Manager Shadowing Program

In this program, over a 2- to 3-day visit, regulatory project managers will accompany their industry counterparts in their day-to-day activities. The primary objective of the shadowing program is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, project tracking mechanisms, and regulatory submission operations. The overall benefit to regulatory project managers will be exposure to project management and team techniques and processes employed by the pharmaceutical industry, professional and personal growth, and enhanced job satisfaction and performance through increased understanding of the industry processes and procedures that directly relate to their jobs.

C. Site Selection

All travel expenses associated with the site tours and/or shadowing programs will be the responsibility of CDER, therefore, selection of potential facilities will be based on available resources for this program.

If your firm is interested in learning more about these training opportunities, please contact Deborah L. Kallgren (address above).

Dated: October 25, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–28564 Filed 11–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99P–0895]

Gastroenterology-Urology Devices; Denial of Request for Change in Classification of Fiber Optic Light Sources

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; denial of petition.

SUMMARY: The Food and Drug Administration (FDA) is denying the petition submitted by QED, Inc. (QED) to reclassify fiber optic light sources used as accessories to endoscopes from class II to class I. The agency is denying the petition because QED failed to provide any new information to establish that general controls would provide reasonable assurance of the safety and effectiveness of the device. This notice also summarizes the basis for the agency's decision. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the FDA Modernization Act of 1997 (the FDAMA).

EFFECTIVE DATE: November 3, 1999.

FOR FURTHER INFORMATION CONTACT: Donald J. St. Pierre, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194.

SUPPLEMENTARY INFORMATION:

I. Classification and Reclassification of Devices Under the 1976 Amendments

The act (21 U.S.C. 301 *et seq.*), as amended by the 1976 amendments (Public Law 94–295), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory control needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices under the 1976 amendments were class I (general controls), class II (performance standards), and class III (premarket approval). Except as provided in section 520(c) of the act (21 U.S.C. 360j(c)), FDA may not use confidential information concerning a device's safety and effectiveness as a basis for reclassification of the device from class III into class II or class I.

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendment devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act (21 U.S.C. 360c(f)) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

Reclassification of classified preamendments devices is governed by section 513(e) of the act (21 U.S.C. 360c(e)). This section provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based on ''new information.'' The reclassification can be initiated by FDA or by the petition of an interested person. The term ''new information,'' as used in section 513(e) of the act and 515(b)(2)(A)(iv) of the act (21 U.S.C. 360e(b)(2)(A)(iv)), includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not available, or not developed at the time. (See, e.g., *Holland Rantos* v. *United States Department of Health, Education, and Welfare*, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard*, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell* v. *Goddard*, supra, 366F.2d at 181; *Ethicon, Inc.* v. *FDA*, 762 F.Supp. 382,389–91 (D.D.C. 1991)), or in light of changes in ''medical science.'' (See *Upjohn* v. *Finch*, supra, 422 F.2d at 951.) Regardless of whether data before the agency are past or new data, the ''new information'' upon which reclassification under section 513(e) of the act is based must consist of ''valid scientific evidence,'' as defined in section 513(a)(3) of the act (21 U.S.C. 360c(a)(3)) and 21 CFR 860.7(c)(2). FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. For the purpose of reclassification, the valid scientific evidence upon which the agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending premarket approval application. (See section 520(c) of the act (21 U.S.C. 360j(c)).

II. Reclassification Under the SMDA

The SMDA (Public Law 101–629) further amended the act to change the definition of a class II device. Under the SMDA, class II devices are those devices which cannot be classified into class I because general controls by themselves are not sufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions the agency deems necessary (section 513(a)(1)(B) of the act (21 U.S.C. 360c(a)(1)(B)). Thus, the definition of the controls for a class II device was changed from ''performance standards'' to ''special controls.'' In order for a device to be reclassified from class II into class I, the agency must determine that special controls are not necessary to provide reasonable assurance of its safety and effectiveness.

III. Background

In the **Federal Register** of November 23, 1983 (48 FR 53012 at 53015), FDA issued a final rule classifying the endoscope and accessories, including fiber optic light sources, into class II (21 CFR 876.1500). The preamble to the proposal (46 FR 7571, January 23, 1981) to classify the device included the recommendations of the Gastroenterology-Urology Device and the General and Plastic Surgery Device Classification Panels (the Panels). Both Panels' recommendations, among other things, identified certain risks to health (misdiagnosis and inappropriate

therapy; infection; trauma, hemorrhage, or perforation; adverse tissue reaction; electrical injury because of improper design or construction; burns and rupture of body cavity, embolism and hypotensive shock) presented by the device. The agency agreed with both Panels' recommendations and proposed classification accordingly.

The agency received one comment on the proposed classification of the endoscope and accessories. The comment suggested that the endoscope and its accessories be classified into class I rather than class II as proposed. The comment stated that the skill of the user is more essential to the safe use of the device than its design and construction. The agency partially agreed with the comment. The agency believed that the principal hazard associated with the use of the device may be due to unskilled users. However, the agency believed then and continues to believe that fiber optic light sources should be classified into class II because the electrical, optical, mechanical, biocompatibility, and lighting characteristics of the device must be controlled by special controls to prevent injury to the patient resulting from devices of improper design and construction.

In the **Federal Register** of January 16, 1996 (61 FR 1117 at 1122), FDA issued a final rule reclassifying 111 generic types of class II devices into class I based on new information respecting such devices. FDA also exempted the 111 generic types of devices from the requirement of premarket notification, with limitations. Fourteen of the 111 generic types of devices were endoscopes and accessories, but did not include fiber optic light sources.

On December 11, 1998, the agency received a petition from QED, a consulting firm, requesting that the fiber optic light sources be reclassified from class II into class I.

IV. Device Description

A fiber optic light source is an accessory device to an endoscope that provides illumination to allow observation of body cavities, hollow organs, and canals.

V. Agency Decision

FDA recognizes that section 513(e) of the act provides that, for a preamendments device for which reclassification is sought, FDA may secure a recommendation concerning the reclassification of the device from the Panel which had made a recommendation on the initial classification of the device. FDA did not, however, refer this petition to the Panel because the petitioner did not present new information to warrant reconsideration of this device by a Panel.

The petition is requesting reclassification based, in part, on the European Union Medical Devices Directive 93/42 EEC (EU MDD), Annex IV, Classification III, Non-invasive Devices 1.1, Rule 1 and the FDA General Device Classification Questionnaire. According to the petition, the EU MDD would support down classifying these devices because it states that all noninvasive devices are class I unless particular exceptions apply and those exceptions are not relevant to the fiber optic light sources used as accessories for endoscopes. The petition also notes that the FDA questionnaire states that, ''if the device is not life supporting; is not a device for a use which is of substantial importance in preventing impairment of human health; does not present a potential unreasonable risk of illness or injury; and there is sufficient information to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness, then the device is class I.'' The petition implies that classification of the device into class I and the use of general controls are sufficient to provide reasonable assurance of safety and effectiveness.

Based on its review of the information contained in the petition, the agency finds that the petition raises the same issues that were evaluated by the device classification Panels and by FDA when issuing the 1983 final rule classifying the endoscope and accessories, including fiber optic light sources, into class II. The petitioner provided no new information to supports its claim that the risks posed by this device are of the type for which general controls alone would provide reasonable assurance of the safety and effectiveness of the device. Nor did the petitioner provide new information justifying a change in the classification of fiber optic light sources.

Furthermore, since the classification of this device, there have been technological advances in fiber optic light sources, i.e., many light sources are now software controlled. The petitioner provided no information as to how to control the risks associated with the software design. Additionally, at the time of the classification, electromagnetic compatibility (EMC) was not recognized as a risk to health. FDA now believes EMC should be considered a risk. Moreover, the agency searched its medical device reporting (MDR) data base in order to determine the extent of reported problems or adverse incidents associated with devices within this generic type. The search revealed several adverse events of the types considered by the Panels and FDA during and since the classification (Ref. 1). FDA believes that fiber optic light sources require special controls to eliminate or reduce the risks associated with them.

Accordingly, FDA believes, on the basis of the information considered in the petition, and for the same reasons stated when the classification regulation issued, as well as on the basis of technological advances and the MDR reports, that the risks to public health posed by these devices continue and that class II is necessary to provide a reasonable assurance of the safety and effectiveness of this type of device. Assuming the petitioner has correctly interpreted the EU MDD, the classification of a device under the EU regulatory system does not describe or establish a similar level of control under the act.

The petitioner's claim that ''light sources do not require special controls and are approved under the UL Safety Standards for Medical Devices, UL 2601'' does not support a reliance on general controls only; UL 2601 is the type of voluntary standard that would qualify as a special control. Similarly, the petitioner's claim that ''there is no potential hazard to the patient or the medical personnel'' because light sources conform to UL 2601 supports the agency's belief that electrical safety controls are needed for light sources.

As stated previously, FDA's search of the MDR data base revealed adverse events relating to electrical safety, such as arcing resulting in a burn; unintentional shutdown of the light source, resulting in a procedural delay; and patient and drape burns related to light cable guides. These are the type of adverse events which special controls are intended to obviate.

In further recognition of EMC and electrical safety risks, under the good guidance practices, FDA has developed a guidance document entitled ''510(k) Checklist for Endoscopic Light Sources Used in Gastroenterology and Urology,'' dated June 22, 1995. This checklist identifies the type of information a premarket notification should include to support a determination of substantial equivalence. The checklist also includes recommendations for EMC testing and electrical safety testing, including UL 2601 cited by the petitioner.

Under section 513(a)(1)(A) of the act, a device is to be classified in class I if it is a device for which the general controls are sufficient to provide reasonable assurance of the safety and

effectiveness of the device. Therefore, the relevant question is whether a device should be classified as class I and be subject only to general controls, or whether class II controls are necessary to provide reasonable assurance of the safety and effectiveness of the device. On the basis of information described previously concerning the risks associated with the fiber optic light sources, FDA believes that this device is appropriately in class II.

The petitioner presented no new information, in the form of valid scientific evidence, on which FDA could rely to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device for its intended use. FDA, therefore, is denying the petition.

VI. Reference

The following information has been placed on display in the Dockets Managements Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Food and Drug Administration, Center for Devices and Radiological Health, Medical Device Reporting Search Information, 5 pp.

Dated: September 9, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–28563 Filed 11–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pulmonary-Allergy Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on November 22, 1999, 8 a.m. to 5 p.m. and November 23, 1999, 7:45 a.m. to 4 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8210 Wisconsin Ave., Bethesda, MD.

Contact Person: Leander B. Madoo, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12545. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 22, 1999, FDA will discuss its regulations related to ozone-depleting substances. In this discussion, FDA will review the Montreal Protocol on substances that deplete the ozone layer and the advanced notice of proposed rulemaking published on March 6, 1997 (62 FR 10242), as discussed at the April 11, 1997, committee meeting. FDA will provide an overview and detailed discussion of the proposed rule published on September 1, 1999 (64 FR 47719), related to the phase-out of chlorofluorocarbons (CFC's) in metered-dose inhalers. The proposed rule outlines the mechanism by which FDA will determine when the use of ozone-depleting substances, including CFC's in metered-dose, inhalers, in any product regulated by FDA is no longer essential under the Clear Air Act. The proposed rule can be downloaded at http://www.fda.gov/ohrma/dockets/98fr/090199b.pdf. FDA has also created a website at http://www.fda.gov/cder/mdi to provide information to the public regarding this proposal and the issues related to CFC use in medical products. The committee will discuss and comment on the proposed rule and on the presentations made during the public hearing.

On November 23, 1999, the committee will discuss the safety and efficacy of new drug application (NDA) 21–077 for three products: (1) Advair™ Diskus® 100 micrograms (μg) (salmeterol xinafoate 50 μg/fluticasone propionate 100 μg inhalation powder), (2) Advair™ Diskus® 250 μg (salmeterol xinafoate 50 μg/fluticasone inhalation powder), and (3) Advair™ Diskus® 500 μg (salmeterol xinafoate 50 μg/fluticasone propionate 500 μg inhalation powder), Glaxo Wellcome, for the maintenance treatment of asthma as prophylatic therapy in patients 12 years of age and older.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 12, 1999. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 12:30 p.m. on November 22, 1999, and between approximately 8 a.m. and 8:30 a.m. on November 23, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 12, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 22, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–28559 Filed 11–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–4491]

FDA's Proposed Strategy on Reuse of Single Use Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''FDA's Proposed Strategy on Reuse of Single-Use Devices.'' The document presents the agency's current thinking about the best way to address the concerns regarding the practice of reprocessing and reusing devices that are labeled, or otherwise intended, for one use only (referred to as ''single use devices'' (SUD's)). The strategy outlined in the document is based, in part, on information and suggestions the agency received during the May 5 and 6, 1999, conference on Reuse of Single-Use Devices, which the agency cosponsored with the Association for the Advancement of Medical Instrumentation (AAMI). The document reflects FDA's belief that the optimum approach to this issue will involve action by the agency and all of the affected stakeholders. The agency is soliciting comments, proposals for alternative approaches, and information on this issue. In a future issue of the **Federal Register**, the agency will announce an open meeting, to be held

in Rockville, Maryland on December 14, 1999, to gather comments on the agency's proposed strategy.

DATES: Submit written comments at anytime.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the document. Submit written requests for single copies (on a 3.5″ diskette) of ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' to the Dockets Management Branch, (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Larry D. Spears, Center for Devices and Radiological Health (HFZ–340), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4646.

SUPPLEMENTARY INFORMATION:

I. Background

Reuse of SUD's is the practice of cleaning, disinfecting, sterilizing, and reusing medical devices that are intended for only one use. Reuse has raised concerns regarding patient safety, informed consent, and equitable regulation of reuse under the Federal Food, Drug, and Cosmetic Act. On May 5 and 6, 1999, FDA and AAMI cosponsored a conference on Reuse of Single-Use Devices to help examine policy alternatives regarding the practice of reuse. At that time, the agency committed to publishing a response to the positions expressed at the conference in the **Federal Register** by no later than October 1999. ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' is that response.

II. Significance of the Proposed Strategy Document

''FDA's Proposed Strategy on Reuse of Single-Use Devices'' represents options that the agency is considering on the reuse of single-use devices.

III. Electronic Access

In order to receive ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number 2525 followed by the pound sign (). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes ''FDA's Proposed Strategy on Reuse of Single-Use Devices,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

IV. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments regarding this document. Submit two copies of any comments, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. The agency will consider such comments when determining their final strategy. ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' and any received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 28, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–28807 Filed 11–1–99; 12:19 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4114]

Draft ''Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors.'' The draft guidance document applies to the manufacture of gene therapy retroviral vector products intended for in vivo or ex vivo use and to followup monitoring of patients who have received retroviral vector products. When finalized, the draft guidance document is intended to supplement the guidance document entitled ''Guidance for Industry: Guidance for Human Somatic Cell Therapy and Gene Therapy,'' dated March 1998, and a letter to Sponsors of an IND Using Retroviral Vectors, dated September 20, 1993.

DATES: Written comments may be submitted at any time, however, comments should be submitted by February 1, 2000, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–

835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors.'' The draft guidance document applies to the manufacture of gene therapy retroviral vector products intended for in vivo or ex vivo use and to followup monitoring of patients who have received retroviral vector products. The draft document provides guidance for replication competent retrovirus (RCR) testing during manufacture, including timing, amount of material to be tested, and general testing methods. The draft document also provides guidance on monitoring patients for evidence of retroviral infection. When finalized, the draft guidance document is intended to supplement the guidance and recommendations pertaining to RCR testing given in the following documents: (1) ''Guidance for Industry: Guidance for Human Somatic Cell Therapy and Gene Therapy'' dated March 1998 (issued on the Internet); and (2) letter to Sponsors of an IND Using Retroviral Vectors, dated September 20, 1993.

The new recommendations are based on data and analyses generated by CBER and members of the gene therapy community. Public discussion and development of these recommendations have taken place during the retroviral breakout sessions at the ''1996 Gene Therapy Conference: Development and Evaluation of Phase I Products and Workshop on Vector Development'' (61 FR 18749, April 29, 1996), and the ''Forum 1997 Gene Therapy Conference.''

The draft guidance document represents the agency's current thinking regarding testing for RCR in retroviral vector based gene therapy products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

The draft guidance document is being distributed for comment purposes only, and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by February 1, 2000, to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance document using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: October 19, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–28560 Filed 11–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources And Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1891.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project

Querying the National Practitioner Data Bank—New.

Under the Health Resources and Services Administration (HRSA), Bureau of Health Professions (BHPr), the Division of Quality Assurance (DQA) is planning to conduct a survey to obtain information on the degree of user satisfaction with the National Practitioner Data Bank's (NPDB) reporting and querying processes, how users believe these processes can be improved, and how users perceive the usefulness of information they obtained from the NPDB for licensing and credentialing of health care entities, *e.g.* managed care organizations, State licensing boards for physicians and dentists, and professional societies. The study will also identify and survey non-user entities. The information obtained in this study will be interpreted in relation to similar information from previous studies conducted by DQA and the Office of the Inspector General.

The estimated response burden is as follows:

Questionnaire version	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Reporting:					
Hospital	1,031	1	1,031	.2	206.2
Group Practice	210	1	210	.2	42.0
HMOs	161	1	161	.2	32.2
State boards	81	1	81	.2	16.2
Malpractice Payers	188	1	188	.2	37.6
Professional Societies	67	1	67	.2	13.4
Other	209	1	209	.2	41.8
Querying:					
Hospital	770	1	770	.4	308
Group Practice	173	1	173	.4	69.2
HMOs	153	1	153	.4	61.2
State boards	74	1	74	.4	29.6
Malpractice Payers	(*)				
Professional Societies	66	1	66	.4	26.4
Other	184	1	184	.4	73.6
Match Response:					
Hospital	770	3	2,310	1	2,310
Group Practice	173	3	519	1	519
HMOs	153	3	459	1	459
State boards	74	3	222	1	2,222
Malpractice Payers	(*)				
Professional Societies	66	3	198	1	198
Other	184	3	552	1	552
Total					5,217.4

* Cannot query the NPDB; thus these entities do not receive query or match response questionnaires.

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–33, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Written comments should be received within 60 days of this notice.

Dated: October 28, 1999.

Claude Earl Fox,

Administrator.

[FR Doc. 99–28705 Filed 11–2–99; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4445–N–26]

Notice of Proposed Information Collection: Comment Request; Computation of Surplus Cash Distributions and Residual Receipts and Fund Authorizations

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* January 3, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., L'Enfant Building, Room 8202, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Willie Spearmon, Office of Business Products, Office of Multifamily Housing Programs, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, telephone (202) 708–3000 for copies of the proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Computation of Surplus Cash Distributions and Residual Receipts and Funds Authorizations.

OMB Control Number, if applicable: 2502–0314.

Description of the need for the information and proposed use: Handbook 4350.1, Rev. 1, Chapter 25, Multifamily Asset Management and Project Servicing, applies to all non-profit and limited dividend multifamily projects with HUD-insured and HUD-held mortgages, including the Section 202 Program projects. Generally, all projects owned by non-profit mortgagors and all Section 236 and 221(d)(3) projects owned by limited distribution (LD) mortgagors as well, as Section 8 New Construction/Substantial Rehabilitation projects subject to the 1979/80 revised Section 8 regulations, are required to establish a Residual Receipts Account. The requirement for a Residual Receipts Account is

established by a Regulatory Agreement or a project-based subsidy contract such as Section 8 Housing Assistance Payments.

HUD–93486 is used to calculate allowable distributions and any amounts that may be due for deposit to the Residual Receipts Account. HUD–9250 is a form used by HUD Field Offices and the Mortgagor/Managing Agent authorizing the release of funds for Reserve for Replacements or Residual Receipts.

Agency form numbers, if applicable: HUD–93486, HUD–9250.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: The estimated number of respondents are 23,473, frequency of responses is 1 per respondent, and the hours of response is estimated to be 1 hour for HUD–93486 and 1 hour for HUD–9250, totaling 46,946 annual burden hours.

Status of the proposed information collection: Reinstatement without change.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C., Chapter 35, as amended.

Dated: October 28, 1999.

William C. Apgar,

Assistant Secretary for Housing-Federal Housing Commission.

[FR Doc. 99–28690 Filed 11–2–99; 8:45 am]

BILLING CODE 4210–27–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4445–N–25]

Notice of Proposed Information Collection: Comment Request, Advance of Escrow Funds

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* January 3, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW, L'Enfant Building, Room 8202, Washington, D.C. 20410.

FOR FURTHER INFORMATION CONTACT: Willie Spearmon, Department of Housing and Urban Development, 451 7th Street, SW, Washington, DC 20410, telephone (202) 708–3000 (this is not a toll free number) for copies of the forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Advance of Escrow Funds.

OMB Control Number, if applicable: 2502–0018.

Description of the need for the information and proposed use: 24 CFR, Section 200.50—Requirements Incident to Insured Advances—Building Loan Agreement—states that the mortgagor and mortgagee must execute a building loan agreement approved by the Commissioner, that sets forth the terms and conditions under which progress payments may be advanced during construction, before initial endorsement of the mortgage for insurance.

Agency form numbers, if applicable: HUD–92464.

Form HUD–92464, is the form utilized to control the disposition to escrow funds for offside facilities, construction changes, and unpaid construction costs and repairs pending completion or not paid at final endorsement. The face of the form contains two parts. The top part is used by the depository to request approval of advance of such funds. The bottom part is used by HUD to authorized approval.

Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: The estimated number of respondents is 525, the frequency of responses is 1, the estimated time to complete form HUD–92464 is 2 hours, and the estimated annual burden hours requested is 1,050.

Status of the proposed information collection: Reinstatement with change.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C., Chapter 35, is amended.

Dated: October 25, 1999.

William C. Apgar,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 99–28691 Filed 11–2–99; 8:45 am]

BILLING CODE 4210–27–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WO–320–1990–00]

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposal for collection of information listed below has been submitted to the Office of Management and Budget (OMB) for approval under the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). On July 27, 1999 (64 FR 40618), the Bureau of Land Management (BLM) published a notice in the **Federal Register** requesting comments on extending the currently approved information collection. BLM received no public comments as a result of that notice.

You can obtain copies of the proposed collection of information and explanatory material by contacting BLM's Clearance Officer at the telephone number listed below. OMB is required to respond to the request within 60 days but may respond after 30 days. For maximum consideration, your comments and suggestions on the requirements should be made within 30 days directly to the Bureau Clearance Officer and the Office of Management and Budget, Office of Information and Regulatory Affairs (1004–0114), 725 17th St., NW, Washington, DC 20503, telephone: (202) 395–7340.

Title: Recordation of Location Notices and Annual filings for Mining Claims, Mill Sites, and Tunnel Sites; Payment of Location and Maintenance Fees and Service Charges.

OMB Approval Number: 1004–0114.

Abstract: The information collected is used to determine whether or not mining claimants have met the statutory

requirements of section 314 of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1744); the Mining Claim Rights Restoration Act of 1995 (30 U.S.C. 621 *et seq.*); the Oregon and California Railroad and Reconveyed Coos Bay Wagon Road Grant Lands Act of 1948, referred to after this as the ''O and C Lands Act,'' (62 Stat. 162); the General Mining Law of 1872 (30 U.S.C. 22–54); and the Act of October 21, 1998 (112 Stat. 2681–235). Mining claimants must record location notices or certificates of mining claims, mill sites, and tunnel sites with BLM within 90 days of their location. Claimants who do not pay the maintenance fee must make an annual filing by December 30. Failure to record the mining claim or site or to submit an annual filing when required causes the claimant to forfeit the mining claim or site by operation of law.

The Act of October 21, 1998, requires payment of a $100-per-claim or site maintenance fee for fiscal years 1999 through 2001. The payment is due at the time of recording and by each September 1st after that. The Act also requires a $25 location fee for all new claims or sites located, payable at the time of recording with BLM. Certain ''small miners'' owning 10 or fewer claims and sites may file by each September 1st a waiver from payment of the maintenance fee and record an annual filing as in the past. Failure to pay the fee or file for a waiver by September 1st makes the mining claim or site forfeited by operation of law. The Act of October 21, 1998, expires on September 30, 2001, unless Congress renews it.

The Act of April 16, 1993 (43 U.S.C. 299[b]), established new procedures for locating mining claims on the reserved mineral estate of the United States where the mineral estate was reserved under the authority of the Stockraising Homestead Act of 1916, as amended. The locator must now file a ''Notice of Intent to Locate Mining Claims (NOITL)'' with BLM and serve a copy of the NOITL on the surface owner of record, as given in local tax records. The locator must wait 30 days after serving the surface owner before entering the lands or locating mining claims on them. The notice segregates the lands from mining claim location or mineral sale on behalf of the locator for 90 days from BLM's acceptance of the notice. BLM must respond to the NOITL on its official land records. The surface owner does not have to file an NOITL and may locate mining claims at any time the mineral estate is not encumbered.

Bureau Form Numbers: 3830–2 and 3830–3.

Frequency: Once for notices and certificates of location, NOITL's, and payment of location fees. Once each year for annual filings, payment of maintenance fees or filing of waivers. As needed for recording of amendments to a previously recorded notice or certificate of location or transfer of interest.

Description of Respondents: Respondents range from individuals to multi-national corporations engaged in exploring for and developing mineral resources on federal lands.

Estimated Completion Time: 8 minutes for each document or payment.

Annual Responses: 364,000.

Estimated Burden Hours: 48,652 annually.

Bureau Clearance Officer: Carole Smith, (202) 452–0367.

Dated: September 27, 1999.

Carole J. Smith,

BLM Clearance Officer.

[FR Doc. 99–28683 Filed 11–2–99; 8:45 am]

BILLING CODE 4310–84–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[UT–00–934–1610–00]

Notice of Intent To Modify Scope of Statewide Environmental Impact Statement (EIS) and Multiple Plan Amendments Considering Establishment of New Wilderness Study Areas (WSAs) on Selected Public Lands in Utah, and Call for Additional Information

AGENCY: Bureau of Land Management, Interior.

SUMMARY: The BLM has modified the scope of its planning effort considering establishment of new WSAs on public lands in Utah. Instead of preparing a single EIS/Plan Amendment for all inventory areas under study throughout the state, the BLM will now use a staged approach that will break the plan amendment process into four components. Selected inventory areas will be grouped in four regional studies to address whether or not new WSAs should be established. The first such regional grouping will include 35 inventory areas within the southeast region, encompassing approximately 815,000 acres of BLM lands administered by the Moab and Monticello Field Offices. This change is due, in part, to the large number of scoping comments that provided detailed information on specific areas and regions. Focusing planning on a regional basis will allow for a more thorough consideration of public input that has already been received, and is anticipated, as the National Environmental Policy Act (NEPA) process proceeds. Some adjustment is also necessary because new legislation prohibits the BLM from proceeding with WSA planning in certain areas in the West Desert region of the state until the Department of Defense completes a study to evaluate the impact upon military training, testing, and operational readiness of any proposed changes in land designations or management of the ''Utah national defense lands.''

The scope of this first planning effort has also been modified to include all of the BLM lands that were inventoried and shown in the 1999 Utah Wilderness Inventory Report within the areas under study. This includes approximately 162,000 acres of public land currently under study that were initially found lacking wilderness characteristics by the BLM. These include the Arch and Mule Canyon inventory area and portions of 30 other inventory areas within the southeast region. This modification is in response to extensive scoping comments on these areas, and to provide the public additional opportunities to comment on all public lands that were reviewed during the BLM's field inventory.

FOR FURTHER INFORMATION CONTACT: Don Banks, Project Manager (Phone: 801–539-4063 or E-mail: *dbanks@ut.blm.gov*), or by mail to: Utah State Office, Attention: Wilderness Project, P.O. Box 45155, Salt Lake City, Utah 84145.

Copies of the 1999 Utah Wilderness Inventory Report are available for public review at all BLM field offices within Utah and at depository libraries throughout the state. This report is also available on the BLM's Internet web page (*http://www.ut.blm.gov/wilderness*) established for the WSA planning project. This 300-page document provides maps, narratives, and summary reports of the inventory areas. The 35 areas included in the first grouping are contained in this report. In addition, inventory unit permanent documentation files containing aerial photographs, topographic maps, slides, voluminous field log notes and other useful information are available for public review. A complete set of all files can be found at the Utah State Office in Salt Lake City. The documentation files for the relevant inventory areas in the southeast region are also located in BLM's Moab and Monticello Field Offices, respectively.

DATES: All scoping comments regarding this planning effort conducted under the

authority of Section 202 of the Federal Land Policy Management Act (FLMPA), must be received in writing by the BLM Utah State Office no later than December 31, 1999. It is not anticipated that any new scoping meetings would be required for this modified action. All information gathered to date through the scoping process will continue to be considered for this effort.

SUPPLEMENTARY INFORMATION: On March 18, 1999, BLM published in the **Federal Register** a Notice of Intent to Prepare a Statewide EIS and multiple plan amendments for consideration of new WSAs on public land identified as having wilderness characteristics in the 1999 Utah Wilderness Inventory. Since that time, BLM has engaged in an extensive public involvement process to gather scoping information. To date, BLM has received nearly 13,000 comment letters, many of which contain very specific and detailed comments and new information.

On October 5, 1999 the National Defense Authorization Act for Fiscal Year 2000 was signed into law. Section 2815 of this legislation precludes the BLM from completing any land use plan amendment or statewide amendment package for the ''Utah national defense lands'' until the Secretary of Defense submits to Congress a report evaluating the impact upon military training, testing, and operational readiness of any proposed changes in land designations or management of the ''Utah national defense lands''. ''Utah national defense lands'' are defined in Section 2815 as ''public lands under the jurisdiction of the Bureau of Land Management in the state of Utah that are adjacent to or near the Utah Test and Training Range and Dugway Proving Ground or beneath the Military Operating Areas, Restricted Areas, and airspace that make up the Utah Test and Training Range.'' This provision affects approximately 13 inventory areas encompassing approximately 186,000 acres of BLM lands under consideration for possible establishment as WSAs.

The BLM will now proceed through a series of four regional studies to address the question as to whether or not new WSAs will be established. The first area for which an EIS and plan amendments will be completed, and for which public comments are currently being solicited, is in the southeast region. This region includes inventoried public lands within 35 areas, encompassing approximately 815,000 acres. Establishment of new WSAs would amend the Grand and San Juan Resource Management Plans (RMPs). These land use plans are administered by the Moab and Monticello Field Offices, respectively. The following land use plans and associated wilderness inventory areas depict the areas currently under study: Grand RMP: Beaver Creek, Behind the Rocks, Fisher Towers, Goldbar, Granite Creek, Hatch Wash, Hunter Canyon, east portion of Labyrinth Canyon, Lost Spring Canyon, Mary Jane Canyon, Mill Creek Canyon, Negro Bill Canyon, Shafer Canyon, and Westwater Canyon Inventory Areas. San Juan RMP: Arch and Mule Canyons, Bridger Jack Mesa, Butler Wash, Cheesebox Canyon, Comb Ridge, Cross Canyon, Dark Canyon, Fish and Owl Creeks, Fort Knocker Canyon, Gooseneck, Grand Gulch, Gravel and Long Canyons, Harmony Flat, Harts Point, Indian Creek, Mancos Mesa, Nokai Dome, Road Canyon, San Juan River, Sheep Canyon, Squaw and Papoose Canyon. The Gooseneck and Harts Point inventory areas involve both of the RMPs.

Three additional regional groupings of areas will be subject to WSA planning and studies in the future: Uintah and Book Cliffs/San Rafael Swell/Henry Mountains (eastern areas); the Grand Staircase Escalante National Monument/ Kane County/Washington Counties (south-central/southwest areas); and inventory areas found in the West Desert of Utah. All WSA planning is expected to be completed statewide by 2004.

Scoping comments should focus on all lands within the southeastern Utah region that encompass the 35 areas previously identified in the 1999 Utah Wilderness Inventory Report. Comments would be particularly helpful if they address one or more of the following elements:

(a) Any additional information concerning wilderness characteristics within the 35 inventoried areas of the southeastern region, including those lands found by the BLM in the 1999 Utah Wilderness Inventory to be lacking wilderness characteristics.

(b) Information regarding manageability opportunities or conflicts including information on valid existing rights which could be exercised (developed) during the next ten to fifteen years and thereby preclude effective management under the IMP.

(c) Specific information on other resource uses within the inventoried areas, including such uses as grazing practices, rights of way, corridor development, recreation development or mechanical uses, off highway vehicle use, development for mineral extraction, or oil and gas exploration and production.

(d) The proposed planning criteria described further below.

Those members of the public who have previously submitted comments regarding all or portions of the inventoried areas in the southeast region do not need to resubmit scoping comments on these areas, as BLM will take all of the existing comments into consideration. Additional comments focused on the lands initially found by BLM not to have wilderness characteristics are appropriate at this time and would be helpful in identifying and addressing specific issues in these areas. Proposed planning criteria were originally made available in the **Federal Register** Notice of March 18, 1999.

1. BLM will amend the RMPs based on the information contained in the Utah Wilderness Inventory of 1999, as supplemented by information gathered and analyses contributed in this planning/NEPA process.

2. This planning/NEPA process will conform to all applicable laws, such as the Clean Water Act, Archeological Resource Protection Act, and the Endangered Species Act.

3. To the extent possible under Federal law, and within the framework of proper long-term management of the public lands, BLM will strive to ensure that its management prescriptions and planning actions take into consideration related programs, plans, or policies of other resource agencies. This will include the formal consistency review by the State of Utah Governor's office. BLM will work closely with the Governor's Office to help facilitate the consistency review process.

4. BLM will provide local, state and Federal agencies a copy of the Draft EIS with a written request to comment. Agencies may identify in writing any inconsistencies with formally approved land use plans or their related jurisdictions.

5. Existing WSAs will continue to be managed under the provisions of the Interim Management Policy for Lands Under Wilderness Review (IMP). The current plan amendment process will not address suitability recommendations for existing WSAs.

6. Planning decisions made through this BLM process will apply only to Federal public lands.

7. All valid existing rights will continue to be recognized.

8. Any WSAs designated pursuant to this process will contain the following recommended setbacks:

- 300 feet from the centerline of high standard paved roads,
- 100 feet from the centerline of high

standard graveled roads,

– 30 feet from the centerline of low standard dirt roads, Unless resource conditions warrant granting exceptions.

9. The plan amendment process will address off highway vehicle designations in the inventory areas, consistent with the provisions of the IMP as necessary to protect wilderness characteristics.

Alternatives that are currently proposed for consideration include: (1) No Action—Under this alternative, none of the inventory areas would be designated as WSAs and the lands would continue to be managed according to the existing land use plans; (2) All areas would be designated as WSAs, and IMP would be applied to all lands; (3) Selected WSAs—Some of the 35 inventoried areas, or portions thereof, would be designated as WSAs and IMP would be applied, while other inventoried areas, or portions thereof, would not be designated as WSAs. The EIS would provide information and analysis to identify impacts associated with each alternative.

Planning for the southeastern region is expected to be completed in the Fall of 2000. A draft EIS is expected to be published by Spring of 2000.

The public will have opportunities to provide further input, review information, and to comment on the draft EIS. Anyone wanting to be added to the mail list for this planning project should contact the BLM at the address given above. Comments received, including names and addresses of respondents will be available for public review at the Utah State Office and will be subject to disclosure under the Freedom of Information Act. Individual respondents may request confidentiality. If you wish to withhold your name or street address from public review and disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your written scoping letter. Such requests will be honored to the extent allowed by law. All submissions from organizations or businesses, will be made available for public inspection in their entirety.

Dated: October 28, 1999.

Linda S. Coleville,

Acting Utah State Director.

[FR Doc. 99–28698 Filed 11–2–99; 8:45 am]

BILLING CODE 4310–DQ–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[UTU–76561, UTU–77365]

Utah; Proposed Reinstatement of Terminated Oil and Gas Leases

In accordance with Title IV of the Federal Oil and Gas Royalty Management Act (Public Law 97–451), a petition for reinstatement of oil and gas leases UTU–76561 and UTU–77365 for lands in Duchesne and Emery Counties, Utah, was timely filed and required rentals accruing from September 1, 1999, the date of termination, have been paid.

The lessee has agreed to new lease terms for rentals and royalties at rates of $5 per acre and 16⅔ percent, respectively. The $500 administrative fee for each lease has been paid and the lessee has reimbursed the Bureau of Land Management for the cost of publishing this notice.

Having met all the requirements for reinstatement of the leases as set out in Section 31 (d) and (e) of the Mineral Leasing Act of 1920 (30 U.S.C. 188), the Bureau of Land Management is proposing to reinstate leases UTU–76561 and UTU–77365, effective September 1, 1999, subject to the original terms and conditions of the lease and the increased rental and royalty rates cited above.

Robert Lopez,

Chief, Branch of Minerals Adjudication.

[FR Doc. 99–28697 Filed 11–2–99; 8:45 am]

BILLING CODE 4310–D9–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV–056–1430–ES; N–65825]

Notice of Realty Action: Segregation Terminated, Lease/Conveyance for Recreation and Public Purposes

AGENCY: Bureau of Land Management.

ACTION: Segregation terminated, recreation and public purpose lease/conveyance.

SUMMARY: The following described public land in Las Vegas, Clark County, Nevada was segregated on July 23, 1997 for exchange purposes under serial number N–61855. The exchange segregation on the subject lands will be terminated upon publication of this notice in the **Federal Register**. The land has been examined and found suitable for lease/conveyance for recreational or public purposes under the provisions of the Recreation and Public Purposes Act, as amended (43 U.S.C. 869 *et seq.*). Clark County proposes to use the lands for a fire station and training facility.

Mount Diablo Meridian, Nevada

T. 21 S., R. 62 E.,
Sec. 2, Lot 15.

Containing 40.00 acres, more or less, located at Hollywood Ave. and Sahara Ave.

The land is not required for any federal purpose. The lease/conveyance is consistent with current Bureau planning for this area and would be in the public interest. The lease/patents, when issued, will be subject to the provisions of the Recreation and Public Purposes Act and applicable regulations of the Secretary of the Interior, and will contain the following reservations of the United States:

1. A right-of-way thereon for ditches or canals constructed by the authority of the United States, Act of August 30, 1890 (43 U.S.C. 945).

2. All minerals shall be reserved to the United States, together with the right to prospect for, mine and remove such deposits from the same under applicable law and such regulations as the Secretary of the Interior may prescribe and will be subject to:

1. Easements in accordance with the Clark County Transportation Plan.

2. Those rights for telephone purposes which have been granted to Sprint Central Telephone by right-of-way CC–017422A under the Act of March 4, 1911 (43 USC 961).

3. Those rights for gas line purposes which have been granted to Southwest Gas Corporation by right-of-way Nev-061333 under the Act of February 25, 1920 (30 USC 185 sec. 28).

4. Those rights for water line purposes which have been granted to the Bureau of Reclamation by right-of-way N–1521 under the Act of December 5, 1924 (43 Stat. 0672).

5. Those rights for roadway purposes which have been granted to Clark County by right-of-way N–56936 under the Act of October 21, 1976 (43 USC 1761).

Detailed information concerning this action is available for review at the office of the Bureau of Land Management, Las Vegas Field Office, 4765 W. Vegas Drive, Las Vegas, Nevada.

Upon publication of this notice in the **Federal Register**, the above described land will be segregated from all other forms of appropriation under the public land laws, including the general mining laws, except for lease/conveyance under the Recreation and Public Purposes Act, leasing under the mineral leasing laws and disposals under the mineral material disposal laws.

For a period of 45 days from the date of publication of this notice in the **Federal Register**, interested parties may submit comments regarding the proposed lease/conveyance for classification of the lands to the Las Vegas Field Office Manager, Las Vegas Field Office, 4765 Vegas Drive, Las Vegas, Nevada 89108.

Classification Comments

Interested parties may submit comments involving the suitability of the land for a fire station and training facility. Comments on the classification are restricted to whether the land is physically suited for the proposal, whether the use will maximize the future use or uses of the land, whether the use is consistent with local planning and zoning, or if the use is consistent with State and Federal programs.

Application Comments

Interested parties may submit comments regarding the specific use proposed in the application and plan of development, whether the BLM followed proper administrative procedures in reaching the decision, or any other factor not directly related to the suitability of the land for a fire station and training facility.

Any adverse comments will be reviewed by the State Director. In the absence of any adverse comments, the classification of the land described in this Notice will become effective 60 days from the date of publication in the **Federal Register**. The lands will be offered for lease/conveyance until after the classification becomes effective.

Dated: October 20, 1999.

Sharon DiPinto,

Acting Assistant Field Office Manager, Las Vegas, NV.

[FR Doc. 99–28555 Filed 11–2–99; 8:45 am]

BILLING CODE 1430–HC–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–010–1430–ES; WYW–146136/WYW–146153]

Realty Action; Lease for Recreation and Public Purposes; Washakie and Hot Springs Counties, Worland Field Office, Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of realty action.

SUMMARY: The following public lands in Washakie and Hot Springs Counties, Wyoming have been examined and found suitable for classification for lease to the Washakie County Fair Board and the Hot Springs County Recreation Board under the provisions of the Recreation and Public Purposes Act, as amended (43 U.S.C. 869 *et seq.*). The Counties propose to use the lands for radio controlled airplane flying areas.

Sixth Principal Meridian

WYW–146136—Washakie County Fair Board
T. 47 N. R. 92 W.
Section 33, within lot 1, E1/2SW1/4NW1/4; comprising 34 acres more or less; and
WYW–146153—Hot Springs County Recreation Board
T. 43 N. R. 95 W.
Section 20, NE1/4SW1/4; comprising 40 acres more or less.

The lands are not needed for federal purposes. Lease is consistent with current BLM land use planning and would be in the public interest.

The lease, when issued, will be subject to the following terms and conditions:

1. Provisions of the Recreation and Public Purposes Act and to all applicable regulations of the Secretary of the Interior.
2. All valid existing rights documented on the official public land records at the time of lease issuance.
3. Site specific mitigation measures to protect the public lands and users on the leases.

Detailed information concerning this action is available for review at the office of the Bureau of Land Management, Worland Field Office, 101 South 23rd Street, Worland, Wyoming.

Upon publication of this notice in the **Federal Register**, the lands will be segregated from all other forms of appropriation under the public land laws, including the general mining laws, except for lease under the Recreation and Public Purposes Act and leasing under the mineral leasing laws. For a period of 45 days from the date of publication of this notice in the **Federal Register**, interested persons may submit comments regarding the proposed conveyance or classification of the lands to the Field Manager, Worland Field Office, PO Box 119, Worland WY 82401.

Classification Comments

Interested parties may submit comments involving the suitability of the land for radio controlled airplane flying areas. Comments on the classification are restricted to whether the land is physically suited for the proposal, whether the use will maximize the future use or uses of the land, whether the use is consistent with local planning and zoning, or if the use is consistent with State and Federal programs.

Application Comments

Interested parties may submit comments regarding the specific use proposed in the application and plan of development, whether the BLM followed proper administrative procedures in reaching the decision, or any other factor not directly related to the suitability of the land for radio controlled airplane flying areas.

Any adverse comments will be reviewed by the State Director. In the absence of any adverse comments, the classification will become effective 60 days from the date of publication of this notice in the **Federal Register**.

SUPPLEMENTARY INFORMATION: Comments, including names and street addresses of respondents will be available for public review at the Worland District Office, 101 South 23rd Street, Worland, Wyoming during regular business hours (7:30 a.m. to 4:30 p.m.) Monday through Friday, except holidays. Individual respondents may request confidentiality. If you wish to withhold your name or address from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your comments. Such requests will be honored to the extent allowed by law. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public inspection in their entirety.

Dated: October 21, 1999.

Darrell Barnes,

Worland Field Manager.

[FR Doc. 99–28782 Filed 11–2–99; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Woodbridge Irrigation District and City of Lodi's Lower Mokelumne River Restoration Program, San Joaquin County, CA

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of availability of the Draft Environmental Impact Report/ Draft Environmental Impact Statement (DEIR/DEIS) INT–DES–99–50.

SUMMARY: Pursuant to the National Environmental Policy Act and the California Environmental Quality Act, the Bureau of Reclamation (Reclamation), Woodbridge Irrigation District (WID), and the City of Lodi have

prepared a joint DEIR/DEIS for the Lower Mokelumne River Restoration Program (LMRRP). The LMRRP encompasses an area located in northern San Joaquin County along the lower Mokelumne River between Camanche Dam and the Mokelumne and Cosumnes Rivers. The Proposed Project comprises four elements: (1) Improving fish passage at Woodbridge Dam, (2) upgrading the fish screen at the WID diversion, (3) placing screens on unscreened or underscreened riparian diversions on the Mokelumne River between Camanche Dam and the Cosumnes Rivers on a voluntary basis, and (4) restoring riparian vegetation along the Mokelumne River. The DEIR/DEIS describes and presents the environmental effects of the four elements of the program.

DATES: Submit written comments on the DEIR/DEIS on or before January 4, 2000. Comments may be submitted to Reclamation or WID at the addresses provided below. The public hearing on the DEIR/DEIS will be held on November 16, 1999, at 7:00 p.m.

ADDRESSES: The public hearing will be held in the Carnegie Forum, located at 305 West Pine Street, next to City Hall, in Lodi, California.

Written comments on the DEIR/DEIS should be addressed to Mr. Anders Christensen, WID, 18777 N. Lower Sacramento Road, Woodbridge, California 95258, or to Mr. Buford Holt, Reclamation, 16349 Shasta Dam Boulevard, Shasta Lake, California 96019.

Copies of the DEIR/DEIS may be requested from Mr. Christensen at the above address or by calling (209) 369–6808.

See **SUPPLEMENTARY INFORMATION** section for locations where copies of the DEIR/DEIS are available for public inspection.

FOR FURTHER INFORMATION CONTACT: Mr. Anders Christensen, WID, at (209) 369–6808; or Mr. Buford Holt, Reclamation, at (530) 275–1554.

SUPPLEMENTARY INFORMATION: The LMRRP was developed to implement important elements from resource management plans prepared by the CALFED Bay-Delta Program (CALFED), the United States Fish and Wildlife Service, and the Department of Fish and Game. The goal of the LMRRP is to substantially increase fall-run chinook salmon and steelhead populations, enhance critical and limiting aquatic habitats, and restore riparian ecosystem integrity and diversity. In addition to a No-Project Alternative, which involves the continued operation of the existing Woodbridge Dam and fish passage facilities, four action alternatives are examined, including: (1) Construct new fish passage facilities on the existing Woodbridge Dam; (2) construct a new Woodbridge Dam with operable weir gates and new fish passage facilities; (3) construct a new Woodbridge Dam with operable weir gates and new fish passage facilities, and diversion pumps; and (4) replace the existing Woodbridge Dam and pump water from the river.

WID applied to CALFED for funding for the entire LMRRP. CALFED has provided funding through Reclamation for the environmental documentation and permitting of the first two elements, and final design for the first element. The remainder of the LMRRP will be funded by CALFED or by the State of California as funds are available.

Copies of the DEIR/DEIS are available for public inspection and review at the following locations:

- Woodbridge Irrigation District Office, 18777 N. Lower Sacramento Road, Woodbridge, California 95258; telephone: (209) 369–6808.
- Bureau of Reclamation, Office of Policy, Room 7456, 1849 C Street NW, Washington DC 20240; telephone: (202) 208–4662.
- Bureau of Reclamation, Reclamation Service Center Library, Building 67, Room 167, Denver Federal Center, 6th and Kipling, Denver, Colorado 80225; telephone: (303) 445–2072.
- Bureau of Reclamation, Public Affairs Office, 2800 Cottage Way, Sacramento, California 95825–1898; telephone: (916) 978–5100.
- Natural Resources Library, U.S. Department of the Interior, 1849 C Street NW, Main Interior Building, Washington DC 20240–0001.
- Lodi Public Library, 201 W. Locust Street, Lodi, California 95240–2099.

Hearing Process Information

WID staff will make a brief presentation to describe the proposed project, its purpose and need, and alternatives considered. The public may comment on environmental issues addressed in the DEIR/DEIS. If necessary due to large attendance, comments will be limited to 5 minutes per speaker. Written comments will also be accepted.

Dated: October 22, 1999.

Kirk C. Rodgers,

Acting Regional Director.

[FR Doc. 99–28740 Filed 11–2–99; 8:45 am]

BILLING CODE 4310–94–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–99–046]

Sunshine Act Meeting; Notice.

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: November 9, 1999 at 11:00 a.m.

PLACE: Room 101, 500 E Street S.W., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda for future meeting: none
2. Minutes
3. Ratification List
4. Inv. No. 731–TA–812 (Final)(Live Cattle from Canada)—briefing and vote. (The Commission will transmit its determination to the Secretary of Commerce on November 17, 1999.)
5. Inv. No. 731–TA–224 (Review)(Live Swine from Canada)—briefing and vote. (The Commission will transmit its determination to the Secretary of Commerce on November 22, 1999.)
6. Outstanding action jackets: none

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

Issued: October 29, 1999.

By order of the Commission:

Donna R. Koehnke,

Secretary.

[FR Doc. 99–28788 Filed 10–29–99; 4:38 pm]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Antitrust Division

International Competition Policy Advisory Committee (ICPAC); Notice of Meeting

The International Competition Policy Advisory Committee (the ''Advisory Committee'') will hold its next meeting on November 19, 1999. The Advisory Committee was established by the Department of Justice to provide advice regarding issues relating to international competition policy; specifically, how best to cooperate with foreign authorities to eliminate international anticompetitive cartel agreements, how best to coordinate United States' and foreign antitrust enforcement efforts in the review of multijurisdictional mergers, and how best to address issues that interface international trade and competition policy concerns. The meeting will be held at The Carnegie

Endowment for International Peace, Root Conference Room, 1779 Massachusetts Avenue, NW, Washington, DC 20036 and will begin at 10 a.m. EST and end at approximately 7 p.m. The agenda for the meeting will be as follows:

1. Trade and Competition Policy Interface Issues
2. Multijurisdictional Merger Review
3. Enforcement Cooperation
4. Next Steps

Attendance is open to the interested public, limited by the availability of space. Persons needing special assistance, such as sign language interpretation or other special accommodations, should notify the contract person listed below as soon as possible. Members of the public may submit written statements by mail, electronic mail, or facsimile at any time before or after the meeting to the contact person listed below for consideration by the Advisory Committee. All written submissions will be included in the public record of the Advisory Committee. Oral statements from the public will not be solicited or accepted at this meeting. For further information contact: Merit Janow, c/o Marianne Pak, U.S. Department of Justice, Antitrust Division, 601 D Street, NW, Room 10011, Washington, DC 20530, Telephone: (202) 353–9074, Facsimile: (202) 353–9985, Electronic mail: icpac.atr@usdoj.gov.

Merit E. Janow,

Executive Director, International Competition Policy Advisory Committee.

[FR Doc. 99–28736 Filed 11–2–99; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of information collection under review; Application for Asylum and Withholding of Removal.

The Department of Justice, Immigration and Naturalization Service has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for ''sixty days'' until January 3, 2000.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection: Extension of a currently approved collection.*

(2) *Title of the Form/Collection:* Application for Asylum and Withholding of Removal.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form I–589. Office of international Affairs, Immigration and Naturalization Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or Households. This information collection will be used to determine whether an alien applying for asylum and/or withholding of deportation in the United States is classifiable as a refugee, and is eligible to remain in the United States.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 50,000 responses at 12 hours per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 600,000 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 5307, 425 I Street, NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, suite 850, Washington Center, 1001 G Street, NW., Washington, DC 20530.

Dated: October 28, 1999.

Richard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service.

[FR Doc. 99–28747 Filed 11–2–99; 8:45 am]

BILLING CODE 4410–10–M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts; Combined Arts Advisory Panel

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), as amended, notice is hereby given that a meeting of the Combined Arts Advisory Panel, Presenting section (Heritage & Preservation, Education, and Access categories), to the National Council on the Arts will be held from 9:00 a.m. to 4:30 p.m. on December 6, 1999 in Room 716 at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW, Washington, DC 20506.

This meeting is for the purpose of Panel review, discussion, evaluation, and recommendations on financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency. In accordance with the determination of the Chairman of May 12, 1999, these sessions will be closed to the public pursuant to subsection (c)(4), (6) and (9)(B) of section 552b of Title 5, United States Code.

Further information with reference to this meeting can be obtained from Ms. Kathy Plowitz-Worden, Panel Coordinator, National Endowment for the Arts, Washington, DC 20506, or call (202) 682–5691.

Dated: October 28, 1999.

Kathy Plowitz-Worden,

Panel Coordinator, National Endowment for the Arts.

[FR Doc. 99–28685 Filed 11–2–99; 8:45 am]

BILLING CODE 7537–01–M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts; Combined Arts Advisory Panel

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), as amended, notice is hereby given that a meeting of the Combined Arts Advisory Panel, Arts Education section (Education category), to the National Council on the Arts will be held from December 13–17, 1999 in Room 730 at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW, Washington, DC, 20506. The Panel will meet from 9:00 a.m. to 5:30 p.m. on December 13th–16th and from 9:00 a.m. to 4:00 p.m. on December 17th. A portion of this meeting, from 1:00 p.m. to 2:30 p.m. on December 17th, will be open to the public for policy discussion.

The remaining portions of this meeting, from 9:00 a.m. to 5:30 p.m. on December 13th–16th, and from 9:00 a.m. to 1:00 p.m. and 2:30 p.m. to 4:00 p.m. on December 17th, are for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman of May 12, 1999, these sessions will be closed to the public pursuant to (c)(4)(6) and (9)(B) of section 552b of Title 5, United States Code.

Any person may observe meetings, or portions thereof, of advisory panels which are open to the public, and, if time allows, may be permitted to participate in the panel's discussions at the discretion of the panel chairman and with the approval of the full-time Federal employee in attendance.

If you need special accommodations due to a disability, please contact the Office of AccessAbility, National Endowment for the Arts, 1100 Pennsylvania Avenue, NW, Washington, DC 20506, 202/682–5532, TDY–TDD 202/682–5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Kathy Plowitz-Worden, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC, 20506, or call 202/682–5691.

Dated: October 28, 1999.

Kathy Plowitz-Worden,

Panel Coordinator, Panel Operations, National Endowment for the Arts.

[FR Doc. 99–28686 Filed 11–2–99; 8:45 am]

BILLING CODE 7537–01–M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Combined Arts Advisory Panel

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), as amended, notice is hereby given that a meeting of the Combined Arts Advisory Panel, Multidisciplinary section (Heritage & Preservation, Education, and Access categories), to the National Council on the Arts will be held from December 7–10, 1999 in Room 716 at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW, Washington, DC, 20506. A portion of this meeting, from 1:30 p.m. to 3:00 p.m. on December 10th, will be open to the public for policy discussion.

The remaining portions of this meeting, from 9:00 a.m. to 6:00 p.m. on December 7th–December 9th and from 9:00 a.m. to 1:30 p.m. and 3:00 p.m. to 4:00 p.m. on December 10th, are for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman of May 12, 1999, these sessions will be closed to the public pursuant to (c)(4)(6) and (9)(B) of section 552b of Title 5, United States Code.

Any person may observe meetings, or portions thereof, of advisory panels which are open to the public, and, if time allows, may be permitted to participate in the panel's discussions at the discretion of the panel chairman and with the approval of the full-time Federal employee in attendance.

If you need special accommodations due to disability, please contact the Office of AccessAbility, National Endowment for the Arts, 1100 Pennsylvania Avenue, NW, Washington, DC 20506, 202/682–5532, TDY–TDD 202/682–5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Kathy Plowitz-Worden, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC 20506, or call 202/682–5691.

Dated: October 28, 1999.

Kathy Plowitz-Worden,

Panel Coordinator, Panel Operations, National Endowment for the Arts.

[FR Doc. 99–28687 Filed 11–2–99; 8:45 am]

BILLING CODE 7537–01–M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Combined Arts Advisory Panel

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), as amended, notice is hereby given that a meeting of the Combined Arts Advisory Panel, Theater/Musical Theater section (Heritage & Preservation, Education, and Access categories), to the National Council on the Arts will be held from November 15–19, 1999 in Room 714 at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW, Washington, DC, 20506. A portion of this meeting, from 3:00 p.m. to 5:00 p.m. on November 17th, will be open to the public for policy discussion.

The remaining portions of this meeting, from 9:30 a.m. to 6:30 p.m. on November 15th, 16th and 18th, from 9:30 a.m. to 3:00 p.m. to 5:00 to 6:30 p.m. on November 17th, and from 9:30 a.m. to 4:30 p.m. on November 19th, are for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman of May 12, 1999, these sessions will be closed to the public pursuant to (c)(4)(6) and (9)(B) of section 552b of Title 5, United States Code.

Any person may observe meetings, or portions thereof, of advisory panels which are open to the public, and, if time allows, may be permitted to participate in the panel's discussions at the discretion of the panel chairman and with the approval of the full-time Federal employee in attendance.

If you need special accommodations due to a disability, please contact the Office of AccessAbility, National Endowment for the Arts, 1100 Pennsylvania Avenue, NW, Washington, DC 20506, 202/682–5532, TDY–TDD

202/682–5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Kathy Plowitz-Worden, Office of Guidelines & Panel Operations, National Endowment for the Art, Washington, DC, 20506, or call 202/682–5691.

Dated: October 28, 1999.

Kathy Plowitz-Worden,

Panel Coordinator, Panel Operations, National Endowment for the Arts.

[FR Doc. 99–28688 Filed 11–2–99; 8:45 am]

BILLING CODE 7537–01–M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Combined Arts Advisory Panel

Pursuant to Section 10(a)92) of the Federal Advisory Committee Act (Public Law 92–463), as amended, notice is hereby given that two meetings of the Combined Arts Advisory Panel, Music section (Heritage & Preservation, Education and Access categories), to the National Council on the Arts will be held from November 29—December 1 and December 1–3, 1999 in Rooms 714 and 730 at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW, Washington, DC 20506. A portion of each meeting, from 3:00 p.m. to 5:00 p.m. on December 1st and December 3rd, will be open to the public for policy discussion.

The remaining portions of these meetings, (for Panel A) from 9:30 a.m. to 6:30 p.m. on November 29th, from 8:30 a.m. to 6:00 p.m. on November 30th, and from 9:00 a.m. to 3:00 p.m. on December 1st, (for Panel B) from 8:30 a.m. to 6:00 p.m. on December 1st, from 8:30 a.m. to 6:30 p.m. on December 2nd, and from 8:30 a.m. to 3:00 p.m. on December 3rd, are for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman of May 12, 1999, these sessions will be closed to the public pursuant to (c)(4)(6) and (9)(B) of section 552b of Title 5, United States Code.

Any person may observer meetings, or portions thereof, of advisory panels which are open to the public, and, if time allows, may be permitted to participate in the panel's discussions at the discretion of the panel chairman and with the approval of the full-time Federal employee in attendance.

If you need special accommodations due to a disability, please contact the Office of AccessAbility, National Endowment for the Arts, 1100 Pennsylvania Avenue, NW, Washington, DC 20506, 202/682–5532, TDY–TDD 202/682–5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Kathy Plowitz-Worden, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC 20506, or call 202/682–5691.

Dated: October 28, 1999.

Kathy Plowitz-Worden,

Panel Coordinator, Panel Operations, National Endowment for the Arts.

[FR Doc. 99–28689 Filed 11–2–99; 8:45 am]

BILLING CODE 7537–01–M

NUCLEAR REGULATORY COMMISSION

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Notice of pending NRC action to submit an information collection request to OMB and solicitation of public comment.

SUMMARY: The NRC is preparing a submittal to OMB for review of continued approval of information collections under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* 10 CFR part 110—Rules and Regulations for the Export and Import of Nuclear Equipment and Material.

2. *Current OMB approval number:* 3150–0036.

3. *How often the collection is required:* On occasion.

4. *Who is required or asked to report:* Any person in the U.S. who wishes to export or import nuclear material and equipment subject to the requirements of 10 CFR part 110 or to export incidental radioactive material that is a contaminant of shipments of more than 100 kilograms of non-waste material using existing NRC general licenses.

5. *The number of annual respondents:* 125.

6. *The number of hours needed annually to complete the requirement or request:* Reporting, 130 hours (1.3 hours per response); recordkeeping, 150 hours (1.2 hours per respondent). The total burden is 280 hours.

7. *Abstract:* 10 CFR part 110 provides application, reporting, and recordkeeping requirements for exports and imports of nuclear material and equipment subject to the requirements of a specific license or a general license and exports of incidental radioactive material. The information collected and maintained pursuant to 10 CFR part 110 enables the NRC to authorize only imports and exports which are not inimical to U.S. common defense and security and which meet applicable statutory, regulatory, and policy requirements.

Submit, by January 3, 2000, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the draft supporting statement may be viewed free of charge at the NRC Public Document Room, 2120 L Street NW, (lower level), Washington, DC. OMB clearance requests are available at the NRC worldwide web site (http://www.nrc.gov/NRC/PUBLIC/OMB/index.html). The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments and questions about the information collection requirements may be directed to the NRC Clearance Officer, Brenda Jo. Shelton, U.S. Nuclear Regulatory Commission, T–6 E6, Washington, DC 20555–0001, or by telephone at 301–415–7233, or by Internet electronic mail at BJS1@NRC.GOV.

Dated at Rockville, Maryland, this 28th day of October 1999.

For the Nuclear Regulatory Commission.

Brenda Jo. Shelton,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 99–28761 Filed 11–2–99; 8:15 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Public Meeting on Fatigue Effects on Metal Components

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of meeting.

SUMMARY: A public meeting on the issue of fatigue effects will be held at Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, MD 20814 to discuss issues related to fatigue of metal components in nuclear power plants. The discussion topics will include: a plan to integrate results from NRC and industry efforts addressing fatigue; NRC and industry efforts addressing various aspects of the overall fatigue problems; and general views concerning fatigue and the fatigue-related issues being addressed today. This meeting is also expected to facilitate the progress on the resolution of Generic Safety Issue (GSI–190), ''Fatigue Evaluation of Metal components for 60-year Plant life.''

DATES: November 17, 1999, from 8:30 a.m. to 5:00 p.m.

ADDRESSES: Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, MD 20814.

FOR FURTHER INFORMATION CONTACT: Khalid Shaukat, Mail Stop T10–E10, U.S. Nuclear Regulator Commission, Washington, DC 20555–0001. Telephone: (301) 415–6592; FAX: (301) 415–5153; Internet: SKS1@NRC.GOV . Or: Mike Mayfield, Mail Stop T10–E10, U.S. Nuclear Regulator Commission, Washington, DC 20555–0001. Telephone: (301) 415–6690; FAX: (301) 415–5074; Internet: *MEM2@NRC.GOV*.

Dated at Rockville, Maryland, this 28th day of October, 1999.

For the Nuclear Regulatory Commission.

Michael E. Mayfield,

Chief, Materials Engineering Branch, Division of Engineering Technology, Office of Nuclear Regulatory Research.

[FR Doc. 99–28758 Filed 11–2–99; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Nuclear Waste; Notice of Meeting

The Advisory Committee on Nuclear Waste (ACNW) will hold its 114th meeting on November 17–19, 1999, Room T–2B3, 11545 Rockville Pike, Rockville, Maryland.

Wednesday, November 17, 1999

8:30 A.M.–8:40 A.M.: Opening Remarks by the ACNW Chairman (Open)—The ACNW Chairman will make opening remarks regarding the conduct of the meeting.

8:40 A.M.–12:00 Noon: ACNW Planning and Procedures (Open)—The Committee will hear a briefing from its staff on issues to be covered during this meeting. The Committee will also consider topics proposed for future consideration by the full Committee and Working Groups. This will include strategic planning and self assessment as well as topics for the next Commission briefing. The Committee will discuss ACNW-related activities of individual members. The Committee may also discuss potential ACNW members. (Note: The new members portion may be closed to discuss information the release of which would constitute a clearly unwarranted invasion of personal privacy per 5 U.S.C. 552b(c)(6)).

1:00 P.M.–3:00 P.M.: Department of Energy's Yucca Mountain Draft Environmental Impact Statement (DEIS) (Open)—The Committee will discuss with the NRC staff the staff's review of the DEIS. The Committee plans to submit a letter report on this topic.

3:15 P.M.–5:00 P.M.: NRC's Yucca Mountain Specific High-Level Waste Regulation (Open)—The Committee will review the latest version of 10 CFR Part 63, ''Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, Nevada. The tenor of public comments will also be explored.

Thursday, November 18, 1999

8:30 A.M.–8:40 A.M.: Opening Remarks by the ACNW Chairman (Open)—The ACNW Chairman will make opening remarks regarding the conduct of the meeting.

8:40 A.M.–10:00 A.M.: Rubblization (Open)—The Committee will review this decommissioning option and prepare comments on the concept.

10:15 A.M.–11:30 A.M.: Annotated Outline for Yucca Mountain Review Plan (Open)—The Committee will hear a briefing from the NRC staff which will describe the transition from Issue Resolution Status Reports to a Yucca Mountain review plan.

12:30 P.M.–2:00 P.M.: Research Plan for Environmental Transport (Open)—The ACNW will review generic codes used to predict radionuclide transport in the geosphere. The Committee intends to submit comments on this review.

2:15 P.M.–5:00 P.M.: Preparation of ACNW Reports (Open)—The Committee will discuss planned reports on the following topics: a White Paper on Near-Field Chemistry issues, a joint ACRS/ACNW letter report on an NMSS approach to risk-informed, performance-based regulation in NMSS, the Yucca Mountain DEIS, NRC's Yucca Mountain specific high-level waste disposal regulation, rubblization decommissioning option, waste related research, NRC staff comments on the U.S. Environmental Protection Agency's Proposed Rule on Environmental Radiation Protection Standards For Yucca Mountain, NV (40 CFR part 197), and other topics discussed during this and previous meetings as the need arises.

Friday, November 19, 1999

8:30 A.M.–8:40 A.M.: Opening Remarks by the ACNW Chairman (Open)—The ACNW Chairman will make opening remarks regarding the conduct of the meeting.

8:40 A.M.–9:35 A.M.: Meeting with the Office of Nuclear Material Safety and Safeguards (NMSS) Management (Open)—The Committee will meet with NMSS managers to discuss items of mutual interest.

9:35 A.M.–3:00 P.M.: Preparation of ACNW Reports (Open)—The Committee will discuss planned reports on the following topics: a White Paper on Near-Field Chemistry issues, a joint ACRS/ACNW letter report on an NMSS approach to risk-informed, performance-based regulation in NMSS, the Yucca Mountain DEIS, NRC's Yucca Mountain specific high-level waste disposal regulation, rubblization decommissioning option, waste related research, NRC staff comments on the U.S. Environmental Protection Agency's Proposed Rule on Environmental Radiation Protection Standards For Yucca Mountain, NV (40 CFR part 197), and other topics discussed during this and previous meetings as the need arises.

3:00 P.M.–3:30 P.M.: Miscellaneous (Open)—The Committee will discuss miscellaneous matters related to the conduct of Committee and organizational activities and complete discussion of matters and specific issues that were not completed during previous meetings, as time and availability of information permit.

Procedures for the conduct of and participation in ACNW meetings were published in the **Federal Register** on September 28, 1999 (64 FR 52352). In accordance with these procedures, oral or written statements may be presented by members of the public, electronic recordings will be permitted only during those portions of the meeting

that are open to the public, and questions may be asked only by members of the Committee, its consultants, and staff. Persons desiring to make oral statements should notify Richard K. Major, ACNW, as far in advance as practicable so that appropriate arrangements can be made to schedule the necessary time during the meeting for such statements. Use of still, motion picture, and television cameras during this meeting will be limited to selected portions of the meeting as determined by the ACNW Chairman. Information regarding the time to be set aside for taking pictures may be obtained by contacting the ACNW office, prior to the meeting. In view of the possibility that the schedule for ACNW meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should notify Mr. Major as to their particular needs.

In accordance with Subsection 10(d) Pub. L. 92–463, I have determined that it is necessary to close portions of this meeting noted above to discuss information the release of which would constitute a clearly unwarranted invasion of personal privacy per 5 U.S.C. 552b(c)(6)).

Further information regarding topics to be discussed, whether the meeting has been canceled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by contacting Mr. Richard K. Major, ACNW (Telephone 301/415–7366), between 8:00 A.M. and 5:00 P.M. EDT. ACNW meeting notices, meeting transcripts, and letter reports are now available for downloading or reviewing on the internet at http://www.nrc.gov/ACRSACNW.

Videoteleconferencing service is available for observing open sessions of ACNW meetings. Those wishing to use this service for observing ACNW meetings should contact Mr. Theron Brown, ACNW Audiovisual Technician (301–415–8066), between 7:30 a.m. and 3:45 p.m. EDT at least 10 days before the meeting to ensure the availability of this service. Individuals or organizations requesting this service will be responsible for telephone line charges and for providing the equipment and facilities that they use to establish the videoteleconferencing link. The availability of videoteleconferencing services is not guaranteed.

The ACNW meeting dates for Calendar Year 2000 are provided below:

ACNW meeting No.	Meeting date
January 2000—No meeting.	
116th (Rockville, MD)	February 15–17, 2000.
117th (Rockville, MD)	March 14–16, 2000.
April 2000—No meeting.	
118th (Rockville, MD)	May 16–18, 2000.
119th (Rockville, MD)	June 20–22, 2000.
120th (San Antonio, Texas)	July 18–20, 2000.
August 2000—No meeting.	
121st (Amargosa Valley, Nevada)	September 19–21, 2000.
122nd (Rockville, MD)	October 17–19, 2000.
123rd (Rockville, MD)	November 15–17, 2000.
December 2000—No meeting.	

Dated: October 29, 1999.

Andrew L. Bates,

Advisory Committee Management Officer.

[FR Doc. 99–28786 Filed 11–2–99; 8:45 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 Public Law 97–415, the U.S. Nuclear Regulatory Commission (the Commission or NRC staff) is publishing this regular biweekly notice. Public Law 97–415 revised section 189 of the Atomic Energy Act of 1954, as amended (the Act), to require the Commission to publish notice of any amendments issued, or proposed to be issued, under a new provision of section 189 of the Act. This provision 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 October 8, 1999, through October 22, 1999. The last biweekly notice was published on October 20, 1999 (64 FR 56526).

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.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received before action is taken. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance

and provide for opportunity for a hearing 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, Rules and Directives Branch, Division of Administration 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 6D59, 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 NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC. The filing of requests for a hearing and petitions for leave to intervene is discussed below.

By December 10, 1999, 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 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and electronically from the ADAMS Public Library component on the NRC Web site, http://www.nrc.gov (the Electronic Reading Room). If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.714, 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 factors: (1) the Nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide 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 to relief. A petitioner who fails to file such a supplement which satisfies 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, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, 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 with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington DC, by the above date. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and to the attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for a hearing will not be entertained absent a determination by the Commission, the presiding officer or the Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of factors specified in 10 CFR 2.714(a)(1)(i)–(v) and 2.714(d).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and electronically from the ADAMS Public Library component on the NRC Web site, http://www.nrc.gov (the Electronic Reading Room).

Carolina Power & Light Company, et al., Docket No. 50–325, Brunswick Steam Electric Plant, Unit 1, Brunswick County, North Carolina

Date of amendment request: September 28, 1999.

Description of amendment request: The licensee has proposed to revise Technical Specification (TS) 2.1.1, ''Reactor Core Safety Limits,'' and TS 5.6.5, ''Core Operating Limits Report.'' These revisions would remove cycle-specific safety limit restrictions which are no longer necessary.

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. The proposed license amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The procedures for determining the MCPR [Minimum Critical Power Ratio] Safety Limit are described in General Electric Standard Application for Reactor Fuel (i.e., topical report NEDE–24011–P–A, otherwise referred to as GESTAR II). The basis for the MCPR Safety Limit calculation is to ensure that greater than 99.9 percent of all fuel rods in the core avoid transition boiling in the event of a postulated accident. The existing MCPR Safety Limit preserves this margin to transition boiling and fuel damage. The MCPR Safety Limits for the BSEP [Brunswick Steam Electric Plant], Unit 1 TSs, and their use in determining cycle-specific operating limits documented in the Core Operating Limits Report, are determined using NRC-approved methods (i.e., GESTAR II). The use of these methods ensures that the MCPR Safety Limit values are within the existing design and licensing bases, and cannot increase the probability or consequences of an accident previously evaluated.

2. The proposed license amendment will not create the possibility of a new or different kind of accident from any accident previously evaluated.

The MCPR Safety Limit is a TS numerical value that has been established to ensure that fuel damage from transition boiling does not occur in at least 99.9 percent of the fuel rods in the core as a result of a limiting postulated accident. The MCPR Safety Limit is not an accident initiator; therefore, it cannot create the possibility of any new type of accident. The MCPR Safety Limits are calculated using NRC-approved methods. The function, location, operation, and handling of the fuel will remain unchanged. In addition, the initiating sequence of events for previously evaluated accidents has not been changed. Therefore, no new or different kind of accident has been created.

3. The proposed license amendment does not involve a significant reduction in a margin of safety.

The MCPR Safety Limit preserves the existing margin to transition boiling and fuel damage in the event of a postulated accident. The margin of safety, as defined in the TS Bases, will remain the same. The MCPR Safety Limit remains unchanged, and will ensure that greater than 99.9 percent of all fuel rods in the core will avoid transition boiling if the limit is not violated, thereby preserving the fuel cladding integrity. The MCPR Safety Limits will continue to be calculated using NRC-approved generic and cycle-specific methodologies that are described in GESTAR II. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

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: William D. Johnson, Vice President and Corporate Secretary, Carolina Power & Light Company, Post Office Box 1551, Raleigh, North Carolina 27602

NRC Section Chief: Ron Hernan, Acting.

Carolina Power & Light Company, Docket No. 50–261, H. B. Robinson Steam Electric Plant, Unit No. 2, Darlington County, South Carolina

Date of amendment request: September 28, 1999.

Description of amendment request: The amendment revises Technical Specifications (TS) surveillance requirement (SR) 3.7.6.2 ''Component Cooling Water (CCW) System,'' to change the CCW pump automatic start actuation signal basis from Engineered Safety Feature Actuation Signal (ESFAS) to Loss-of-Power Diesel Generator (LOP DG). This change is required to reflect the original plant design which was not properly incorporated during conversion of the TS to Improved TS.

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:

Carolina Power & Light (CP&L) Company has evaluated the proposed Technical Specification change and has concluded that it does not involve a significant hazards consideration. The CP&L conclusion is in accordance with the criteria set forth in 10 CFR 50.92. The bases for the conclusion that the proposed change does not involve a significant hazards consideration are discussed below.

1. Does the change involve a significant increase in the probability or consequences of an accident previously evaluated?

The proposed change to Surveillance Requirement (SR) 3.7.6.2 does not involve any physical alteration of plant systems, structures or components, changes in parameters governing normal plant operation, or methods of operation. The safety function of the Loss of Power (LOP) Diesel Generator (DG) start signal for the Component Cooling Water (CCW) pumps is to start the CCW pumps in order to provide the minimum heat removal capability assumed in the safety analysis for the systems to which it supplies cooling water. The CCW System provides a heat sink for the removal of process and operating heat from safety related components during a Design Basis Accident (DBA) or transient. During normal operation, the CCW System also provides this function for various nonessential components, as well as the spent fuel storage pool. The CCW System serves as a barrier to the release of radioactive byproducts between potentially radioactive systems and the Service Water System, and thus to the environment. The CCW pumps start upon receipt of a LOP DG start signal from undervoltage on the emergency bus. The LOP DG start signal to the CCW pumps is not an Engineered Safety Features Actuation System (ESFAS) signal. Since this proposed change only corrects the description of the start signal, the proposed change does not involve an 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?

The proposed change does not involve any physical alteration of plant systems, structures or components, changes in parameters governing normal plant operation, or methods of operation. The proposed change does not introduce a new mode of operation or changes in the method of normal plant operation. Therefore, the possibility of a new or different kind of accident from any accident previously evaluated is not created.

3. Does this change involve a significant reduction in a margin of safety?

The proposed change corrects the word description of the start signal for the CCW pumps and does not alter any plant design margin or analysis assumption as described in the Updated Safety Analysis Report. The proposed change does not affect any limiting safety system setpoint, calibration method, or setpoint calculation. Therefore, the proposed change does not involve a reduction in a margin of safety.

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: William D. Johnson, Vice President and Corporate Secretary, Carolina Power & Light Company, Post Office Box 1551, Raleigh, North Carolina 27602 .

NRC Section Chief: Sheri R. Peterson.

CBS Corporation (licensee), Westinghouse Test Reactor, Waltz Mill Site, Westmoreland, Pennsylvania, Docket No. 50–22, License No. TR–2

Date of amendment request: September 15, 1999, as supplemented on October 4, 1999.

Description of amendment request: CBS Corporation is the licensee for the Westinghouse Test Reactor (WTR) at Waltz Mill, Pennsylvania. The licensee is authorized to only possess the reactor and a decommissioning plan has been approved.

The licensee is planning to revise four Technical Specifications (TS) in their approved Decommissioning Plan. The

first TS change deals with what doors need to be closed when restricted activities are taking place within containment. Access to containment is through three locations, i.e., the truck lock door and the east and west airlock doors. Each entry point has two doors, an outer door and an inner door. In the existing TS either door could be closed except during personnel ingress or egress or while equipment is being passed through the doorways. In the proposed TS the licensee has specified the following. For the truck lock door the inner door to containment needs to be closed. The reason given for the change is that the containment boundary is more accurately defined as the interior access door between the truck lock area and containment. The truck lock area was transferred to the SNM–770 license in April 1970 and the outer doors are controlled by this license.

For the east and west airlock doors, fire doors with an interior crash bar have been installed at the outer door as a safety feature to minimize the risk of personnel being trapped in containment during an emergency. The airlock doors (inner doors) do not allow quick and efficient egress during a postulated fire in containment; therefore, the original air lock doors have been removed and confinement is maintained by the newly installed fire doors.

Therefore the proposed TS require that the inner truck lock door be closed and the outer east and west lock doors be closed except during personnel ingress or egress or while equipment is being passed through the doorways, and this meets the original goal of the existing TS.

The second TS change deals with the condition of the containment when the containment is open for removal of materials and equipment. In the existing TS Restricted Activities in containment are suspended. In the proposed TS, containment extension is permitted if an enclosure is provided around the opening to effectively isolate the containment from the outside environment. If these extensions are not in place, all Restricted Activities in containment are suspended. Negative pressure (airflow into containment) is maintained in containment in the existing as well as the proposed TS. Containment isolation is effectively maintained under the proposed TS as it was in the existing TS.

The third TS change deals with the control of access into containment. In the existing TS the outer doors in the air lock and the truck lock outer doors shall be locked or blocked closed to prevent unauthorized entry except when authorized personnel are inside the containment building or outside with the door in view. In the proposed TS access into containment is through a Health Physics (HP) control point, which is on the first floor of the G-Building. To prevent unauthorized entry the accesses into and out of containment shall be locked or blocked closed except when this access control point is supervised and the provisions of the first TS change are implemented.

Normal access to the containment is through a door in the G-Building basement (east and west airlock doors). The G-Building basement is a ''Radiation Area''. Routine activities during the day may require workers to exit containment (rest, lunch, equipment change out, etc). Locking or blocking the doors after workers temporarily exit during the working day does not minimize radiation dose and reduces worker efficiency. Access control will be established on the first floor of the G-Building outside the radiation area. Therefore, the access control point would provide positive control into and out of containment and meets the original intent of the TS.

The fourth TS is being changed to include the HP control point in the monthly visual surveillance, which assures that accesses into containment are locked or blocked when no on is inside containment and the HP control point is not occupied.

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 considerations. The proposed amendment to a license of a facility involves no significant hazards consideration if 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 the margin of safety.

The staff agrees with the licensee's no significant hazards consideration determination submitted on September 15, 1999, for the following reason:

The changes are consistent with the original intent of the TS, i.e., to maintain confinement during Restricted Activities and to prevent uncontrolled spread of contamination. Access control is still being maintained.

Based on a review of the licensee's analysis, and on the staff's analysis detailed above, 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: William David Wall, Assistant General Counsel, CBS Corporation, 11 Stanwix Street, Pittsburgh, Pennsylvania 15222.

NRC Branch Chief: Ledyard B. Marsh.

Consolidated Edison Company of New York, Docket No. 50–247, Indian Point Nuclear Generating Unit No. 2, Westchester County, New York

Date of amendment request: June 2, 1999, as supplemented August 25, 1999.

Description of amendment request: The proposed amendment would relocate the quality assurance (QA) related requirements to the licensee's Quality Assurance Program Description (QAPD) in accordance with NRC Administrative Letter (AL) 95–06, ''Relocation of Technical Specifications Administrative Controls Related to Quality Assurance,'' dated December 12, 1995. Specifically, Technical Specification (TS) Section 6.5, ''Review and Audit,'' TS Section 6.8, ''Procedures and Programs,'' and TS Section 6.10, ''Record Retention'' would be relocated from the current TS to the QAPD in accordance with 10 CFR 50.36 (60 FR 30957).

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 license amendment involve a significant increase in the probability or consequences of an accident previously analyzed?

Response: This amendment application does not involve a significant increase in the probability or consequences of an accident previously analyzed. The relocation of the administrative controls from the Technical Specification to the Quality Assurance Program Description (QAPD) does not alter the performance or frequency of these activities. Any future changes to the QA Program Description, which might constitute a reduction in commitments, are governed by 10 CFR 50.54(a). Therefore, sufficient controls for these requirements exist and these changes do not involve a significant increase in the probability or consequences of an accident previously analyzed.

2. Does the proposed license amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: This amendment application does not create the possibility of a new or different kind of accident from any accident previously evaluated. The proposed changes involve the relocation of requirements from the Technical Specifications to the QAPD.

Relocation of these requirements does not affect plant equipment or the way the plant operates. The functions continue to be performed in the identical manner as they are currently being performed. Therefore, the proposed revisions can not create a new or different kind of accident.

3. Does the proposed license amendment involve a significant reduction in a margin of safety?

Response: This amendment application does not involve a significant reduction in a margin of safety. The requested Technical Specification revisions relocate the administrative control requirements from the Technical Specifications to the QAPD. These requirements are not being altered by this relocation. The functions continue to be performed in the identical manned as they are currently being performed. Any future changes to the QA Program Description, which might constitute a reduction in commitments, are governed by 10 CFR 50.54(a). Therefore, sufficient controls for these requirements exist and these changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Brent L. Brandenburg, Esq., 4 Irving Place, New York, New York 10003.

NRC Section Chief: Sheri Peterson.

Detroit Edison Company, Docket No. 50–341, Fermi 2, Monroe County, Michigan

Date of amendment request: July 30, 1999 (NRC–99–0048).

Description of amendment request: The proposed amendment would revise the Technical Specifications (TSs) to include provisions related to enabling the oscillation power range monitor (OPRM) upscale trip function in the average power range monitor. This change is associated with the power range neutron monitoring (PRNM) system installed during the last refueling outage. The associated Bases would also be revised.

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. The proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed change is to enable the OPRM Upscale Function that is contained in the previously installed PRNM equipment. Enabling the OPRM hardware provides the long-term stability solution required by Generic Letter 94–02. This hardware incorporates the Option III detect and suppress solution reviewed and approved by the NRC in the Reference 6, 7, and 8 [of the licensee's application dated July 30, 1999] Licensing Topical Reports and their Supplements. The OPRM is designed to meet all requirements of GDC [General Design Criteria] 10 and 12 by automatically detecting and suppressing design basis thermal-hydraulic power oscillations prior to violating the fuel MCPR [minimum critical power ratio] Safety Limit. The OPRM system provides this protection in the region where Interim Corrective Actions (ICAs) restricted operation because of stability concerns. Thus, the ICA restrictions on plant operation are deleted from the TS, including region avoidance and the requirement for the operator to manually scram the reactor with no recirculation loops operating. Operation at high core powers with low core flows may cause a slight, but not significant, increase in the probability that an instability may occur. This slight increase is acceptable because subsequent to the automatic detection of an instability, the OPRM Upscale function provides an automatic scram signal to the RPS that is faster than the operator-initiated manual scram required by the current ICAs. Because of this rapid automatic action, the consequences of an instability event are not increased as a result of the installation of the OPRM system because it eliminates dependence on operator actions.

Based on the above discussion, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed change permits Fermi 2 to enable the OPRM power oscillation detect and suppress function provided in previously installed PRNM hardware, and it simultaneously deletes certain restrictions which preclude operation in regions of the power-flow map where oscillations potentially may occur. Enabling the OPRM Upscale function does not create any new system hardware interfaces nor create any new system interactions. Potential failures of the OPRM Upscale function result either in failure to perform a mitigation action or in spurious initiation of a reactor scram. These failures would not create the possibility of a new or different kind of accident.

Based on the above discussion, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The change does not involve a significant reduction in the margin of safety.

The OPRM Upscale function implements BWROG [Boiling Water Reactor Owners Group] Stability Option III, which was developed to meet the requirements of GDC 10 and GDC 12 by providing a hardware system that detects the presence of thermal-hydraulic instabilities and automatically initiates the necessary actions to suppress the oscillations prior to violating the MCPR Safety Limit. The NRC has reviewed and accepted the Option III methodology described in the Reference 6, 7, and 8 [of the licensee's application dated July 30, 1999] Licensing Topical Reports and their supplements, and concluded that this solution will provide the intended protection. Therefore, it is concluded that there will be no reduction in the margin of safety as defined in the TS as a result of enabling the OPRM Upscale function and simultaneously removing the operating restrictions previously imposed by the ICAs.

Based on the above discussion, the proposed change does not involve a significant reduction in the margin of safety.

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: John Flynn, Esq., Detroit Edison Company, 2000 Second Avenue, Detroit, Michigan 48226.

NRC Section Chief: Claudia M. Craig.

Detroit Edison Company, Docket No. 50–341, Fermi 2, Monroe County, Michigan

Date of amendment request: September 10, 1999.

Description of amendment request: The proposed amendment would revise Technical Specification (TS) Surveillance Requirements (SRs) 3.8.4.1, 3.8.4.6, and 3.8.6.2 to accommodate changes in battery parameters associated with the replacement of the Division I battery. The licensee also plans to revise the Bases section for SR 3.8.6.2.

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. The changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed changes do not involve a change in the manner in which the plant is operated. TS Sections [SRs] 3.8.4.1, 3.8.4.6, 3.8.6.2 and Bases Surveillance Requirement Section 3.8.6.2 are being revised to reflect the new Division I battery cell/system characteristics and associated requirements. The new battery will have an increased capacity over the present battery, while maintaining the existing battery system voltage requirements. This is possible because the present and new battery specific gravity (1.215) and type (lead calcium) are the same. Also, the end of battery system discharge voltage remains the same as 210 VDC. The Division I batteries will continue

to furnish power to redundant essential loads as required and as designed. The new surveillance requirement voltages are based on the same volts/cell criteria used for the existing batteries. Furthermore, failure or malfunction of the station batteries does not initiate any of the analyzed accidents previously evaluated in the UFSAR [updated final safety analysis report]. The changes described will therefore not involve an increase in the probability or consequences of an accident previously evaluated.

2. The changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

The new battery is Class 1E qualified equipment and is being maintained within the same overall design parameters as the existing battery. That is, the battery terminal voltage on float voltage conditions (2.167 volt[s]/cell), overvoltage conditions (2.5 volts/cell) and charger capability (2.15 volts/cell) are the same as the original design. Furthermore, the end of system discharge voltage of the battery system is maintained the same; therefore, there is no negative impact to plant loads supplied by the batteries. Failures of the batteries and chargers have been considered in both the existing and modified configurations. The proposed changes will not change performance or reliability nor introduce any new or different failure modes or common mode failure and will therefore not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The changes do not involve a significant reduction in the margin of safety.

The changes act to increase overall battery capacity from 560 ampere-hours to 1200 ampere-hours with the minimum battery discharge voltage remaining at 210 VDC (or 105 VDC per battery). The battery terminal voltage on float voltage conditions (2.167 volt[s]/cell), overvoltage conditions (2.5 volts/cell) and charger capability (2.15 volts/cell) are the same as the original design. The new surveillance requirement voltages are based on the same volts/cell criteria used for the existing batteries. The batteries' ability to satisfy the design requirements (battery duty cycle) of the dc system will not be reduced from original plant design and will therefore not have any negative impact to plant loads [that] the battery supplies. The proposed changes therefore do not involve a reduction in the margin of safety.

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: John Flynn, Esq., Detroit Edison Company, 2000 Second Avenue, Detroit, Michigan 48226.

NRC Section Chief: Claudia M. Craig.

Duke Energy Corporation, Docket Nos. 50–269, 50–270, and 50–287, Oconee Nuclear Station, Units 1, 2, and 3, Oconee County, South Carolina

Date of amendment request: April 5, 1999; supplemented October 7, 1999.

Description of amendment request: The proposed amendments would revise the Improved Technical Specifications (TS), Updated Final Safety Analysis Report (UFSAR), and Core Operating Limits Report to incorporate Topical Report (TR) DPC-NE–3005–P, ''Thermal-Hydraulic Transient Analysis Methodology.'' The proposed changes are: (1) Modification of a note for TS Surveillance Requirement (SR) 3.4.1.2, ''RCS [Reactor Coolant System] Pressure, Temperature, and Flow DNB [Departure from Nucleate Boiling] Limits,'' to add that the SR would apply for the condition where there is a 0°F delta-Tcold setpoint; (2) modification of TS 3.4.10, ''Pressurizer Safety Valves,'' to increase the setpoint range of the lift settings for the pressurizer safety valves; (3) modification of SR 3.4.10.1 to specify that the pressurizer safety valve lift settings shall be within plus or minus 1 percent; (4) addition of TS 3.7.4, ''Atmospheric Dump Valve (ADV) Flow Paths,'' to address the applicability and required actions related to the ADS valves; (5) addition of TS 3.9.7, ''Unborated Water Source Isolation Valves,'' to require valves that are used to isolate unborated water sources to be secured in the closed position while in Mode 6, provide required actions if one or more of the valves is not secured in the closed position, and related SRs; (6) TS 5.6.5b would be changed to update the Core Operating Limits Report references; and (7) modification of the appropriate Bases to reflect the above changes and consistentcy with the revision to the TR analysis. In addition, proposed changes to the UFSAR revisions were provided.

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. Involve a significant increase in the probability or consequences of an accident previously evaluated?

No. The proposed changes to the Technical Specifications, Bases, Updated Final Safety Analysis Report (UFSAR), and Core Operating Limits Report (COLR) incorporate the accident analyses established in Topical Report DPC–NE–3005–P, ''UFSAR Chapter 15 Transient Analysis Methodology, Revision 1.'' On February 1, 1999, Duke submitted Topical Report DPC–NE–3005–P to the NRC for approval. The NRC found DPC–NE–3005–P acceptable as noted in SER [Safety Evaluation Report] dated May 25, 1999.

The analyzed events are initiated by the failure of specific plant structures, systems or components. These proposed changes do not impact the condition or performance of those structures, systems or components.

The revised accident analyses in DPC–NE–3005–P demonstrate that the applicable acceptance criteria are met. In addition, the calculations show that the applicable radiological and environmental acceptance criteria will continue to be met.

Based on the above, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Create the possibility of a new or different kind of accident from any accident previously evaluated?

No. The proposed changes do not involve a physical alteration of the plant. No new or different equipment is being installed, and no installed equipment is being operated in a new or different manner. Where setpoints and operating limits have been revised, the revised accident analyses demonstrate that the applicable acceptance criteria are met. As a result, no new failure modes are being introduced.

Based on the above, the proposed changes do not create the possibility of any new or different kind of accident from any accident previously evaluated.

3. Involve a significant reduction in a margin of safety?

No. The margin of safety is established through the design of the plant structures, systems and components, the parameters within which the plant is operated, and the establishment of the setpoints for the actuation of equipment relied upon to respond to an event. The proposed changes do not involve a physical alteration of the plant. No new or different equipment is being installed, and no installed equipment is being operated in a new or different manner. Where setpoints and operating limits have been revised, the revised accident analyses in DPC–NE–3005–P demonstrate that the applicable acceptance criteria are met.

Based on the above, the proposed changes do not involve a significant reduction in a margin of safety.

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: Anne W. Cottington, Winston and Strawn, 1200 17th Street, NW., Washington, DC.

NRC Section Chief: Richard L. Emch, Jr.

FirstEnergy Nuclear Operating Company, Docket No. 50–440, Perry Nuclear Power Plant, Unit 1, Lake County, Ohio

Date of amendment request: September 9, 1999.

Description of amendment request: The proposed amendment would increase the authorized rated thermal power level of 3579 megawatts thermal by 5 percent to 3758 megawatts thermal. The proposal follows the NRC-approved generic format and content for Boiling Water Reactor power uprate licensing topical reports documented in NEDC–31897P–A, ''Generic Guidelines for General Electric Boiling Water Reactor Power Uprate,'' and NEDC–31984P, ''Generic Evaluations of General Electric Boiling Water Reactor Power Uprate.''

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) Will the change involve a significant increase in the probability or consequences of an accident previously evaluated?

The increase in power level discussed herein will not significantly increase the probability or consequences of an accident previously evaluated.

The probability (frequency of occurrence) of Design Basis Accidents occurring is not affected by the increased power level, as the regulatory criteria established for plant equipment (ASME code, IEEE standards, NEMA standards, Regulatory Guide criteria, etc.) are still complied with at the uprated power level. An evaluation of the boiling water reactor (BWR) probabilistic risk assessments concludes that the calculated core damage frequencies do not significantly change due to power uprate. Scram setpoints (equipment settings that initiate automatic plant shutdowns) are established such that there is no significant increase in scram frequency due to uprate. No new challenge to safety-related equipment results from power uprate.

The changes in consequences of hypothetical accidents which would occur from 102% of the uprated power, compared to those previously evaluated from greater than or equal to 102% of the original power, are in all cases insignificant, because the accident evaluations from power uprate compared with 105% of original power do not result in exceeding the NRC-approved acceptance limits. The spectrum of hypothetical accidents and transients has been investigated, and shown to meet the plant's currently licensed regulatory criteria. In the area of core design, for example, the fuel operating limits such as Maximum Average Planar Linear Heat Generation Rate (MAPLHGR) and Safety Limit Minimum Critical Power Ratio (SLMCPR) are still met at the uprated power level, and fuel reload analyses will show plant transients meet the criteria accepted by the NRC as specified in NEDO–24011, ''GESTAR II.'' Challenges to fuel (ECCS performance) are evaluated, and shown to still meet the criteria of 10 CFR 50.46 and Appendix K (Section 4.3 above, and Regulatory Guide 1.70 Safety Analysis Report Section 6.3).

Challenges to the containment have been evaluated, and the containment and its associated cooling systems will continue to meet 10 CFR Appendix A Criterion 38, Long Term Cooling, and Criterion 50, Containment.

Radiological release events (accidents) have been evaluated, and shown to meet the guidelines of 10 CFR 100 (Regulatory Guide 1.70 Safety Analysis Report Chapter 15).

(2) Will the change create the possibility of a new or different kind of accident from any accident previously evaluated?

As summarized below, this change will not create the possibility of a new or different kind of accident from any accident previously evaluated.

Equipment that could be affected by power uprate has been evaluated. No new operating mode, safety-related equipment lineup, accident scenario or equipment failure mode was identified. The full spectrum of accident considerations defined in Regulatory Guide 1.70 has been evaluated and no new or different kind of accident has been identified. Power uprate uses existing technology, and applies it within the capabilities of already existing plant equipment in accordance with existing regulatory criteria and includes NRC approved codes, standards, and methods. General Electric has designed BWRs of higher power and no new power dependent accidents have been identified.

The technical specifications needed to implement power uprate require some small adjustments, with no change to the plant's physical configuration. All technical specification changes have been evaluated and are acceptable.

(3) Will the change involve a significant reduction in a margin of safety?

As summarized below, this change will not involve a significant reduction in a margin of safety.

The calculated loads on all affected structures, systems and components remain within their design allowables for all design basis event categories. No NRC acceptance criteria are exceeded. Some design and operational margins are affected by power uprate, however, the margins of safety originally designed into the plant are not affected by power uprate. Because the plant configuration and reactions to transients and hypothetical accidents do not exceed the presently approved NRC acceptance limits, power uprate does not involve a significant reduction in a margin of safety.

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: Mary E. O'Reilly, Attorney, FirstEnergy Corporation, 76 South Main Street, Akron, OH 44308.

NRC Section Chief: Anthony J. Mendiola.

FirstEnergy Nuclear Operating Company, Docket No. 50–440, Perry Nuclear Power Plant, Unit 1, Lake County, Ohio

Date of amendment request: September 9, 1999.

Description of amendment request: The proposed amendment would revise Perry Operating License Appendix B, the Perry Environmental Protection Plan. The proposed change will eliminate the requirement in the Environmental Protection Plan to sample Lake Erie sediment in the Perry and Eastlake Plant area for *Corbicula,* since *Corbicula* and zebra mussels have already been identified, and control and treatment plans have been implemented which are effective on both species.

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) The proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The Perry Plant water source (Lake Erie) is now known to have mussels and clams present. Therefore, it is no longer necessary to use lake sampling techniques designed to provide advance notice of their arrival. Treatment programs and monitoring for system fouling are in place. The treatment programs and system monitoring for fouling makes it highly likely that equipment degradation due to *Corbicula* would be avoided or readily identified, allowing time for corrective actions. Therefore, the programs will ensure that plant systems remain capable of performing their intended functions. Since the lake sampling was designed to allow time to implement a control program, and the control program is now in place, elimination of the lake sampling program will not involve a significant increase in the probability or radiological consequences of an accident previously evaluated.

(2) The proposed change would not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed change will eliminate the lake sampling program designed to detect the arrival of *Corbicula,* a particular species of clam, at the Perry Plant. Since the clam is now known to exist in the vicinity, and control methods are developed and implemented, advanced detection is no longer required. Since the proposed change involves only a monitoring program and does not change or modify the design, maintenance or operation of any plant equipment, the proposed change would not create the possibility of a new or different

kind of accident from any accident previously evaluated.

(3) The proposed change will not involve a significant reduction in the margin of safety.

The current requirements for aquatic monitoring are designed to detect *Corbicula* prior to plant cooling water systems and heat exchangers becoming infested with clams and flow becoming degraded, and thus reducing the cooling available to safety systems.

Since an effective control method has already been implemented, the deletion of a lake sampling method to provide advance warning of clams in the area provides no significant benefit. The proposed change will continue to provide the same level of protection against system or component fouling that currently exists, thus the proposed change will not involve a significant reduction in the margin of safety.

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: Mary E. O'Reilly, Attorney, FirstEnergy Corporation, 76 South Main Street, Akron, OH 44308

NRC Section Chief: Anthony J. Mendiola.

First Energy Nuclear Operating Company, Docket No. 50–440, Perry Nuclear Power Plant, Unit 1, Lake County, Ohio

Date of amendment request: September 9, 1999.

Description of amendment request: The proposed amendment includes nine separate changes to the Perry technical specifications. The proposed changes include increasing the minimum water volume of the condensate storage tank, clarification of minimum ECCS pump differential pressures, clarifications to Required Action and Condition statements, as well as minor nomenclature and editorial changes.

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) The proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

A summary of the proposed changes is:

1. (Condensate Storage Tank (CST) Level-Low.) The Allowable Values for the CST low water level limits (Technical Specification (TS) Table 3.3.5.1–1 Function 3.d and Table 3.3.5.2–1 Function 3) are being revised from greater than or equal to 59,700 gallons to greater than or equal to 90,300 gallons based on recent revisions to calculations taking into account potential vortex issues. This change also results in raising the TS Surveillance Requirement (SR) 3.5.2.2.b value for the normal CST level limit to greater than or equal to 249,700 gallons.

2. (Emergency Core Cooling System Pump Differential Pressure) TS SRs 3.5.1.4 and SR 3.5.2.5 are being revised to better describe what the differential pressures listed in the SRs represent at Perry Nuclear Power Plant, in lieu of the phrase ''pump differential pressure'.

3. (RCIC/RHR Steam Line Flow-High) The proposed change revises the nomenclature on a table to match the plant-specific instrument nomenclature.

4. (Containment Average Temperature-To-Relative-Humidity) This revision is a clarification to prevent misinterpretation of the Required Actions.

5. (Containment Vacuum Breakers) T 3.6.1.11 Required Action A.2 is being revised to clarify the proper actions to take if the required number of vacuum breakers is not operable. Required Action A.2 is being revised to add the word ''required'.

6. (Reporting Requirements) TS Administrative Controls Reporting Requirement 5.6.1 is being revised to clarify the definition of the time period of the report. ''Calendar'' is being removed from the term ''calendar year'' to clarify the time period that the Occupational Radiation Exposure Report is required to cover, to be consistent with the revised wording in 10 CFR 20.1003.

7. (High Radiation Area) TS Administrative Control 5.7 is being revised to update the titles of individuals responsible for radiation protection. The term ''health physics'' is being revised to ''radiation protection'' to be consistent with plant terminology.

8. (ECCS Instrumentation) Required Action E.1 Note 1 is being revised for consistency with other specifications. The word ''in'' is being added.

9. (Electrical Power Systems) In TS 3.8.3, the word ''continued'' is being added to the bottom of the page for consistency with other specifications.

The CST level change is adjusted in a conservative direction, as recommended by NRC inspectors during a Safety System Functional Inspection (SSFI) that was conducted in the spring of 1997. The current setpoints were reviewed and determined to be adequate, however it was suggested that some additional margin should be added. The ''low level'' limits are being raised to move the setpoint further away from the level at which vortexing would begin, and the normal water level limit is also being raised to ensure that at least 150,000 gallons of water would be available for HPCS and RCIC. Since the existing limits are already considered adequate, and the proposed changes are in the conservative direction, the proposed change does not involve a significant increase in the probability or radiological consequences of an accident previously evaluated.

The other eight proposed changes are administrative only, and can have no effect on any previously evaluated accident scenario. These eight changes have no effect on plant hardware, plant design, safety limit settings, or system operation and therefore do not modify or add any initiating parameters that would significantly increase the probability of an accident previously evaluated, or the radiological consequences of an event.

(2) The proposed changes would not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed changes will raise the Condensate Storage Tank level, which is conservative, and also includes some administrative changes to improve clarity, update titles or terminology. None of these changes can create the possibility of a new of different kind of accident from any accident previously evaluated.

(3) The proposed changes will not involve a significant reduction in the margin of safety.

The Condensate Storage Tank level change increases the margin of safety by providing more margin between the setpoint that causes the HPCS and RCIC suctions to shift from the CST to the Suppression Pool and the beginning of the formation of a vortex at their pump suctions. The other administrative changes have no effect on the margin of safety. Therefore the proposed change will not involve a significant reduction in the margin of safety.

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: Mary E. O'Reilly, Attorney, FirstEnergy Corporation, 76 South Main Street, Akron, OH 44308.

NRC Section Chief: Anthony J. Mendiola.

FirstEnergy Nuclear Operating Company, Docket No. 50–440, Perry Nuclear Power Plant, Unit 1, Lake County, Ohio

Date of amendment request: September 14, 1999.

Description of amendment request: The proposed amendment would delete one Operating License Condition, and revise another. License Condition 2.C.10 regarding controls over the containment air locks during plant outages would be deleted due to the effective implementation of Shutdown Safety administrative controls at Perry. License Condition 2.F would be revised to clarify the intent of reporting requirements for violations of the technical specifications and the Environmental Protection Plan.

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) The proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed changes delete or revise two Operating License Conditions, one that addresses administrative controls on air locks during refueling outages, and one regarding reporting of violations of the technical specifications and the Environmental Protection Plan.

These proposed changes to the Operating License are administrative only, and have no effect on any previously evaluated accident scenario. The proposed changes have no effect on plant hardware, plant design, safety limit setting, or plant system operation and therefore do not modify or add any initiating parameters that would significantly increase the probability of an accident previously evaluated.

The changes will not alter the operation of equipment assumed to be available for the mitigation of accidents or transients, nor will they alter the operation of equipment important to safety previously evaluated in the accident analyses.

The proposed activity does not affect accident mitigation capabilities or the radiation release amounts for postulated accidents. Since there are no changes to previous accident analyses, the radiological consequences associated with these analyses remain unchanged.

Therefore, the proposed change does not significantly increase the probability or consequences of an accident previously evaluated.

(2) The proposed change would not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed changes are administrative in nature, and do not involve any physical alteration of the plant (no new or different type of equipment will be installed). They do not alter the design assumptions, conditions, configuration of the facility or the manner in which the plant is operated. The proposed changes have no impact on component and system interactions.

The safety functions of plant structures, systems, and components are also not changed in any manner, nor is the reliability of any structure, system, or component reduced.

The proposed changes are not providing for operation in a mode that is not already evaluated. These changes do not affect the operation of any systems or components, nor do they involve any potential initiating events that would create any new or different kind of event.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

(3) The proposed change will not involve a significant reduction in the margin of safety.

The proposed changes are administrative in nature (they delete or revise two license conditions). Administrative controls will continue to be applied to the opening of the air locks during plant shutdown periods, and to the reporting of violations of the technical specifications and the Environmental Protection Plan.

There is no impact on safety limits or limiting safety system settings. The changes do not affect any plant safety parameters or setpoints. No physical or operational changes to the facility will result from the proposed changes.

The proposed changes have no impact on any safety analysis assumptions. Consequently, no margin of safety as described in the Final Safety Analysis Report or defined in the basis of any technical specification is reduced as a result of these changes. These proposed changes do not detrimentally affect the ability of structures, systems, and components important to safety to fulfill their intended safety functions.

Therefore, the proposed changes do not cause a significant reduction in the margin of safety.

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: Mary E. O'Reilly, Attorney, FirstEnergy Corporation, 76 South Main Street, Akron, OH 44308.

NRC Section Chief: Anthony J. Mendiola.

Indiana Michigan Power Company, Docket Nos. 50–315 and 50–316, Donald C. Cook Nuclear Plant, Units 1 and 2, Berrien County, Michigan

Date of amendment requests: October 12, 1999.

Description of amendment requests: The proposed amendments would revise Technical Specification (T/S) Surveillance Requirement (SR) 4.6.2.2.d for the spray additive system to relocate the details associated with the acceptance criteria and test parameters to the associated T/S Bases. Additionally, certain administrative text format changes are being proposed.

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 change involve a significant increase in the probability of occurrence or consequences of an accident previously evaluated?

The proposed changes relocate the details associated with the acceptance criteria and test parameters from the T/S SR to the associated Bases and do not affect system operability or performance. The format changes in the text on each page are administrative in nature and do not result in any change in plant operation. Relocation of this information to the Bases is administrative in nature and does not affect the probability or consequences of any accident previously evaluated. No actual change to the requirement is made. Actual plant operation is not affected by the administrative changes. No methods of operation of plant systems, structures or components are changed. Operation of accident mitigation features is not changed. Consequently, there is no affect upon the probability of any previously analyzed accident, transient, accident initiators, or precursor events. Additionally, because there is no actual change in plant design or operation, there is no affect upon radioactive material inventories, plant shielding, or effluent release points. Therefore, these changes do not significantly increase the probability of occurrence 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?

The proposed changes relocate the details associated with the acceptance criteria and test parameters from the T/S SR to the associated Bases and do not affect system operability or performance. The format changes in the text on each page are administrative in nature and do not result in any change in plant operation. Facility operation and procedures are not changed. Relocation of this information to the Bases is administrative in nature and does not affect [sic] create any new accident scenarios, accident initiators, or precursor events. Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the change involve a significant reduction in a margin of safety?

The proposed changes relocate the details associated with acceptance criteria and test parameters from the T/S SR to the associated Bases and do not modify T/S safety settings, setpoints, or other values. The format changes in the text on each page are administrative in nature and do not result in any change in plant operation. There is no effect upon operating margins and accident margins because the administrative changes do not change the manner of operation of plant systems, structures, or components. Plant emergency and abnormal operating procedures are not affected. There is no change of actual testing methodology, test parameters, or acceptance criteria. The response of the plant to an event is the same. Potential offsite doses are unaffected because operation of the facility is unchanged. Relocation of the testing details to the Bases is acceptable because controls are in place for T/S Bases changes which require evaluation of changes under the provisions of 10 CFR 50.59. Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

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 requests involve no significant hazards consideration.

Attorney for licensee: Jeremy J. Euto, Esq., 500 Circle Drive, Buchanan, MI 49107.

NRC Section Chief: Claudia M. Craig.

Northern States Power Company, Docket No. 50–263, Monticello Nuclear Generating Plant, Wright County, Minnesota

Date of amendment request: September 30, 1999.

Description of amendment request: The proposed amendment would change the Technical Specification surveillance periodicity requirements for the control room emergency filtration system.

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. The proposed amendment will not involve a significant increase in the probability or consequences of an accident previously evaluated.

During an accident, the Control Room Emergency Filtration [EFT] System provides filtered air to pressurize the Control Room to minimize the activity, and therefore the radiological dose, inside the Control Room. Technical Specification surveillance requirements are established in order to ensure that the EFT System will perform its safety function during an accident. The proposed amendment eliminates unnecessary testing which is not required to show that the filters are operable and which causes unnecessary wear and tear on the system. The remaining surveillances adequately show that the system is operable and capable of performing its safety function. Dose to the public and the Control Room operators are not affected by the proposed change.

The proposed Technical Specification change does not introduce new equipment operating modes, nor does the proposed change alter existing system relationships. The proposed amendment does not introduce new failure modes.

Therefore, the proposed amendment will not significantly increase the probability or the consequences of an accident previously evaluated.

2. The proposed amendment will not create the possibility of a new or different kind of accident from any accident previously analyzed.

The proposed Technical Specification change does not introduce new equipment operating modes, nor does the proposed change alter existing system relationships. The proposed amendment does not introduce new failure modes. The proposed surveillance requirements are consistent with industry and regulatory guidance and show that the system is capable of performing its safety function. System reliability is enhanced by the proposed change by eliminating unnecessary wear on the system.

Therefore, the proposed amendment will not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The proposed amendment will not involve a significant reduction in the margin of safety.

The proposed amendment is within current industry and regulatory standards for testing filters. The proposed amendment maintains margins of safety. Off-site and Control Room dose assessments are not affected by the proposed amendment, since the ability of the EFT System to perform its safety function is shown by the proposed surveillance requirements. The proposed change to the surveillance provides assurance that the system will perform at the filter efficiency used in the evaluation of the radiological consequences of the postulated events. Therefore, the proposed amendment will not involve a significant reduction in the margin of safety.

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: Gerald Charnoff, Esq., Shaw, Pittman, Potts and Trowbridge, 2300 N Street, NW, Washington, DC 20037.

NRC Section Chief: Claudia M. Craig.

Public Service Electric & Gas Company, Docket No. 50–354, Hope Creek Generating Station, Salem County, New Jersey

Date of amendment request: September 30, 1999.

Description of amendment request: The proposed amendment would revise the Technical Specifications associated with the Safety Limit Minimum Critical Power Ratios (SLMCPRs) in order to support the operation of Hope Creek in the upcoming Cycle 10 with a mixed core of General Electric (GE) and Asea Brown Bovieri/Combustion Engineering (ABB/CE) fuel. In addition, administrative changes would be made to the Technical Specifications to reflect the change in fuel vendor from GE to ABB/CE.

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. The proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

The derivation of the revised SLMCPRs for Hope Creek for incorporation into the Technical Specifications, and its use to determine cycle-specific thermal limits, have been performed using NRC [U.S. Nuclear Regulatory Commission] approved methods. These calculations do not change the method of operating the plant and have no effect on the probability of an accident initiating event or transient.

There are no significant increases in the consequences of an accident previously evaluated. The basis of the MCPR Safety Limit is to ensure that no mechanistic fuel damage due to clad overheating is calculated to occur if the limit is not violated. The new SLMCPRs preserve the existing margin to transition boiling and the probability of fuel damage is not increased.

Removal of the cycle specific footnote for the Safety Limit applicability will not involve a significant increase in the probability or consequences of an accident previously evaluated since the change is administrative and does not affect the plant or fuel design or operation.

Likewise, the proposed changes to the Average Planar Heat Generation Rate (APLHGR), Minimum Critical Power Ratio (MCPR), Recirculation Loop Limiting Condition for Operation (LCO) Action Statements, and references to fuel vendor analyses and reports do not involve a significant increase in the probability or consequences of an accident previously evaluated. The changes to the APLHGR, MCPR and Recirculation Loop LCOs are considered to be administrative in nature since the Core Operating Limits Report (COLR) will continue to be used to appropriately control and limit the bounds of plant operation with slow control rods or during single recirculation loop operation, and the COLR will still be developed in accordance with NRC approved methods. Similarly, the revised references to the fuel vendor throughout the Technical Specifications are also considered to be administrative in nature since they reflect the current status of NRC approval of methodologies utilized by PSE&G [Public Service Electric and Gas Company] and the fuel vendor to develop operating and safety limits for the fuel and core designs. These proposed changes do not alter the method of operating the plant and have no effect on the probability of an accident initiating event or transient.

There are no significant increases in the consequences of an accident previously evaluated. The basis of the COLR and the PSE&G and fuel vendor methodologies is to ensure that no mechanistic fuel damage is calculated to occur if the limits on plant operation are not violated. The COLR will continue to preserve the existing margin to fuel damage and the probability of fuel damage is not increased.

Therefore, the proposed change does not involve an increase in the probability or consequences of an accident previously evaluated.

2. The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed changes contained in this submittal result from an analysis of the reload core using the same fuel types as previous cycles and an ABB/CE fuel design with extensive operating experience. These changes do not involve any new method for operating the facility and do not involve any facility modifications for the reload core operation. No new initiating events or transients result from these changes. Therefore, the proposed Technical Specification changes do not create the possibility of a new or different kind of accident, from any accident previously evaluated.

Removal of the cycle specific footnote for the Safety Limit applicability does not create the possibility of a new or different kind of accident from any accident previously evaluated since the change is administrative and does not affect the plant or fuel design or operation.

The changes to the APLHGR, MCPR and Recirculation Loop LCOs are considered to be administrative in nature since the Core Operating Limits Report (COLR) will continue to be used to appropriately control and limit the bounds of plant operation with slow control rods or during single recirculation loop operation, and the COLR will still be developed in accordance with NRC approved methods. These changes do not involve any new method for operating the facility and do not involve any facility modifications in addition to the new fuel design. No new initiating events or transients result from these changes. Therefore, the proposed Technical Specification changes do not create the possibility of a new or different kind of accident.

The revised references to the fuel vendor throughout the Technical Specifications are also considered to be administrative in nature since they reflect the current status of NRC approval of methodologies utilized by PSE&G and the fuel vendor to develop operating and safety limits for the fuel and core designs. These changes do not involve any new method for operating the facility and do not involve any facility modifications in addition to the new fuel design. No new initiating events or transients result from these changes. Therefore, the proposed Technical Specification changes do not create the possibility of a new or different kind of accident.

3. The proposed change does not involve a significant reduction in a margin of safety.

The margin of safety as defined in the Technical Specification bases will remain the same. The new SLMCPRs are calculated using NRC approved methods, which are in accordance with the current fuel designs, and licensing criteria. The MCPR Safety Limit remains high enough to ensure that greater than 99.9% of all fuel rods in the core will avoid transition boiling if the limit is not violated, thereby preserving the fuel cladding integrity. Therefore, the proposed Technical Specification changes do not involve a significant reduction in a margin of safety.

Removal of the cycle specific footnote for the Safety Limit applicability does not create the possibility of a new or different kind of accident from any accident previously evaluated since the SLMCPR will continue to be evaluated on a cycle-specific basis.

The margin of safety as defined in the Technical Specification bases will likewise remain unaffected by the proposed changes to APLHGR, MCPR and Recirculation Loop LCOs, and the revised references to the fuel vendor throughout the Technical Specifications. These changes establish controls for plant operation and establish bases for fuel analyses that reflect NRC approved methods, and are in accordance with the current fuel design and licensing criteria. These changes will continue to ensure that the plant is operated within specified acceptable fuel design limits. Therefore, the proposed Technical Specification changes do not involve a significant reduction in a margin of safety.

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: Jeffrie J. Keenan, Esquire, Nuclear Business Unit—N21, P.O. Box 236, Hancocks Bridge, NJ 08038.

NRC Section Chief: James W. Clifford.

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: September 8, 1999.

Description of amendment request: The proposed amendments would revise Technical Specification (TS) 3/4.8.1, ''A.C. Sources, Operating,'' and associated Bases, by eliminating the requirement for accelerated testing of the standby diesel generators and the associated reporting requirements. The TS Index would also be revised to reflect these changes.

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 change involve a significant increase in the probability or consequences of an accident previously evaluated?

The proposed changes do not involve hardware changes nor do they affect the operational limits or design of the standby diesel generators or power systems. These changes do not alter assumptions made in the safety analysis. In conjunction with the maintenance rule program, these changes continue to assure the operability and reliability of the standby diesel generators while minimizing the number of required engine starts and associated wear. These changes are also consistent with the guidance provided in Generic Letter 94–01, ''Removal of Accelerated Testing and Special Reporting Requirements for Emergency Diesel Generators.''

Therefore, the proposed changes do not involve an 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?

The proposed changes minimize the number of required standby diesel generator starts; they do not affect the operational limits or design. The performance capability of the standby diesel generators is not affected. These changes do not alter the plant configuration (no new or different type of equipment will be installed) or make changes in methods governing normal plant operation. These changes do not alter assumptions made in the safety analysis. These changes are also consistent with the guidance provided in Generic Letter 94–01.

Therefore, the changes will not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the change involve a significant reduction in a margin of safety?

The proposed changes do not involve a change in the operational limits or design of the emergency power system. The design and capabilities of the standby diesel generators are not affected by these changes. These changes are also consistent with the guidance provided in Generic Letter 94–01.

The proposed changes do not involve a significant reduction in margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the request for amendments involves no significant hazards consideration.

Attorney for licensee: Jack R. Newman, Esq., Morgan, Lewis & Bockius, 1800 M Street, NW., Washington, DC 20036–5869.

NRC Section Chief: Robert A. Gramm.

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: September 8, 1999.

Description of amendment request: The proposed amendments would revise Technical Specification 3/4.8.1, ''A.C. Sources, Operating,'' and associated Bases, by relocating the 18-month surveillance to subject the standby diesel generator to inspections in accordance with procedures prepared in conjunction with its manufacturer's recommendations, to the Updated Final Safety Analysis Report.

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 change involve a significant increase in the probability or consequences of an accident previously evaluated?

The proposed change moves the requirement to perform manufacturer's recommended inspections of the Standby Diesel Generators from the Technical Specifications to the Updated Final Safety Analysis Report (UFSAR). The change does not result in any hardware or operating procedure changes. The requirement being removed from the Technical Specifications is not the initiator of any analyzed event. The UFSAR is maintained using the provisions of 10 CFR 50.59. Since any changes will be evaluated per 10 CFR 50.59, no significant increase in the probability or consequences of an accident previously evaluated will be allowed without prior NRC approval. Therefore, the changes do 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?

The proposed change moves the requirement to perform manufacturer's recommended inspections of the Standby Diesel Generators from the Technical Specifications to the Updated Final Safety Analysis Report (UFSAR). The change does not alter the plant configuration (no new or different type of equipment will be installed) or make changes in methods governing normal plant operation. The change does not impose different requirements. The change does not alter assumptions made in the safety analysis and licensing basis. Therefore, the change will not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does this change involve a significant reduction in a margin of safety?

The proposed change moves the requirement to perform manufacturer's recommended inspections of the Standby Diesel Generators from the Technical Specifications to the Updated Final Safety Analysis Report (UFSAR). The change does not reduce the margin of safety since the location of details has no impact on any safety analysis assumptions. In addition, the requirement being transposed from the Technical Specification to the UFSAR [is the] same as the existing Technical Specification. Also, the UFSAR is maintained using the provisions of 10 CFR 50.59. Since any changes will be evaluated per 10 CFR 50.59, no significant reduction in a margin of safety will be allowed without prior NRC approval.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the request for amendments involves no significant hazards consideration.

Attorney for licensee: Jack R. Newman, Esq., Morgan, Lewis & Bockius, 1800 M Street, NW., Washington, DC 20036–5869.

NRC Section Chief: Robert A. Gramm.

Tennessee Valley Authority (TVA), Docket Nos. 50–260 and 50–296, Browns Ferry Nuclear Plant, Units 2 and 3, Limestone County, Alabama

Date of amendment request: September 28, 1999.

Description of amendment request: The proposed amendment would revise the Technical Specifications to increase the maximum allowable leakage rates for main steam isolation valves.

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:

A. The proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

TVA proposes to utilize the main steam drain lines to preferentially direct MSIV leakage to the main condenser. This drain path takes advantage of the large volume of the steam lines and condenser to provide holdup and plate-out of fission products that may leak through the closed MSIVs. In this approach, the main steam lines, steam drain piping, and the main condenser are used to mitigate the consequences of an accident to limit potential off-site exposures below those specified in 10 CFR 100 and 10 CFR 50 Appendix A, GDC 19 for control room dose limits.

Seismic verification walkdowns and evaluations of representative piping/supports were performed to demonstrate the main steam line piping and components that comprise the ALT path were rugged, and able to perform the safety function of MSIV leakage control following an Design Basis Earthquake (DBE). Thus, it has been concluded the primary components in the MSIV alternate treatment flow path can be relied upon to maintain structural integrity.

Therefore, the proposed amendment does not involve changes to structures, components, or systems which would affect the probability of an accident previously evaluated in the Browns Ferry Final Safety Analysis Report (FSAR).

A plant-specific radiological analysis has been performed to assess the effects of the proposed increase in MSIV leakage criteria in terms of off-site doses and main control room dose. This analysis uses the holdup and plate-out factors described in NEDC–31858P, Revision 2. The analysis shows the dose contribution from the proposed increase in leakage criteria is acceptable compared to doses limits prescribed in 10 CFR 100 and 10 CFR 50, Appendix A, GDC 19. Therefore, the proposed changes do not significantly increase the consequences of an accident previously evaluated.

B. The proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed changes require the use of the main steam piping and the condenser to process MSIV leakage. This additional function does not compromise the reliability of these systems. They will continue to function as intended and not be subject to a failure of a different kind than previously considered. In addition, MSIV functionality will not be adversely impacted by the increased leakage limit. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

C. The proposed amendment does not involve a significant reduction in a margin of safety.

The proposed change to TS Surveillance Requirement 3.6.1.3.10 to increase the allowable MSIV leakage does not involve a significant reduction in the margin of safety. The allowable leak rate specified for the MSIVs is used to quantify a maximum amount of leakage assumed to bypass containment. The results of the re-analysis supporting these changes were evaluated against the dose limits contained in 10 CFR 100 for off-site doses and 10 CFR 50, Appendix A, GDC 19 for control room doses. Sufficient margin relative to the regulatory limits is maintained even when conservative assumptions and methods are utilized. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

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: General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, ET l0H, Knoxville, Tennessee 37902.

NRC Section Chief: Sheri R. Peterson.

Tennessee Valley Authority, Docket Nos. 50–259, 50–260 and 50–296, Browns Ferry Nuclear Plant (BFN), Units 1, 2 and 3, Limestone County, Alabama

Date of amendment request: September 30, 1999.

Description of amendment request: The proposed amendments consist of administrative revisions to the Operating Licenses for BFN Units 1, 2 and 3 that delete license conditions that have become outdated, are no longer applicable, or are redundant, and consolidate license conditions which currently exist in two locations in each units' Technical Specifications.

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:

A. The proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The changes requested by this submittal are administrative in nature and do not change the way BFN operates. The proposed changes are intended to: delete redundant paragraphs, delete requirements and authorizations for modifications that have been completed, delete an authorization to temporarily store radioactive material on site, delete an exemption from a General Design Criterion which has expired, and consolidate license conditions which currently exist in two locations in each units Technical Specifications.

The change does not affect any design bases accident or the ability of any safe shutdown equipment to perform its design function. There are no physical modifications that are required to implement this license condition update. There is no impact on plant equipment or changes to operating procedures. Therefore, the proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

B. The proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The changes described above are administrative in nature and do not change the way BFN operates. There are no physical modifications authorized by the proposed changes and there are no procedure or process changes that are requested. Changes requested are intended to ensure the license conditions reflect the current status of the plant. There is no impact on any accident analysis created by this change. Therefore, the proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

C. The proposed amendment does not involve a significant reduction in a margin of safety.

The changes described above are administrative in nature and do not change the way BFN operates. There are no procedural or physical changes required by this amendment. The license conditions are being updated partially as a result of NRC Information Notice 97–43 which highlighted the importance of periodically verifying compliance with the Operating License. These changes are intended to delete license conditions which are no longer needed or are redundant in order to ensure the license conditions accurately reflect the current status of the licensed facility. The change does not affect any design bases accident or the ability of any safe shutdown equipment to perform its design function, therefore no margins of safety have been affected by any of these changes. Accordingly, the proposed amendment does not involve a significant reduction in a margin of safety.

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: General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, ET l0H, Knoxville, Tennessee 37902.

NRC Acting Section Chief: Ronald W. Hernan.

Previously Published Notices of Consideration of Issuance of Amendment to Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The following notices were previously published as separate individual notices. The notice content of the same as above. They were published as individual notices either because the time did not allow the Commission to wait for this biweekly notice or because the action involved exigent circumstances. They are repeated here because the biweekly notice lists all amendments issued or proposed to be issued involving no significant hazards considerations.

For details, see the individual notice in the **Federal Register** on the day and page cited. This notice does not extend the notice period of the original notice.

Arizona Public Service Company, et al., Docket Nos. STN 50–528, STN 50–529, and STN 50–530, Palo Verde Nuclear Generating Station, Units 1, 2, and 3, Maricopa County, Arizona

Date of amendment requests: June 8, 1999.

Brief description of amendments request: The proposed amendments would revise Technical Specification (TS) 3.7.15, ''Fuel Storage Pool Boron Concentration,'' TS 3.7.17, ''Spent Fuel Assembly Storage,'' and TS 4.3.1, ''Criticality,'' to increase spent fuel pool storage capacity by crediting soluble boron and decay time in the safety analysis for the spent fuel pool storage racks. The proposed amendments would also increase the maximum radially averaged fuel enrichment from 4.3 weight percent to 4.8 weight percent.

Date of publication of individual notice in **Federal Register**: September 20, 1999 (64 FR 50835)

Expiration date of individual notice: October 20, 1999.

Arizona Public Service Company, et al., Docket Nos. STN 50–528, STN 50–529, and STN 50–530, Palo Verde Nuclear Generating Station, Units 1, 2, and 3, Maricopa County, Arizona

Date of amendment requests: October 8, 1999.

Brief description of amendments request: The proposed amendment would revise Technical Specification (TS) Section 3.8.4, ''DC Sources—Operating,'' to waive, on a one-time basis, the requirement to perform Surveillance Requirement (SR) 3.8.4.8 for Unit 1 channels A, B, and C.

Date of publication of individual notice in **Federal Register**: October 19, 1999 (64 FR 56369).

Expiration date of individual notice: For comments on proposed no significant hazards consideration determination: November 2, 1999; for opportunity for hearing: November 18, 1999.

Southern California Edison Company, et al., Docket Nos. 50–361 and 50–362, San Onofre Nuclear Generating Station, Units 2 and 3, San Diego County, California

Date of amendment request: October 20, 1998 (PCN 485), as supplemented August 13, 1999.

Brief description of amendment request: The proposed amendments would revise the San Onofre Nuclear Generating Station Units 2 and 3 technical specifications Surveillance Requirement 3.3.9 to include a response time testing requirement for the control room isolation signal.

Date of publication of individual notice in **Federal Register**: October 12, 1999 (64 FR 55311.

Expiration date of individual notice: November 12, 1999.

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 51.12(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, the Gelman Building, 2120 L Street, NW., Washington, DC, and electronically from the ADAMS Public Library component on the NRC Web site, *http://www.nrc.gov* (the Electronic Reading Room).

Carolina Power & Light Company, et al., Docket Nos. 50–325 and 50–324, Brunswick Steam Electric Plant, Units 1 and 2, Brunswick County, North Carolina

Date of amendment request: October 27, 1998.

Brief description of amendment: The amendments update the Operating Licenses for the Brunswick Steam Electric Plant, Units 1 and 2.

Date of issuance: October 5, 1999.

Effective date: October 5, 1999.

Amendment No.: 206 and 236.

Facility Operating License Nos. DPR–71 and DPR–62: Amendment revises the Operating Licenses.

Date of initial notice in **Federal Register***:* December 30, 1998 (63 FR 71964).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 5, 1999.

No significant hazards consideration comments received: No.

Carolina Power & Light Company, et al., Docket No. 50–400, Shearon Harris Nuclear Power Plant, Unit 1, Wake and Chatham Counties, North Carolina

Date of application for amendment: June 2, 1999, as supplemented on September 1, 1999.

Brief description of amendment: This amendment relocates Technical Specification (TS) Section 6.5, ''REVIEW AND AUDIT,'' TS 6.8.2, TS 6.8.3, and TS Section 6.10, ''RECORD RETENTION,'' intact from the Harris Nuclear Plant (HNP) TS to the Quality Assurance Program Description (QAPD) currently located in HNP Final Safety Analysis Report Section 17.3. Future changes to the associated relocated TS will be processed in accordance with 10 CFR 50.54(a). The change is consistent with NUREG–1431, Revision 1, ''Standard Technical Specifications, Westinghouse Plants,'' dated April 1995, and with the guidance provided in NRC Administrative Letter 95–06, ''Relocation of Technical Specification Administrative Controls related To Quality Assurance,'' dated December 12, 1995.

Date of issuance: October 19, 1999.

Effective date: October 19, 1999.

Amendment No.: 92.

Facility Operating License No. NPF–63. Amendment revises the Technical Specifications.

Date of initial notice in **Federal Register***:* June 30, 1999 (64 FR 35201).

The September 1, 1999, submittal contained clarifying information only, and did not change the initial no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 19, 1999.

No significant hazards consideration comments received: No.

Commonwealth Edison Company, Docket Nos. STN 50–454 and STN 50–455, Byron Station, Unit Nos. 1 and 2, Ogle County, Illinois; Docket Nos. STN 50–456 and STN 50–457, Braidwood Station, Unit Nos. 1 and 2, Will County, Illinois

Date of application for amendments: June 30, 1999.

Brief description of amendments: The amendments revised the requirements related to the cross-tie of DC power buses between units, remove references to the AT&T batteries which have been replaced at Braidwood Station, and remove references to the 10-day allowed outage time (AOT) required for replacement of the AT&T batteries at Braidwood, Unit 2, which was granted in Amendment Nos. 99 and 99 issued to Braidwood Station, Unit Nos. 1 and 2, on March 26, 1999.

Date of issuance: October 13, 1999.

Effective date: Immediately, to be implemented within 30 days.

Amendment Nos.: 111 and 104.

Facility Operating License Nos. NPF–37, NPF–66, NPF–72 and NPF–77: The amendments revised the Technical Specifications.

Date of initial notice in **Federal Register***:* August 11, 1999 (64 FR 43767).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 13, 1999.

No significant hazards consideration comments received: No.

Commonwealth Edison Company, Docket Nos. 50–373 and 50–374, LaSalle County Station, Units 1 and 2, LaSalle County, Illinois

Date of application for amendments: November 9, 1998, and July 7, 1999.

Brief description of amendments: The amendments revised Technical Specification Table 3.3.3–2, ''Emergency Core Cooling System Actuation Instrumentation Setpoints,'' to modify the degraded voltage second level undervoltage relay setpoint and allowable value.

Date of issuance: October 15, 1999.

Effective date: Immediately, to be implemented prior to startup from L1R08 for Unit 1 and prior to startup from L2R08 for Unit 2.

Amendment Nos.: 135 and 120.

Facility Operating License Nos. NPF–11 and NPF–18: The amendments revised the Technical Specifications.

Date of initial notice in **Federal Register***:* January 13, 1999 (64 FR 2245) and August 11, 1999 (64 FR 43769).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 15, 1999.

No significant hazards consideration comments received: No.

Commonwealth Edison Company, Docket Nos. 50–373 and 50–374, LaSalle County Station, Units 1 and 2, LaSalle County, Illinois

Date of application for amendments: August 13, 1999, as supplemented on August 27, 1999.

Brief description of amendments: The amendments revise Technical Specification (TS) Section 1.0, ''Definitions,'' Item 1.7, ''Core Alteration,'' to specify that instrumentation and control rod movements are not considered core alterations if there are no fuel assemblies in the associated cell. The amendments also revise TS Sections 3/4.1, 3/4.3, and 3/4.9 to reflect the change in definition. In addition, a license condition is added as follows: ''The licensee is prohibited from moving any fuel assemblies within the reactor pressure vessel unless all control rods except one are fully inserted during refueling in Mode 5''.

Date of issuance: October 18, 1999.

Effective date: Immediately, to be implemented within 30 days.

Amendment Nos.: 136 and 121.

Facility Operating License Nos. NPF–11 and NPF–18: The amendments revised the Operating Licenses and Technical Specifications.

Date of initial notice in **Federal Register***:* September 8, 1999 (64 FR 48860).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 18, 1999.

No significant hazards consideration comments received: No.

Connecticut Yankee Atomic Power Company, Docket No. 50–213, Haddam Neck Plant, Middlesex County, Connecticut

Date of application of amendment: June 3, 1999, and as supplemented by letter dated August 24, 1999 .

Brief description of amendment: The amendment revises the Operating License to clarify that the license is not terminated until the Commission notifies the licensee in writing, and relocates certain Technical Specification (TS) requirements to licensee-controlled documents. The administrative controls section of the TSs have been revised to more closely conform to the standardized TSs. Administrative controls have been added for the control of radioactive effluents. A TS Bases Control Program has been added. The weight limit for loads carried over the spent fuel pool (SFP) has been increased. The amendment deletes certain TSs that are either (1) no longer applicable to the permanently shutdown and defueled state of the reactor, or (2) which duplicate regulatory requirements, or (3) which duplicate information located in the Updated Final Safety Analysis Report. A number of editorial changes were made to clarify the language used, to correct typographical errors, to renumber the listings, to remove section numbers that no longer contain requirements, and to renumber the pages in the TSs.

Date of issuance: October 19, 1999.

Effective date: As of the date of issuance and shall be implemented within 60 days of issuance.

Amendment No.: 195.

Facility Operating License No. DPR–61: The amendment revised the Operating License and the Technical Specifications.

Date of original notice in **Federal Register:** July 14, 1999 (64 FR 38024).

The August 24, 1999, supplement contained clarifications of the June 3, 1999 amendment request. The supplemental information did not change the staff's initial proposed no significant hazards consideration determination nor expand the scope of the original notice. The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 19, 1999.

No significant hazards consideration received: No.

Detroit Edison Company, Docket No. 50–341, Fermi 2, Monroe County, Michigan

Date of amendment request: September 24, 1999.

Description of amendment request: The amendment revises current Technical Specification (TS) 3.6.1.8 by adding footnote ''**'' to Action b. The footnote allows continued operation of Fermi 2 with the leakage of penetration X–26 exceeding the limit in TS 4.6.1.8.2, provided certain compensatory measures are taken. Operation is allowed to continue until the next plant shutdown.

Because the NRC staff issued the Fermi 2 improved standard TSs (ITS) on September 30, 1999, with implementation within 90 days, this amendment also provides pages that are compatible with the ITS. The amendment adds a new special operations TS, ITS 3.10.8, to address the compensatory actions and other requirements associated with penetration X–26.

Date of issuance: October 19, 1999.

Effective date: October 19, 1999, and shall be implemented within 5 days.

Amendment No.: 135.

Facility Operating License No. NPF–43: Amendment revises the Technical Specifications.

Public comments requested as to proposed no significant hazards consideration (NSHC): Yes (64 FR 53421, dated October 1, 1999). The notice provided an opportunity to submit comments on the Commission's proposed NSHC determination. No comments have been received. The notice also provided for an opportunity to request a hearing by November 1, 1999, but indicated that if the Commission makes a final NSHC determination, any such hearing would take place after issuance of the amendment.

The Commission's related evaluation of the amendment, finding of exigent circumstances, and final NSHC determination are contained in a Safety Evaluation dated October 19, 1999.

Attorney for licensee: John Flynn, Esq., Detroit Edison Company, 2000 Second Avenue, Detroit, Michigan 48226.

NRC Section Chief: Claudia M. Craig.

Entergy Operations, Inc., System Energy Resources, Inc., South Mississippi Electric Power Association, and Entergy Mississippi, Inc., Docket No. 50–416, Grand Gulf Nuclear Station, Unit 1, Claiborne County, Mississippi

Date of application for amendment: June 23, 1999, as supplemented by letters dated August 6, September 8, and October 4, 1999.

Brief description of amendment: The amendment revises Technical Specification requirements for handling irradiated fuel in the Containment Building and in the Auxiliary Building, and selected specifications associated with performing core alterations.

Date of issuance: October 20, 1999.

Effective date: As of the date of issuance and shall be implemented within 30 days of issuance.

Amendment No: 139.

Facility Operating License No. NPF–29: The amendment revises the Technical Specifications and Operating License.

Date of initial notice in **Federal Register***:* August 25, 1999 (64 FR 46435).

The August 6, September 8, and October 4, 1999, submittals provided additional clarifying information and did not change the initial proposed no significant hazards consideration determination and did not expand the scope of the original application.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 20, 1999.

No significant hazards consideration comments received: No.

Florida Power and Light Company, Docket Nos. 50–250 and 50–251, Turkey Point Plant, Units 3 and 4, Dade County, Florida

Date of application for amendments: March 8, 1999.

Brief description of amendments: The amendments revised the Technical Specifications (TS), Section 6.0, Administrative Controls, by removing requirements that are adequately controlled by existing regulations other than 10 CFR 50.36 and the TS. The amendments also relocate selected requirements from TS 6.0 to licensee-controlled documents or programs (e.g., the final safety analysis report or the quality assurance plan). Guidance on the changes was developed by the NRC and provided in the Standard Technical Specifications for Pressurized Water Reactor Plants, NUREG–1431, and Administrative Letter 95–06, ''Relocation of Technical Specification

Administrative Controls Related to Quality Assurance,'' issued on December 12, 1995.

Date of issuance: October 6, 1999.

Effective date: As of date of issue, to be implemented within 90 days of issuance.

Amendment Nos.: 201 and 195.

Facility Operating License Nos. DPR–31 and DPR–41: Amendments revised the TS.

Date of initial notice in **Federal Register**: April 7, 1999 (64 FR 17025).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 6, 1999.

No significant hazards consideration comments received: No.

IES Utilities Inc., Docket No. 50–331, Duane Arnold Energy Center, Linn County, Iowa

Date of application for amendment: May 10, 1999, as supplemented July 16 and October 4, 1999.

Brief description of amendment: The amendment revised Duane Arnold Energy Center (DAEC) Technical Specification (TS) 2.1.1.2 to revise the Safety Limit Minimum Critical Power Ratio (SLMCPR) to support operation with GE–12 fuel with a 10x10 pin array.

Date of issuance: October 20, 1999.

Effective date: Immediately, to be implemented within 30 days

Amendment No.: 229.

Facility Operating License No. DPR–49: The amendment revised the Technical Specifications.

Date of initial notice in **Federal Register**: July 14, 1999 (64 FR 38029).

The July 16 and October 4, 1999, letters provided additional clarifying information within the scope of the original **Federal Register** notice and did not affect the NRC staff's initial proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 20, 1999.

No significant hazards consideration comments received: No.

Indiana Michigan Power Company, Docket Nos. 50–315 and 50–316, Donald C. Cook Nuclear Plant, Units 1 and 2, Berrien County, Michigan

Date of application for amendments: September 14, 1998.

Brief description of amendments: The amendments revise Technical Specification page 3/4 5–6, ''Limiting Conditions for Operation and Surveillance Requirements—Emergency Core Cooling Systems (ECCS),'' and its associated Bases to change pump runout limits for a safety injection pump to 675 gallons per minute (gpm) unless the pump is specifically tested to a higher flow rate not to exceed 700 gpm for Units 1 and 2.

Date of issuance: October 21, 1999.

Effective date: October 21, 1999, with full implementation within 45 days.

Amendment Nos.: 229 and 212.

Facility Operating License Nos. DPR–58 and DPR–74: Amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** August 31, 1999 (64 FR 47533).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 21, 1999.

No significant hazards consideration comments received: No.

Indiana Michigan Power Company, Docket Nos. 50–315 and 50–316, Donald C. Cook Nuclear Plant, Units 1 and 2, Berrien County, Michigan

Date of application for amendments: May 21, 1999.

Brief description of amendments: The amendments change the Technical Specifications (TS) to allow reactor coolant system temperature changes in certain Mode 5 and 6 action statements if the shutdown margin is sufficient to accommodate the expected temperature change. In addition, footnotes regarding additions of water from the refueling water storage tank to the reactor coolant system are clarified and relocated to action statements. Additional actions are added in Table 3.3–1, ''Reactor Trip System Instrumentation,'' when the required source range neutron flux channel is inoperable. Corresponding changes are proposed for the Bases for TS 3/4.1.1, ''Boration Control,'' and TS 3/4.1.2, ''Boration Systems.'' Administrative changes are proposed to improve clarity. Finally, additions are made to shutdown margin TS surveillance requirements to address use of a boron penalty (requirement for additional boron) during residual heat removal system operation in Modes 4 and 5.

Date of issuance: October 21, 1999.

Effective date: As of the date of issuance and shall be implemented within 45 days.

Amendment Nos.: 230 and 213.

Facility Operating License Nos. DPR–58 and DPR–74: Amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** July 12, 1999 (64 FR 37574).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 21, 1999.

No significant hazards consideration comments received: No.

Northern States Power Company, Docket No. 50–263, Monticello Nuclear Generating Plant, Wright County, Minnesota

Date of application for amendment: December 31, 1998, as supplemented May 17, 1999.

Brief description of amendment: The amendment revises the technical specification reactor pressure vessel (RPV) pressure-temperature limit curves, deletes completed RPV sample surveillance requirements, deletes the requirement to withdraw a specimen at the next refueling outage, removes the standby liquid control system relief valve setpoint, and makes associated administrative changes.

Date of issuance: October 12, 1999.

Effective date: October 12, 1999, with full implementation within 45 days.

Amendment No.: 106.

Facility Operating License No. DPR–22. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** February 10, 1999 (64 FR 6706). The May 17, 1999, submittal added clarifying information that was within the scope of the original **Federal Register** notice and did not change the staff's initial proposed no significant hazards considerations determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 12, 1999.

No significant hazards consideration comments received: No.

Power Authority of The State of New York, Docket No. 50–286, Indian Point Nuclear Generating Unit No. 3, Westchester County, New York

Date of application for amendment: April 9, 1999.

Brief description of amendment: The amendment changes the Technical Specifications by increasing the allowable outage time for any one safety injection pump.

Date of issuance: October 12, 1999.

Effective date: As of the date of issuance to be implemented within 30 days.

Amendment No.: 196.

Facility Operating License No. DPR–64: Amendment revises the Technical Specifications.

Date of initial notice in ***Federal Register***: June 2, 1999 (64 FR 297147).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 12, 1999.

No significant hazards consideration comments received: No.

Power Authority of The State of New York, Docket No. 50–286, Indian Point Nuclear Generating Unit No. 3, Westchester County, New York

Date of application for amendment: January 29, 1999, as supplemented August 2, 1999.

Brief description of amendment: The amendment changes the Technical Specifications by increasing the allowable control rod misalignment when operating at or below 85% power.

Date of issuance: October 14, 1999.

Effective date: As of the date of issuance to be implemented within 30 days.

Amendment No.: 197.

Facility Operating License No. DPR–64: Amendment revises the Technical Specifications.

Date of initial notice in ***Federal Register****:* April 21, 1999 (64 FR 19564).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 14, 1999.

No significant hazards consideration comments received: No.

South Carolina Electric & Gas Company, South Carolina Public Service Authority, Docket No. 50–395, Virgil C. Summer Nuclear Station, Unit No. 1, Fairfield County, South Carolina

Date of application for amendment: August 19, 1999, as supplemented by letter dated October 8, 1999.

Brief description of amendment: The amendment revises the TS to incorporate the new Pressure/Temperature Limits Curves consistent with the analysis results of reactor specimen W.

Date of issuance: October 21, 1999.

Effective date: October 21, 1999.

Amendment No.: 143.

Facility Operating License No. NPF–12: Amendment revises the Technical Specifications.

Date of initial notice in ***Federal Register****:* September 8, 1999 (64 FR 48865). The October 8, 1999, submittal contained clarifying information only, and did not change the initial no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 21, 1999.

No significant hazards consideration comments received: No.

Tennessee Valley Authority, Docket Nos. 50–327 and 50–328, Sequoyah Nuclear Plant, Units 1 and 2, Hamilton County, Tennessee

Date of application for amendments: March 2, 1999 (TS 98–05).

Brief description of amendments: The amendments delete the Sequoyah Nuclear Plant. License Conditions that require an Independent Safety Engineering Group.

Date of issuance: October 12, 1999.

Effective date: As of the date of issuance to be implemented no later than 45 days after issuance.

Amendment Nos.: 248 and 239.

Facility Operating License Nos. DPR–77 and DPR–79: Amendments revise the License.

Date of initial notice in **Federal Register***:* May 5, 1999 (64 FR 24201).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 12, 1999.

No significant hazards consideration comments received: No.

Vermont Yankee Nuclear Power Corporation, Docket No. 50–271, Vermont Yankee Nuclear Power Station, Vernon, Vermont

Date of application for amendment: August 18, 1999.

Brief description of amendment: The amendment revises the definition of ''Surveillance Frequency'' to incorporate provisions that apply upon the discovery of a missed Technical Specification surveillance. This change allows a delay in performing the actions of the associated limiting conditions for operation for up to 24 hours or up to the limit of the specified frequency, whichever is less, when it is discovered that a surveillance was not performed within its specified frequency.

Date of Issuance: October 13, 1999.

Effective date: October 13, 1999, and shall be implemented within 30 days.

Amendment No.: 179.

Facility Operating License No. DPR–28. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register***:* September 9, 1999 (64 FR 48867).

The Commission's related evaluation of this amendment is contained in a Safety Evaluation dated October 13, 1999.

No significant hazards consideration comments received: No.

Wolf Creek Nuclear Operating Corporation, Docket No. 50–482, Wolf Creek Generating Station, Coffey County, Kansas

Date of amendment request: July 8, 1999, as supplemented by letter dated September 2, 1999.

Brief description of amendment: The amendment increased the allowable values for engineered safety features actuation system (ESFAS) loss-of-power 4 kV undervoltage trips in the current Technical Specifications (TSs) Table 3.3–4 (functional units 8.a and 8.b) and in surveillance requirement (SR) 3.3.5.3 of the improved TSs. The word ''nominal'' is also added to describe the trip setpoint in SR 3.3.5.3 and in the Bases of the improved TSs. The improved TSs were issued in Amendment 123 dated March 31, 1999, but have not yet been implemented.

Date of issuance: October 12, 1999.

Effective date: October 12, 1999, to be implemented within 60 days from the date of issuance.

Amendment No.: 128.

Facility Operating License No. NPF–42. The amendment revised the Technical Specifications.

Date of initial notice in **Federal Register***:* August 11, 1999 (64 FR 43782).

The September 2, 1999, supplemental letter provided additional clarifying information, did not expand the scope of the application as originally noticed, and did not change the staff's initial no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 12, 1999.

No significant hazards consideration comments received: No.

Yankee Atomic Electric Co., Docket No. 50–29, Yankee Nuclear Power Station (YNPS) Franklin County, Massachusetts

Date of application for amendment: March 17, 1999

Brief description of amendment: Revises the Possession Only License by deleting technical specifications related to hours of work and putting these requirements in appropriate Administrative Procedures.

Date of issuance: October 8, 1999.

Effective date: October 8, 1999, Implementation of this amendment includes incorporation of hours of work restrictions into the Administrative Procedures as described in the licensee's application dated March 17, 1999, and evaluated in the staff's safety evaluation attached to the amendment, and written notification to NRC that the amendment has been fully implemented.

Amendment No.: 153.

Facility Operating License No. DPR–3. Amendment revises the Technical Specifications.

Date of initial notice in **Federal Register***:* April 7, 1999 (64 FR 17032).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 8, 1999.

No significant hazards consideration comments received: No.

Dated at Rockville, Maryland, this 27th day of October 1999.

For the Nuclear Regulatory Commission.

Suzanne C. Black,

Deputy Director, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 99–28598 Filed 11–2–99; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–220 and 50–410]

Niagara Mohawk Power Corporation Nine Mile Point Nuclear Station, unit Nos. 1 and 2 Issuance of Final Director's Decision Under 10 CFR 2.206

Notice is hereby given that the Director, Office of Nuclear Reactor Regulation, has taken action with regard to a letter dated April 5, 1999, (Petition) filed by Robert Norway (Petitioner) pursuant to § 2.206 of Title 10 of the Code of Federal Regulations (10 CFR 2.206). The Petitioner requested that the U.S. Nuclear Regulatory Commission (Commission or NRC) take action with regard to Niagara Mohawk Power Corporation (NMPC) and its senior nuclear and corporate management. The Petitioner requested that the Commission (1) take enforcement action against NMPC and its senior nuclear and corporate management and, as a minimum, against three named individuals, for submitting an altered 1994 employee record to the NRC at a predecisional enforcement conference on May 10, 1996; (2) take enforcement action against these same parties for presenting at this predecisional enforcement conference a false written record of what the Administrative Law Judge determined in the Department of Labor's proceeding in 95–ERA–005; (3) take enforcement action against these same parties for placing confidential employee information into the public record in violation of 10 CFR 2.790; and (4) take enforcement action against these same parties for an additional act of discrimination, pursuant to 10 CFR 50.7, for destroying the Petitioner's credibility and reputation in the nuclear industry. The Petitioner also requested that the NRC forward these issues to the Department of Justice for consideration of criminal prosecution.

In addition to these requests for enforcement actions, the Petitioner also requested that the following other actions be implemented: (1) That the agency perform an independent review of all of NMPC's docketed files associated with the individuals who committed the alleged fraud; (2) that the NRC forward the complaint to the NRC's Office of the Inspector General for an investigation of possible deliberate misconduct on the part of the NRC staff; (3) that an independent oversight group be established to oversee the NMPC Human Resources Department and Employee Concerns Program; (4) that a public meeting be held to obtain public comments pertaining to a number of issues, including discrimination and the placement of fraudulent documentation into public records; and (5) that the NRC publicly post NMPC's Safety Evaluation 96–09, which addresses the Residual Heat Removal Alternate Shutdown Cooling for Unit 2, to make it available for public comment, or require NMPC to re-perform this safety evaluation.

The Director of the Office of Nuclear Reactor Regulation has complied with the Petitioner's request to have his complaint forwarded to the NRC's Office of the Inspector General. The Petitioner's technical concern has been addressed independent of the Director's Decision by the NRC staff's letter to the Petitioner dated October 6, 1999. The Petitioner's additional requests are not supported for the reasons that are explained in the ''Final Director's Decision Pursuant to 10 CFR 2.206'' (DD–99–13). The complete text of the Final Director's Decision follows this notice and is available for public inspection at the Commission's Public Document Rooms located in the Gelman Building, 2120 L Street, NW., Washington, DC, and in the Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

A copy of the Decision will be filed with the Secretary of the Commission for the Commission's review in accordance with 10 CFR 2.206(c) of the Commission's regulations. As provided for by this regulation, the Decision will constitute the final action of the Commission 25 days after the date of issuance of the Decision unless the Commission, on its own motion, institutes a review of the Decision within that time.

Dated at Rockville, Maryland, this 28th day of October 1999.

For the Nuclear Regulatory Commission.

Samuel J. Collins,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. 99–28759 Filed 11–2–99; 8:15 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Notice of Availability of Draft Revision To NUREG–1574; Standard Review Plan for Antitrust Reviews

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability: Draft Revision 1 to Nureg 1574, ''Standard Review Plan (SRP) for Antitrust Reviews''.

SUMMARY: The NRC is seeking public comment on a Draft Revision to NUREG–1574, ''Standard Review Plan on Antitrust Reviews.'' The Standard Review Plan (SRP) is being revised in accordance with Commission guidance to remove any implication that the NRC would conduct antitrust reviews of license transfers after issuance of an operating license. The draft revised SRP is being published to obtain public comments which will be considered in evaluating whether the NRC review process in this area should be changed. The revised draft SRP will be available on NRC electronic bulletin boards and in the NRC's Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC 20555–001. A free single copy of Draft Revision 1 to NUREG–1574, to the extent of supply, may be requested by writing to U.S. Nuclear Regulatory Commission, Records Management Branch, Washington, DC 20555–0001.

DATES: The public is invited to submit comments on the revised draft SRP by January 3, 2000. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date. On the basis of the submitted comments, the Commission will determine whether to modify the revised draft SRP before issuing it in final form.

ADDRESSES: Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

Deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m., Federal workdays.

SUPPLEMENTARY INFORMATION: The Draft Revision to NUREG–1574, ''Standard Review Plan on Antitrust Reviews,'' describes the procedures used by the NRC staff to implement the antitrust review and enforcement prescribed in Sections 105 and 186 of the Atomic Energy Act of 1954, as amended, and will replace the final NUREG–1574 published in December 1997. These

procedures are principally covered by the Commission's Rules and Regulations in 10 CFR 2.101, 2.102, 2.2, 50.33a, 52.77, 50.80, and 50.90. These procedures set forth the steps and criteria the staff applies in the antitrust review of construction permit/initial operating license applications. In addition, the procedures describe how the staff enforces compliance by licensees with antitrust license conditions.

FOR FURTHER INFORMATION CONTACT: Mr. Michael J. Davis, Generic Issues, Environmental, Financial, and Rulemaking Branch, Division of Regulatory Improvement Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Mr. Davis can be contacted at (301) 415–1016, via E-mail at *mjd1@nrc.gov*, or by writing to: Michael J. Davis, U.S. Nuclear Regulatory Commission, MS O–11F1, Washington, DC 20555.

Dated at Rockville, Maryland, this 18th day of October 1999.

For the Nuclear Regulatory Commission.

David B. Matthews,

Director, Division of Regulatory Improvement Programs, Office of Nuclear Reactor Regulation.

[FR Doc. 99–28760 Filed 11–2–99; 8:15 am]

BILLING CODE 7590–01–P

PANAMA CANAL COMMISSION

Canal Zone Postal Money Orders and Savings Certificates

AGENCY: Panama Canal Commission.

ACTION: Notice.

SUMMARY: The Panama Canal Commission (Commission) hereby provides notice the Commission and the U.S. Government will no longer be responsible for the distribution of any accumulated unpaid balances relating to Canal Zone postal-savings deposits, postal-savings certificates, and postal money orders.

DATES: This action shall become effective December 1, 1999.

FOR FURTHER INFORMATION CONTACT: Eva Chen, Manager, Accounting Division, Department of Financial Management, Telephone 011–507–272–4727, Facsimile 011–507–272–3849.

SUPPLEMENTARY INFORMATION: When the Panama Canal Commission was created in 1979 by Public Law 96–70, approved September 27, 1979, Section 1331 of that law transferred the responsibility for the management of the Postal Savings deposits, certificates and money orders to the Commission. Public Law 140–201, approved September 23, 1996, released the Commission from liability for unpaid balances due on postal-savings deposits and certificates and postal money orders effective December 1, 1999.

(Authority: 22 U.S.C. 3741)

Therefore, under the authority of 22 U.S.C. 3741, the Panama Canal Commission hereby gives notice after December 1, 1999, it will no longer be liable for any unpaid balances due on postal-savings deposits and certificates and postal money orders presented for payment.

Dated: October 13, 1999.

John L. Haines, Jr.,

General Counsel, Panama Canal Commission.

[FR Doc. 99–28785 Filed 11–2–99; 8:45 am]

BILLING CODE 3640–01–P

SECURITIES AND EXCHANGE COMMISSION

Issuer Delisting; Notice of Application To Withdraw From Listing and Registration; (Advantage Marketing Systems, Inc., Common Stock, $.0001 Par Value per Share) File No. 1–13343

October 28, 1999.

Advantage Marketing Systems, Inc. (''Company'') has filed an application with the Securities and Exchange Commission (''Commission''), pursuant to Section 12(d) of the Securities Exchange Act of 1934 (''Act'') and Rule 12d2–2(d) promulgated thereunder, to withdraw the above specified security (''Security'') from listing and registration on the Boston Stock Exchange, Incorporated (''BSE'' or ''Exchange'').

The Security of the Company has been listed for trading on the BSE and, pursuant to a Registration Statement on Form 8–A filed with the Commission which became effective on June 9, 1999, on the American Stock Exchange LLC (''Amex''). Trading in the Company's Security on the Amex commenced at the opening of business on June 15, 1999.

In making its decision to withdraw its Security from listing and registration on the BSE, the Company considered the direct and indirect costs arising from maintaining the listing of such Security on the BSE and Amex simultaneously. Moreover, the Company does not see any particular advantage in having its Security trade in two markets and seeks to avoid fragmenting the market for its Security.

The Company has complied with the rules of the BSE by filing with the Exchange a certified copy of the preambles and resolutions adopted by the Company's Board of Directors authorizing the withdrawal of its Security from listing on the BSE and by setting forth in detail to the Exchange the reasons for the proposed withdrawal and the facts to support thereof.

The BSE has informed the Company that it has no objection to the withdrawal of the Company's Security from listing on the Exchange.

The Company's application relates solely to the withdrawal of the Securities from listing and registration on the BSE and shall have no effect upon their continued listing and registration on the Amex. By reason of Section 12(b) of the Act and the rules and regulations of the Commission thereunder, the Company shall continue to be obligated to file with the Commission and the Amex any reports required under Section 13 of the Act.

Any interested person may, on or before November 18, 1999, submit by letter to the Secretary of the Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549–0609, facts bearing upon whether the application has been made in accordance with the rules of the BSE and what terms, if any, should be imposed by the Commission for the protection of investors. The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 99–28756 Filed 11–2–99; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

Issuer Delisting; Notice of Application To Withdraw From Listing and Registration; (IKON Office Solutions, Inc., Common Stock, No Par Valance, and Associated Preferred Share Purchase Rights) File No. 1–5964

October 28, 1999

IKON Office Solutions, Inc. (''Company'') has filed and application with the Securities and Exchange Commission (''Commission''), pursuant to Section 12(d) of the Securities Exchange Act of 1934 (''Act'') and Rule 12d–2(d) promulgated thereunder, to withdraw the above specified securities (''Securities'') from listing and registration on the Chicago Stock Exchange, Incorporated (''CHX'') and

the Philadelphia Stock Exchange, Inc. (''Phlx'') (the CHX and the Phlx shall be referred to herein collectively as the ''Exchanges'').

The reasons cited in the application for withdrawing the Securities from listing and registration on the Exchanges include the following:

The Securities of the Company have been listed for trading on the CHX, the Phlx and the New York Stock Exchange, Inc. (''NYSE''). The Board of Directors of the Company has authorized the withdrawal of the Securities from the CHX and the Phlx in order to eliminate the costs associated with such listings. Moreover, the Company does not see any particular advantage in having its Securities trade on multiple exchanges.

The Company has complied with the Exchanges' rules by filing with each certified copies of the resolutions adopted by the Company's Board of Directors authorizing the withdrawal of its Securities from listing on the Exchanges and by setting forth in detail to the each Exchange the reasons for the proposed withdrawal and the facts in support thereof.

The CHX and the Phlx have each informed the Company that they have not objections to the Company's withdrawal of its Securities from listing on the respective Exchanges.

The Company's application relates solely to the withdrawal of its Securities from listing on the CHX and the Phlx and shall have no effect upon the continued listing of the Securities on the NYSE. By reason of Section 12(b) of the Act and the rules and regulations of the Commission thereunder, the Company shall continue to be obligated to file reports with the Commission and with the NYSE under Section 13 of the Act.

Any interested person may, on or before November 18, 1999, submit by letter to the Secretary of the Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549–0609, facts bearing upon whether the application has been made in accordance with the rules of the Exchange and what terms, it any, should be imposed by the Commission for the protection of investors. The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 99–28755 Filed 11–2–99; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–42061; File No. SR–NASD–99–08]

Self-Regulatory Organizations; Order Approving a Proposed Rule Change by the National Association of Securities Dealers, Inc. Relating to the Arbitration Process for Claims of Employment Discrimination

October 27, 1999.

On February 1, 1999, the National Association of Securities Dealers, Inc. (''NASD'') or ''Association''), through its wholly-owned subsidiary, NASD Regulation, Inc. (''NASD Regulation''), filed with the Securities and Exchange Commission (''SEC'' or ''Commission''), a proposed rule change pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder.[2] Under its proposal, NASD Regulation has created rules for the resolution of statutory employment discrimination claims. The proposed rule change and Amendment No. 1 [3] to the proposed were published for comment in the **Federal Register** on June 4, 1999.[4] The Commission received four comment letters on the proposal.[5] This order approves the proposed rule change, as amended.

I. Description of the Proposed

NASD Regulation proposes to amend NASD Rules 10201 and 10202, and to add new Rule 3080 and new Rule 10210 Series. The proposed rule change is intended to enhance the dispute resolution process for the handling of employment discrimination claims, and to expand disclosure to employees concerning the arbitration of all disputes.

A. Background

In August 1997, the Board of NASD Regulation and the Board of the NASD (''NASD Boards'') submitted a proposal that removed from the NASD Code of Arbitration Procedure provisions requiring registered persons to arbitrate claims of statutory employment discrimination. That rule change was approved by the Commission, and became effective January 1, 1999.[6] In conjunction with this rule change, the NASD Boards recommended certain enhancements to the voluntary arbitration process for employment discrimination claims. To carry out the Boards' mandate, NASD Regulation staff assembled a working group, including attorneys representing employees, general counsels of member firms, and arbitrators with expertise in employment matters to advise on issues relating to the arbitration of employment discrimination claims.

In addition to several issues that were presented to them by NASD Regulation staff, the working group considered recommendations contained in a document known as ''A Due Process Protocol for Mediation and Arbitration of Statutory Disputes Arising Out of the Employment Relationship'' (''the Protocol''). The Protocol has been adopted by several dispute resolution forums, and the NASD Boards recommended that due process procedures similar to those in the Protocol be considered by the working group for use in the dispute resolution process at the NASD for claims of employment discrimination.

B. Description of Proposed Amendments.

The Proposed Rule 10210 Series contains special rules applicable to statutory employment discrimination claims. These rules supplement and, in some instances, supersede the provisions of the NASD Code that currently apply to the arbitration of employment disputes.

(1) Qualifications for Arbitrators Who Hear Employment Discrimination Cases

In accordance with the Protocol provisions, NASD Regulation proposes

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Letter from Alden S. Adkins, Senior Vice President and General Counsel, NASD Regulation, to Katherine A. England, Assistant Director, Division of Market Regulation (''Division''), Commission, dated May 10, 1999 (''Amendment No. 1''). Amendment No. 1 made substantive changes to the proposed rule language, including the provisions for arbitrator qualifications and coordination of claims filed in court and arbitration.

[4] Securities Exchange Act Release No. 41461 (May 27, 1999), 64 FR 30081 (File No. SR–NASD–99–08.

[5] *See* Letters to Jonathan G. Katz, Secretary, Commission, from: Jeffery A. Norris, President, Equal Employment Advisory Council (''EEAC Letter''), date June 24, 1999; Stephen G. Sneeringer, Chairman of the Arbitration Committee, Securities Industry Association (''SIA Letter''), dated June 30, 1999; and Cliff Palefsky, National Employment Lawyers Association (''NELA Letter''), dated July 7, 1999, and letter from George A. Schieren, Senior Vice President and General Counsel, Merrill Lynch, Pierce, Fenner & Smith Inc. (''Merrill Lynch Letter''), to Margaret H. McFarland, Deputy Secretary, Commission, dated June 30, 1999.

[6] *See* Securities Exchange Act Release No. 40109 (June 22, 1998), 63 FR 35299 (June 29, 1998).

the use of a specialized roster of available arbitrators for intra-industry cases in which statutory discrimination is alleged. Proposed Rule 10211(a) provides that public (non-industry) arbitrators will be selected to consider disputes involving a claim of employment discrimination, including a sexual harassment claim, in violation of a statute. Proposed Rule 10211(a) incorporates by reference the definition of ''public arbitrator'' in the list selection rule, Rule 10308. The definition of ''public arbitrator'' in Rule 10308 excludes not only securities industry employees and their immediate family members, but also attorneys, accountants, and other professionals who have devoted 20% or more of their professional work in the preceding two years to clients who are engaged in the securities business. NASD Regulation believes that the use of the same definition of public arbitrators throughout the NASD Code provides for more efficient administration of the list selection system.

For chairpersons and single arbitrators, NASD Regulation proposes additional qualifications in Rule 10211(b)(1) that should assist NASD Regulation to identify specially qualified and impartial arbitrators to resolve these disputes. In addition, under Rule 10211(b)(2), a chairperson or single arbitrator may not have represented primarily the views of employees or employers within the past five years. For this purpose, NASD Regulation has defined ''primarily'' to mean 50% or more of the arbitrator's business or professional activities within the preceding five years. NASD Regulation states that it is important to the credibility to the forum for the single arbitrator or chairperson not only to be neutral, but to avoid even the appearance of bias toward either employees or employers.

Rule 10211(c) provides that parties may agree, after a dispute arises, to waive any of the special qualifications contained in either paragraphs (a) or (b) of proposed Rule 10211. Such a waiver is not valid if it is contained in a predispute arbitration agreement.

(2) Composition of Panels

NASD Regulation proposes that for each involving claims of employment discrimination, regardless of whether other issues are also involved, all arbitrators must be qualified as public arbitrators under Rule 10211.[7] In addition, proposed Rule 10212(b) provides a higher dollar threshold for single arbitrator cases than is found elsewhere in the Code: a single arbitrator will hear claims of $100,000 or less. NASD Regulation states that this higher threshold reduces the hearing costs for the parties and results in more efficient allocation of qualified employment arbitrators. Proposed Rule 10212(c) provides that claims for more than $100,000 will be assigned to a three-person panel, unless the parties agree to have their case determined by a single arbitrator.

(3) Discovery

NASD Regulation proposes that the provision on depositions in the Protocol should be the standard under its own rules. NASD Regulation proposes that, in considering the need for depositions, arbitrator(s) should consider the relevancy of the information sought from the persons to be deposed, and the issues of time and expenses. These considerations are already provided for in Rule 10321, paragraphs (d) and (e), which set forth procedures for deciding unresolved issues either at the pre-hearing conference or by appointment of a selected arbitrator. The proposed discovery provision relating to depositions is in proposed Rule 10213.

(4) Attorneys' Fees

Proposed Rule 10215 provides that the arbitrator(s) shall have the authority to award reasonable attorneys' fee reimbursement, in whole or in part, as part of the remedy in accordance with applicable law. NASD Regulation notes that this accords with Title VII of the Civil Rights Act of 1964, which authorizes a court, in its discretion, to allow the prevailing party ''a reasonable attorney's fee'' as part of the costs.[8] NASD Regulation states that the intent of proposed Rule 1021 is to allow the award of attorneys' fees if applicable law permits such an award.

(5) Awards

Proposed Rule 10214 provides that arbitrator(s) will be empowered to award any relief that would be available in court under applicable law, and sets forth the information that must be contained in the arbitrators' award. This information includes a summary of the issues, the damages or other relief requested and awarded, a statement of any other issues resolved, and a statement regarding the disposition of any statutory claims.

NASD Regulation has not used the Protocol's phrase ''opinion and award'' in Proposed Rule 10214, but instead has used the term ''award,'' which is also used elsewhere in the NASD Code. This avoids confusion that might result from use of the term ''opinion,'' which could mislead parties into expecting a judicial type of decision, including a detailed explanation, rather than the customary type of arbitration award that contains the specific elements listed in the proposed rule. Consistent with current NASD Regulations practice, however, parties may request that the arbitrator(s) provide reasons for their decision, and the arbitrator(s) have discretion to grant or deny the request.

(6) Coordination of Claims Filed in Court and in Arbitration

Several commenters on the rule change to allow statutory discrimination claims to be filed in court predicted that the change could lead to splitting or bifurcation of cases: the discrimination claims would proceed in court, while other arbitrable employment claims would proceed in arbitration.[9] Some commenters believed bifurcation of statutory and common law claims could impose a financial burden on employees and members, delay the resolution of claims, and cause scheduling and discovery disputes.[10]

NASD Regulation proposes a new rule to address coordination of claims. Proposed Rule 10216 provides that, if the parties agree to resolve all related matters in court, then the matter need not be submitted to arbitration. Moreover, if a discrimination claim is filed in court and related claims subject to mandatory arbitration are filed in arbitration, a respondent in the arbitration would have the option to move to combine all claims in court. As described more fully below, the rule provides several other opportunities for a party to move to compel that a claim be consolidated with other claims in court. Any claims not accepted by the court under any of these methods, however, would continue to be arbitrable.

If the respondent does not agree to consolidate all claims in court, and an arbitration claims is then filed, proposed Rule 10216 provides several methods for coordinating claims filed in court and in arbitration. Paragraph (a)(1)(A) of proposed Rule 10216 addresses the situation in which an

[7] Arbitrators must qualify under the relevant portion of Rule 10211: paragraph (a) for the second and third arbitrators on a three-arbitrator panel, and paragraph (b) for the chairperson or single arbitrator. *See* Letter from Jean I. Feeney, Assistant General Counsel, NASD Regulation, to Richard C. Strasser, Assistant Director, Division, Commission, dated August 20, 1999 (''NASD Regulation Letter'').

[8] 42 U.S.C. 2000e–5(k) (1998).

[9] *See* Securities Exchange Act Rel. No. 40109 (June 22, 1998), 63 FR 35299 (June 29, 1998).

[10] *Id.*

associated person files a statutory discrimination claim in court and files related claims in arbitration against some or all of the same parties. In that situation, any respondent who is named in both proceedings may move to compel the associated person to bring the related arbitration claims in the same court proceeding, to the full extent to which the court will accept jurisdiction over those claims. As noted above, any claims not accepted by the court would remain in arbitration.

Paragraph (a)(1)(B) of proposed Rule 10216 requires a respondent that wishes to exercise this option to notify the claimant in writing that it is exercising this option. This notice is intended to motivate parties to discuss their options and consider consolidating all claims in one forum before either party incurs further expenses.

Paragraph (a)(2)(A) of proposed Rule 10216 provides that if a party has a pending claim in arbitration against an associated person who thereafter assets a related statutory employment discrimination claim in court against the party, that party has the option to assert all arbitration claims and counterclaims in court. This is intended to cover the situation in which arbitration claims is filed before the statutory discrimination claim is filed in court. Paragraph (a)(2)(C) of proposed Rule 10216 provides that a party may not exercise this option after the first hearing has begun on the arbitration claim. This is intended to avoid disruption of the arbitration proceeding when it is farther along in the process.

Paragraph (b) of proposed Rule 10216 provides that the time for consolidating claims in court is extended if the claimant files an amended statement of claim adding new claims not asserted in the original statement of claim. In that situation, a respondent has an opportunity to move to compel the claimant to assert all related claims in the same court proceeding, even if those related claims were asserted in the original statement of claim.

Paragraph (c) of proposed Rule 10216 provides that if a party elects to require a current or former associated person to assert all related claims in court, the party also must assert in the same court proceeding all related claims the party has against the associated person, to the full extent to which the court will accept jurisdiction over the related claims.

Paragraph (d) of proposed Rule 10216 provides that a respondent named in both court and arbitration proceedings may choose to remain in arbitration, even if another respondent has exercised its option to consolidate the proceedings against it in court. Any remaining party may seek a stay of the arbitration proceeding, and the proceeding will be stayed unless the arbitration panel determines that the stay will result in substantial prejudice to one or more of the parties. The presumption in favor of a stay of the arbitration proceeding is designed to avoid the situation in which parties must proceed in two forums at the same time. Nevertheless, a party may object to the stay and have the matter considered by an arbitrator.

If no panel has been appointed yet, a single arbitrator will be appointed to consider the application for a stay, using the Neutral List Selection System to select the arbitrator. That arbitrator is not required to have the special employment arbitrator qualifications described in Rule 10211, since there would be no statutory employment discrimination claims in arbitration at this point. Instead, the single arbitrator would be appointed under the provisions of Rule 10202. Under that rule, the single arbitrator is either an industry arbitrator or a public arbitrator, depending on the claims involved.A single public arbitrator may later appear on a list of arbitrators to be chosen for any hearing on the merits in the same arbitration.

Paragraph (f) of proposed Rule 10216 clarifies that, if an associated person files a claim in court that includes matters that are subject to arbitration, either by the rules of the NASD or by private agreement, the defending party may move to compel arbitration of the claims that are subject to mandatory arbitration. This is a statement of current practice and is intended to apply where the defending party has not exercised an option under other provisions of proposed Rule 10216 to combine all claims in court.

(7) Disclosure Issues

NASD Regulation also proposes a model disclosure statement that would be given to persons who signing the Form U–4 to apply for registration. This disclosure statement would explain the nature and effect of the arbitration clause contained in the Form U–4. It would not address any private arbitration agreement that an applicant might enter into with a member firm. Rather, firms would be responsible for either making proper disclosure to their employees about their private arbitration agreement, or risk an adverse decision in later litigation concerning any inadequacy in the disclosure.

Proposed Rule 3080, entitled ''Disclosure to Associated Persons When Signing a Form U–4,'' was modeled on the disclosure given to customers when signing predispute arbitration agreements with member firms, as required by Rule 3110(f) and proposed amendments to that rule contained in File No. SR–NASD–98–74. The introductory language of the proposed rule requires members to provide each associated person, whenever the associated person is asked to sign a new or amended Form U–4, with specified disclosure language. The specified disclosure language explains that the Form U–4 contains a predispute arbitration clause, and indicates in which Item of the Form U–4 the clause is located.[11]

Subparagraph (1) of proposed Rule 3080 paraphrases the arbitration clause in the Form U–4 and discloses that an associated person is giving up the right to sue in court, except as provided by the rules of the arbitration forum in which a claim be filed. Subparagraph (2) incorporates the language of Rule 10201 regarding an exception to the arbitration requirement for claims of statutory employment discrimination, and indicates that the rules of other arbitration forums may be different. Subparagraph (3) through (7) track the language of the proposed amendments to Rule 3110(f)(1), which sets forth similar disclosures to customers. Those subparagraphs inform associated persons that arbitration awards are generally final and binding, that discovery is generally more limited in arbitration than in court, that arbitrator(s) do not have to explain the reasons for their awards, that the panel of arbitrators may include either public or industry (non-public) arbitrators,[12] and that rules of some arbitration forums may impose time limits for bringing a claim in arbitration.

II. Summary of Comments

The Commission received four comment letters on the proposed rule change.[13] Three commenters generally supported the proposed rule change, believing that it will help ensure the efficient resolution of statutory discrimination claims in a manner fair to all parties.[14] The remaining

[11] The member will be responsible for updating the item number of new disclosure statements if it changes in later versions of the Form U–4.

[12] The language of subparagraph (6) differs slightly from that of proposed Rule 3110(f)(1)(E) because, following adoption of the present proposed rule change, the panel composition for statutory employment discrimination claims will differ from the panel composition for customer claims.

[13] *See supra* note 3.

[14] *See* Letters from EEAC, Merrill Lynch, and NELA. However, NELA stated that the Protocol

Continued

commenter believed the proposal was an unnecessary departure from an arbitration system that has worked well in the past.[15]

A. The Commission's Solicitation of Comments

The Commission specifically solicited comment on the following aspects of proposed Rule 10216: (1) Whether the proposed rule strikes a fair balance in permitting respondents to choose when to bifurcate claims; (2) whether the provision permitting respondents to choose when to bifurcate is necessary to give employers an incentive to allow employees to bring statutory claims in court; (3) whether the bifurcation provisions unreasonably burden individual claimants; and (4) whether the presumptive stay unduly infringes upon the parties' bargain to arbitrate.[16]

Two commenters responded to the Commission's questions.[17] Both commenters stated that the proposal strikes a fair balance in permitting respondents to chose when to bifurcate claims. One of these commenters noted that the provision preserves the effectiveness of the NASD's general arbitration rule for employers and employees, while the other comment focused on the costs of litigation and on its view that claimants already have procedural advantages in bringing their case. Both commenters also stated that without the choice of when to bifurcate, employers would be more likely to require their employees to sign pre-dispute arguments mandating arbitration of all claims.[18] In response to the third question, the commenters stated their views that allowing respondents to coordinate related claims in court does not place an unreasonable burden on claimants because the proposed rule furthers the goals of providing fair and efficient arbitration of statutory employment disputes.[19] Finally, both commenters argued that the presumptive stay does not unduly infringe on the parties bargain to arbitrate, and that parties should not be burdened with simultaneously litigating claims in two different forums.[20]

B. Qualifications of Arbitrators and Composition of Arbitration Panels

One commenter contends that the proposed requirements for qualification of single arbitrators and panel chairs will severely limit the pool of available arbitrators.[21] That commenter recommends that section 10211(b)(2) be deleted. Another commenter argues that the use of ''public arbitrators,'' only as defined in Rule 10308, discriminates against attorneys who primarily represent employers in employment discrimination cases.[22] With respect to the composition of the panel, one commenter suggests that only single arbitrators who have no affiliation with securities industry employers be used in order to improve the fairness, reduce the cost, and increase the efficiency of the arbitration process.[23]

C. Discovery

The Commission received three comments on the discovery provisions contained in proposed Rule 10213.[24] Two commenters believe that the proposed rule would be adequate,[25] although one of those commenters suggested that: (1) The rule contains a presumption of one deposition per side, with arbitrator(s) retaining the authority to order additional depositions of an indispensable witness who is unavailable to attend a hearing; and (2) the rule contain a specific procedure requiring panel approval of the particular deposition the parties intend to take.[26]

The remaining commenter argues that the proposed rule should set more specific limitations and guidance as to how and when depositions should be used.[27] This commenter recommends the adoption of language concerning depositions in SR–NASD–99–07,[28] which discourages the use of depositions and generally advises arbitrator(s) to permit depositions under limited circumstances.[29]

D. Attorneys' Fees

One commenter believes that the proposal correctly limits awards of attorneys' fees to cases in which there is a statutory basis for such an award.[30] One commenter, however, thinks that language of proposed Rule 10215 wrongly suggests that an award of attorneys' fees is required in employment discrimination cases.[31] That commenter recommended modifying the proposal by deleting proposed Rule 10215, and adding the phrase ''including reasonable attorneys' fees where appropriate'' to proposed Rule 10214 to clarify the arbitrator's authority.[32]

E. Miscellaneous Provisions

Finally, one commenter suggests the adoption of the Protocol's requirement that arbitrator(s) are bound by applicable statutes, and that arbitrator(s) should issue a written opinion.[33]

III. Discussion

The Commission finds that the proposed rule change is consistent with the provisions of Section 15A(b)[34] of the Act, in general, and furthers the objectives of section 15A(b)(6)[35] in particular, in that it is designed to promote just and equitable principles of trade, and to protect investors and the public interest.[36] The Commission believes that the proposed rule change will protect the public interest by improving the arbitration process for those individuals who arbitrate claims of statutory employment discrimination. The public interest will be further protected by the expanded disclosure contained in the Form U–4 concerning the arbitration of all disputes.

In June of 1998, the Commission approved the NASD's proposal to remove the requirement to arbitrate statutory claims of employment discrimination.[37] The Commission stated in its order approving the NASD's rule change that ''[i]t is reasonable for the NASD to determine that in this unique area, it will not, as a self-regulatory organization, require arbitration.''[38] That rule change does not affect the obligations of NASD member firms and associated persons under NASD rules to arbitrate other employment-related claims, as well as any business-related claims involving investors or other persons.

Moreover, statutory employment discrimination claims will continue to be resolved in the NASD's forum under private employment agreements between the parties or through post-dispute submissions. The current rule

should be adopted without modification. *See* NELA Letter.

[15] *See* SIA Letter.

[16] *See* notice of the proposed rule change.

[17] *See* Letters from EEAC and Merrill Lynch.

[18] *Id.*

[19] *Id.*

[20] *Id.*

[21] *See* EEAC Letter.

[22] *See* SIA Letter.

[23] *See* NELA Letter.

[24] *See* letters from EEAC, Merrill Lynch, and the SIA.

[25] *See* Letters from EEAC and Merrill Lynch.

[26] *See* Merrill Lynch Letter.

[27] *See* SIA Letter.

[28] Securities Exchange Act Release No. 41833 (September 2, 1999), 64 FR 49256 (September 10, 1999) (order approving proposed rule change relating to the creation of a Discovery Guide for use in NASD arbitrations).

[29] *Id.*

[30] *See* EEAC Letter.

[31] *See* SIA Letter.

[32] *Id.*

[33] *See* NELA Letter.

[34] 15 U.S.C. 78o–3(b).

[35] 15 U.S.C. 78o–3(b)(6).

[36] In approving this rule, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[37] *See supra* note 6.

[38] *Id.*

proposal strengthens the NASD's procedures for administering statutory employment discrimination claims by amending appropriate provisions, including those governing the composition of arbitration panels, discovery, and awards. The proposal also introduces predictable methods for determining how disputes involving both statutory employment discrimination claims filed in court and arbitrable claims will be resolved. In addition, it also provides for clear disclosure to employees about arbitration.

The rules were drafted by the NASD over a two-year period with the contributions of organizations who represent interests of both employers and employees within the securities industry, as well as arbitrators who practice in this area. The proposal includes many of the provisions of the Protocol, and equitably accommodates competing concerns.

The comments on the qualifications for arbitrators in the proposal point out the sharp differences of opinion the NASD worked to bridge in its proposal. One commenter objected to the exclusion of industry arbitrators from the panels, another objected to the additional requirements for those who serve as single arbitrators or panel chairpersons because of the resulting exclusion of certain employment experts from serving in those roles,[39] while yet another commenter objected that the proposal permits the use of arbitrators with too much affiliation with the industry.

Further, a commenter stated that the additional qualifications required for single arbitrators and panel chairs will severely limit the pool of available arbitrators. In response, NASD Regulation stated that it will have enough qualified arbitrators on its roster.[40] The Commission believes that the NASD's proposal resolves these differing views in a fair manner, and should enable the NASD to identify qualified and impartial arbitrators to resolve these disputes.

Another commenter contends that only single arbitrators, rather than a panel, should be used for discrimination cases to reduce the cost and increase the efficiency of the process. The Commission notes, however, that proposed Rule 10212(b) already provides a higher dollar threshold for single arbitrator cases than is found elsewhere the NASD Code. The Commission believes that this threshold should help reduce the hearing costs for the parties in smaller cases.

With respect to discovery provisions of the proposed rule, two commenters urged a more restrictive use of depositions.[41] However, the Commission supports NASD Regulation's adoption of the Protocol's view that ''necessary pre-hearing depositions consistent with the expedited nature of arbitration should be available'' in employment discrimination cases. The Commission notes that arbitrators are as capable of resolving disputes concerning depositions as they are for difficult factual and legal issues. Under the proposal, arbitrators must consider the relevance of the information sought, the expeditious nature of arbitration, and the expense of discovery, prior to permitting the use of depositions.

One commenter argues that arbitrators should issue a written opinion detailing their reasoning for the award. However, the Commission has previously stated that arbitrators are not required to write opinions, although they may voluntarily prepare them.[42]

Another commenter contends that the provisions for attorneys' fees in the proposed rule suggests that an award of attorneys' fees is mandatory. NASD Regulation has stated, however, that the intent of proposed Rule 10215 is to allow the award of attorney's fees only if applicable law permits such an award. There is no difference between the NASD's proposed Rule 10215 and the commenter's suggestion, noted above, that Rule 10214 be amended to include the attorneys' fees reference. As the NASD noted, attorneys' fees may be awarded under current practice under the Code of Arbitration Procedure that is used for all of its cases. The NASD has proposed, and the Commission is today approving, the specific provision governing attorneys fees in cognizance of the special attention to them under the civil rights laws, and in the discussions of the arbitration of these claims that the NASD has sponsored. We also note that awards of attorney's fees by arbitrators remain available to all parties in other cases administered under the Code of Arbitration Procedure, if applicable law permits such an award.

The Commissions did not receive any negative comments with respect to the bifurcation provisions contained in proposed Rule 10216. These provisions appear to strike a fair balance in administering statutory discrimination and other employment disputes.

Finally, the Commission observes that the NASD's proposal includes opportunities for the parties to talk with one another, when determining where to file a claim (including fee savings and reimbursements for employees) and in putting together a mutually acceptable arbitration panel. Providing opportunities for the parties to talk with one another early in the process allows parties to resolve their disputes earlier, and with less cost.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the proposed rule change (SR–NASD–99–08) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[43]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 99–28754 Filed 11–2–99; 8:45 am]

BILLING CODE 8010–01–M

[39] The Commission notes that the additional requirements for chairpersons and single arbitrators do not prevent individuals from serving as one of the other two arbitrators on a three person panel, provided that they qualify as public arbitrators. The Commission further notes that the commenter's concerns about the exclusion of industry arbitrators is addressed, in part, by the NASD's determination to exclude plaintiffs' attorneys from serving as panel chairpersons or single arbitrators (Rule 10211(b)(2)), and the Commission will not interfere with that balancing determination. Moreover, the proposal also allows the parties, after their dispute has arisen, to waive any of the qualifications under the rule and to agree on the use of other arbitrators.

[40] In 1998, 107 claims of employment discrimination were filed with NASD Regulation and, as of August 10, 1999, 40 claims of discrimination have been filed. Approximately 58% of the more than 6,700 arbitrators on the NASD Regulation roster are classified as public arbitrators, and at least 40 arbitrators have already been identified as meeting the additional standards of proposed Rule 10211(b). Due to the fact that many cases are settled or withdrawn before a hearing commences, the NASD believes that there will be enough qualified employment arbitrators. *See* NASD Regulation Letter, *supra* note 7.

[41] As previously noted, one commenter urged the adoption of the language found in the new Discovery Guide for use in NASD arbitrations. The Commission notes, however, that the Discovery Guide only contains suggested guidance on the use of depositions. The policies and procedures set forth in Discovery Guide are discretionary and may be changed by the arbitrators so long as they are consistent with the rules of the forum. *See supra* note 28.

[42] *See* Securities Exchange Act Release No. 26805 (May 10, 1989), 54 FR 21144 (May 16, 1989).

[43] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Privacy Act of 1974; System of Records Notices

AGENCY: Small Business Administration.

ACTION: Notice of new system of record.

SUMMARY: The Small Business Administration is adding a new system of records to the Agency's Privacy Act System of Records. The new system collects information for the Women's Business Center, Small Business

Development Center, Business Information Center, One Stop Capital Shop, Veteran's Assistance, Tribal Business Information Center, and Welfare to Work Programs.

DATES: Submit comments on or before December 3, 1999.

ADDRESSES: Address comments to Monika Edwards Harrison, Associate Administrator for Business Initiatives, Small Business Administration, 409 3rd Street, SW., Suite 6100, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Monika Edwards Harrison, Associate Administrator for Business Initiatives, (202) 205–6665.

SBA 170

SYSTEM NAME:

Entrepreneurial Development—Management Information System (EDMIS), U.S. Small Business Administration (SBA).

SYSTEM LOCATION:

SBA Headquarters.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals using SBA's business counseling and assistance services.

CATEGORIES OF RECORDS IN THE SYSTEM:

Individual and business information on SBA clients.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Pub. L. 85–536; 15 U.S.C. 631 (Small Business Act), sec. 7(j)(1), (Business Counseling); 15 U.S.C. 648 sec. 21 (Small Business Development Centers); 15 U.S.C. 656 sec. 29 (Women's Business Centers); Pub. L. 106–50 (Veterans' Entrepreneurship and Small Business Development Act of 1999); 44 U.S.C. 3101 (Records Management by Federal Agencies); and Pub. L. 103–62 (Results Act).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

These records may be used, disclosed, or referred:

(a) To the Agency service provider (resource partner) who initially collected the individual's information.

(b) To a Congressional office from an individual's record when the office is inquiring on the individual's behalf. The Member's access rights are no greater than the individual's.

(c) To the Federal, state, local or foreign agency or organization which investigates, prosecutes, or enforces violations, statutes, rules, regulations, or orders issued when an agency identifies a violation or potential violation of law, arising by general or program statute, or by regulation, rule, or order.

(d) To Agency volunteers, interns, and contractors for use in their official duties.

(e) To the Department of Justice (DOJ) when:

(1) The agency, or any component thereof; or

(2) Any employee of the agency in his or her official capacity; or

(3) Any employee of the agency in his or her individual capacity where the DOJ has agreed to represent the employee; or

(4) The United States Government, where the agency determines that litigation is likely to affect the agency or any of its components, is a party to litigation or has an interest in such litigation, and the use of such records by the DOJ is deemed by the agency to be relevant and necessary to the litigation, provided, however, that in each case, the agency determines that disclosure of the records to the DOJ is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

(f) To disclose them in a proceeding before a court or adjudicative body before which the Agency is authorized to appear, when:

(1) The agency, or any component thereof; or

(2) Any employee of the agency in his or her official capacity; or

(3) Any employee of the agency in his or her individual capacity where the agency has agreed to represent the employee; or

(4) The United States Government, where the agency determines that litigation is likely to affect the agency or any of its components, is a party to litigation or has an interest in such litigation, and the agency determines that use of such records is relevant and necessary to the litigation, provided, however, that in each case, the agency determines that disclosure of the records to a court or other adjudicative body is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS:

STORAGE:

Electronic form in secured database on a dedicated server.

RETRIEVABILITY:

By SBA Customer Number and cross-referenced by individual or business name.

SAFEGUARDS:

Access and use over the Internet with a restricted numerical password. Access and use is limited to Federal officials with a need-to-know and to designated resource partners. SBA resource partners will have access only to those individual records that were collected by that particular resource partner. Generally, designated program managers in Headquarters and the district director in the field will have access to individual records only as needed for program management.

RETENTION AND DISPOSAL:

In accordance with SBA SOP 00 41 2, Item #65:06, these records are retained a minimum of 3 years and generally destroyed 3 years after last update.

SYSTEM MANAGER(S) AND ADDRESS:

Associate Deputy Administrator of Entrepreneurial Development and designee in Headquarters.

NOTIFICATION PROCEDURE:

An individual may submit a record inquiry either in person or in writing to the Systems Manager or Privacy Act Officer for Headquarters records. Individuals inquiring about this system must follow the SBA Privacy Act Regulations at 13 CFR part 102 subpart B.

RECORDS ACCESS PROCEDURES:

Systems Manager or Privacy Act Officer will determine procedures. Individuals inquiring about this system must follow the SBA Privacy Act Regulations at 13 CFR part 102 subpart B.

CONTESTING RECORD PROCEDURES:

Notify the official listed above and state reason(s) for contesting and the proposed amendment sought, as indicated in 13 CFR part 102 subpart B.

RECORD SOURCE CATEGORIES:

Individuals and businesses to whom the record belongs.

Dated: October 29, 1999.

Mona Koppel Mitnick,

Senior Privacy Act Official.

[FR Doc. 99–28706 Filed 11–2–99; 8:45 am]

BILLING CODE 8025–01–U

DEPARTMENT OF STATE

[Public Notice 3153]

Office of International Religious Freedom Bureau of Democracy, Human Rights and Labor; Designation of Countries of Particular Concern Under The International Religious Freedom Act

Pursuant to section 408(a) of the International Religious Freedom Act of 1998, notice is hereby given that the Secretary of State, under authority delegated by the President, has designated the following countries as ''countries of particular concern'' under section 402(b) of the Act for having engaged in or tolerated particularly severe violations of religious freedom: Burma, China, Iran, Iraq, Sudan.

Dated: October 27, 1999.

Robert A. Seiple,

Ambassador at Large for International Religious Freedom, U.S. Department of State.

[FR Doc. 99–28749 Filed 11–2–99; 8:45 am]

BILLING CODE 4710–18–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activity Under OMB Review

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for extension of currently approved collections. The ICR describes the nature of the information collection and its expected burden. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on June 1, 1999, [FR 64, pages 29404–29405].

DATES: Comments must be submitted on or before December 3, 1999. A comment to OMB is most effective if OMB receives it within 30 days of publication.

FOR FURTHER INFORMATION CONTACT: Judy Street on (202) 267–9895.

SUPPLEMENTARY INFORMATION:

Federal Aviation Administration (FAA)

Title: ACSEP Evaluation Customer Feedback Report.

Type of Request: Extension of a currently approved collection.

OMB Control number: 2120–0605.

Form(s): FAA Form 8100–7.

Affected Public: 450 holders of FAA production approvals and selected suppliers.

Abstract: The information collection will be used by the Aircraft Certification Service's Manufacturing Inspection Officers, Aircraft Certification Offices, and the Production & Airworthiness Certification Division to improve the administration and conduct of the Aircraft Certification Systems Evaluation Program at the local and national levels.

Estimated Annual Burden Hours: 225 burden hours annually.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725–17th Street, NW., Washington, DC 20503, Attention: FAA Desk Officer.

Comments Are Invited On: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued in Washington, DC, on October 28, 1999.

Steve Hopkins,

Manager, Standards and Information Division, APF–100.

[FR Doc. 99–28707 Filed 11–2–99; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activity Under OMB Review

AGENCY: Federal Aviation Administration (FAA) DOT.

ACTION: Notice.

SUMMARY: In compliance with the paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (CR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for extension of currently approved collections. The ICR describes the nature of the information collection and its expected burden. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on June 1, 1999, (FR 64, pages 29404–29405).

DATES: Comments must be submitted on or before December 3, 1999. A comment to OMB is most effective if OMB receives it within 30 days of publication.

FOR FURTHER INFORMATION CONTACT: Judy Street on (202) 267–9895.

SUPPLEMENTARY INFORMATION:

Federal Aviation Administration (FAA)

Title: Kansas City Center Customer Satisfaction Questionnaire.

Type of Request: Estensions of a currently approved collection.

OMB Control Number: 2120–0576.

Form(s): ZKC Form 7010–1.

Affected Public: 100 general aviation pilots, air taxi operators, airlines, military pilots, and adjacent facilities.

Abstract: The information collected on this form represents customer feedback concerning the quality of service provided to the users of Kansas City ARTCC airspace. This information may be used to solve problems, improve safety, and increase system efficiency.

Estimated Annual Burden Hours: 25 burden hours annually.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725—17th Street, NW., Washington, DC 20503, Attention: FAA Desk Officer.

Comments Are Invited On: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued in Washington, DC, on October 28, 1999.

Steve Hopkins,

Manager, Standards and Information Division, APF–100.

[FR Doc. 99–28708 Filed 11–2–99; 8:45 am]

BILLING CODE 4910–03–M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: Bronx County and New York County, NY

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an Environmental Impact Statement (EIS) will be prepared for a proposed bridge improvement project in Bronx County and New York County, New York.

FOR FURTHER INFORMATION CONTACT: (1) Harold J. Brown, Division Administrator, Federal Highway Administration (FHWA), Leo O'Brien Federal Building, 9th Floor, Albany, New York 12207; Telephone: (518) 431–4127 or (2) Richard Maitino, Regional Director, New York State Department of Transportation—Region 11 Office, Hunter's Point Plaza, 47–40 21st Street 8th Floor, Long Island City, New York 11101; Telephone: (718) 482–4526.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the New York State Department of Transportation and the New York City Departmental of Transportation (NYCDOT), will prepare an EIS on the proposal to rehabilitate, reconstruct, or replace the Willis Avenue Bridge over the Harlem River in Bronx County and New York County, New York .

The Willis Avenue Bridge is one of six bridges which span the lower Harlem River, providing a continuous street grid system between upper Manhattan and the southwest Bronx. Opened to traffic in 1901, the four-lane Willis Avenue Bridge, a swing bridge, is now open for one-way Bronx-bound vehicular travel with complementary Manhattan-bound service provided on the Third Avenue Bridge, several blocks to the north. The bridge is used by approximately 70,000 vehicles daily outbound from Manhattan, with 4,800 vehicles in the PM peak hour, when traffic is heaviest. The proposed project raises a number of environmental issues including effects on historic resources, water quality, natural resources, hazardous materials contamination, and parkland.

Improvements to the bridge are considered necessary to provide for the existing and projected traffic demand by improving land width and geometry of the bridge and its approach ramps, reducing the rate of accidents, increasing the bridge's load carrying capacity, improving the bridge's bicycle and pedestrian facilities, and addressing all structural and seismic deficiencies of the present structure. Alternatives under consideration include (1) Taking no action; (2) an on-line rehabilitation of the existing bridge; (3) an on-line replacement, and (4) an off-line replacement. Incorporated into and studied with the various build alternatives will be design variations of bridge type (moveable or fixed) and materials (concrete or steel). All proposed alternatives retain four Bronx-bound lanes.

Letters describing the proposed action and soliciting comments will be sent to appropriate Federal, State, and local agencies, and to private organizations and citizens who have previously expressed or are known to have interest in this proposal. A public scoping meeting, for the purpose of soliciting comments from the public on the proposed scope of work for the EIS, will be held in November 1999. To ensure that the full range of issues related to this proposed action are addressed and that all significant issues are identified in the upcoming EIS, comments and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be directed to the NYSDOT or FHWA at the addresses provided above.

After completion of the Draft EIS, a public hearing will be held. Public notice will be given of the time and place of the meeting and hearing. The Draft EIS will be available for public and agency review and comment prior to the public hearing.

(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 program)

Authority: 23 U.S.C. 315; 23 CFR 771.123.

Issued on October 21, 1999.

Douglas P. Conlan,

District Engineer, FHWA, Albany, New York.

[FR Doc. 99–28781 Filed 11–2–99; 8:45 am]

BILLING CODE 4910–22–M

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 33807]

Washington County Railroad Company—Modified Rail Certificate

On October 6, 1999, Washington County Railroad Company (WCRC), a noncarrier, filed a notice for a modified certificate of public convenience and necessity under 49 CFR 1150, Subpart C, *Modified Certificate of Public Convenience and Necessity,* to operate a 14-mile rail line owned by the State of Vermont (the line).[1]

The line was approved for abandonment by Montpelier and Barre Railroad Company in *Montpelier and Barre Railroad Company—Entire Line Abandonment—From Graniteville to Montpelier Junction in Washington County, VT,* Docket No. AB–202 F (ICC served Mar. 12, 1980), and acquired by the State of Vermont on November 21, 1980. The Washington County Railroad Corporation (WACR) filed a notice for a modified certificate of public convenience and necessity on November 17, 1980, and a modified rail certificate was issued to WACR authorizing it to operate the line as of November 17, 1980.[2] On February 2, 1999, WACR agreed to assign its lease of the line to New England Central Railroad, Inc. (NECR).[3] NECR accepted the assignment on February 9, 1999, and operated the line through the close of business on September 8, 1999, when it terminated operations over the line. Vermont Railway, Inc. (VTR) filed a notice for a modified certificate of public convenience and necessity on September 14, 1999, and a modified rail certificate was issued to VTR for the immediate interim operation of the line while VTR and the State of Vermont negotiated and entered into a lease and operating agreement that would govern future operations of the line by VTR or a subsidiary of VTR.[4] On September 30, 1999, WCRC and the State of Vermont entered into an agreement whereby WCRC would operate the line, unless modified, through June 30, 2004. WCRC states that, effective immediately, it will replace VTR as the operator of the line.[5]

[1] WCRC was incorporated on September 23, 1999, for the purpose of providing rail service over the line for the State of Vermont.

[2] *See Washington County Railroad Corporation—Operations—From Montpelier Junction to Graniteville, VT,* Finance Docket No. 29536F (ICC served Jan. 2, 1981).

[3] *See New England Central Railroad, Inc.—Modified Rail Certificate,* STB Finance Docket No. 33715 (STB served Feb. 26, 1999).

[4] *See Vermont Railway, Inc.''Modified Rail Certificate,* STB Finance Docket No. 33800 (STB served Sept. 24, 1999).

[5] WCRC states that it is owned by the same persons who control VTR. WCRC further states that it has the same officers and directors as VTR and two other Class III carriers, Clarendon & Pittsford Railroad Company, and Green Mountain Railroad Corporation. WCRC states that an exemption will be sought under 49 U.S.C. 10502 from the prior approval requirements of 49 U.S.C. 11323–25 for the control of WCRC by individuals who control other rail carriers. Common control authority or an exemption is needed before WCRC may begin rail carrier operations.

The line extends between Montpelier Junction, VT, and Graniteville, VT, a distance of approximately 14 miles. WCRC expects to conduct operations between Montpelier Junction and Websterville, a distance of approximately 12 miles. At Montpelier Junction, the line connects with NECR.

The rail segment qualifies for a modified certificate of public convenience and necessity. *See Common Carrier Status of States, State Agencies and Instrumentalities and Political Subdivisions,* Finance Docket No. 28990F (ICC served July 16, 1981).

A subsidy is involved. Under the agreement, the State of Vermont's Agency of Transportation (VAOT) agrees to pay WCRC a subsidy equivalent to $5,000 per week, through June 30, 2000. The agreement further provides that VAOT, beginning July 1, 2000 and for each subsequent year of the agreement, agrees to pay a subsidy of $260,000 per year, reduced by a subsidy credit equivalent to 50% of all gross revenues between $150,000 and $670,000.[6] WCRC represents that it has obtained general liability insurance coverage and that there are no preconditions for shippers to meet in order to receive rail service.

This notice will be served on the Association of American Railroads (Car Service Division) as agent for all railroads subscribing to the car-service and car-hire agreement: Association of American Railroads, 50 F Street, N.W., Washington, DC 20001; and on the American Short Line and Regional Railroad Association: American Short Line and Regional Railroad Association, 1120 G Street, N.W., Suite 520, Washington, DC 20005.

Decided: October 28, 1999.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 99–28743 Filed 11–2–99; 8:15 am]

BILLING CODE 4915–00–P

[6] VAOT states that it is authorized under 5 V.S.A. 3401–3409 to administer State-owned railroad properties and to take necessary action to ensure continuity of service over such properties.

DEPARTMENT OF THE TREASURY

Departmental Offices; International Financial Institution Advisory Commission

AGENCY: Department of the Treasury.

ACTION: Notice of meeting.

SUMMARY: Under section 603 of the Foreign Operations, Export Financing and Related Programs Appropriations Act, 1999, the International Financial Institution Advisory Commission (the ''Commission'') shall advise and report to the Congress on the future role and responsibilities of the international financial institutions (defined as the International Monetary Fund, International Bank for Reconstruction and Development, European Bank for Reconstruction and Development, International Development Association, International Finance Corporation, Multilateral Investment Guarantee Agency, African Development Bank, African Development Fund, Asian Development Bank, Inter-America Development Bank, and Inter-American Investment Corporation), the World Trade Organization, and the Bank for International Settlements.

DATES: The fifth meeting of the Advisory Commission will be held on November 16, 1999, beginning at 9:00 a.m. and tentatively ending at 3:00 p.m. in Room HC8 in the U.S. Capitol, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Designated Federal Official: William McFadden, Senior Policy Advisor, Office of International Monetary and Financial Policy, Room 4444, Department of the Treasury, 1500 Pennsylvania Avenue NW. Washington, DC, 20220. Telephone number 202–622–0343, fax number (202) 622–7664.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2.

Agenda of Meeting

Commission members will continue their discussion on the role of the multilateral development banks and tentatively begin discussion on the role of the World Trade Organization.

Procedural

This meeting is open to the public. Please note that the meeting may close early if all business is finished. Members of the public may submit written comments. If you wish to furnish such comments, please provide 16 copies of your written material to the Designated Federal Official. If you wish to have your comments distributed to members of the Commission in advance of the fifth meeting, 16 copies of any written material should be provided to the Designated Federal Official no later than November 9, 1999.

Dated: October 27, 1999.

William McFadden,

Designated Federal Official.

[FR Doc. 99–28684 Filed 11–2–99; 8:45 am]

BILLING CODE 4810–25–M

federal register

Wednesday
November 3, 1999

Part II

Securities and Exchange Commission

17 CFR Parts 239, 240, 270, 271 and 274

Role of Independent Directors of Investment Companies; Proposed Rule

Interpretive Matters Concerning Independent Directors of Investment Companies; Final Rule

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 239, 240, 270 and 274

[Release Nos. 33–7754; 34–42007; IC–24082; File No. S7–23–99]

RIN 3235–AH75

Role of Independent Directors of Investment Companies

AGENCY: Securities and Exchange Commission.

ACTION: Proposed rule.

SUMMARY: The Commission is publishing for comment proposed amendments to certain exemptive rules under the Investment Company Act of 1940 to require that, for investment companies that rely on those rules: independent directors constitute at least a majority of their board of directors; independent directors select and nominate other independent directors; and any legal counsel for the independent directors be an independent legal counsel. We also are proposing amendments to our rules and forms to improve the disclosure that investment companies provide about their directors. These proposed amendments are designed to enhance the independence and effectiveness of boards of directors of investment companies and to better enable investors to assess the independence of directors.

DATES: Comments must be received on or before January 28, 2000.

ADDRESSES: Comments should be submitted in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 5th Street, N.W., Washington, D.C. 20549–0609. Comments also may be submitted electronically at the following E-mail address: rule-comments@sec.gov. All comment letters should refer to File No. S7–23–99; this file number should be included on the subject line if E-mail is used. Comment letters will be available for public inspection and copying in the Commission's Public Reference Room, 450 5th Street, N.W., Washington, D.C. 20549. Electronically submitted comment letters also will be posted on the Commission's Internet web site (http://www.sec.gov).

FOR FURTHER INFORMATION CONTACT: For information regarding the proposed substantive rule amendments, contact Jennifer B. McHugh, Attorney, Office of Regulatory Policy, (202) 942–0690, or regarding the disclosure amendments, contact Annette M. Capretta, Senior Counsel, or Heather A. Seidel, Senior Counsel, Office of Disclosure Regulation, (202) 942–0721, at the Division of Investment Management, Securities and Exchange Commission, 450 5th Street, N.W., Washington, D.C. 20549–0506.

SUPPLEMENTARY INFORMATION: The Securities and Exchange Commission (the ''Commission'') today is proposing for public comment new rules 2a19–3 [17 CFR 270.2a19–3], 10e–1 [17 CFR 270.10e–1], and 32a–4 [17 CFR 270.32a–4] and amendments to rules 0–1 [17 CFR 270.0–1], 2a19–1 [17 CFR 270.2a19–1], 10f–3 [17 CFR 270.10f–3], 12b–1 [17 CFR 270.12b–1], 15a–4 [17 CFR 270.15a–4], 17a–7 [17 CFR 270.17a–7], 17a–8 [17 CFR 270.17a–8], 17d–1 [17 CFR 270.17d–1], 17e–1 [17 CFR 270.17e–1], 17g–1 [17 CFR 270.17g–1], 18f–3 [17 CFR 270.18f–3], 23c–3 [17 CFR 270.23c–3], 30d–1 [17 CFR 270.30d–1], 30d–2 [17 CFR 270.30d–2], and 31a–2 [17 CFR 270.31a–2] under the Investment Company Act of 1940 [15 U.S.C. 80a] (''Investment Company Act'' or ''Act''); amendments to Forms N–1A [17 CFR 274.11A], N–2 [17 CFR 274.11a–1], and N–3 [17 CFR 274.11b] under the Investment Company Act and the Securities Act of 1933 [15 U.S.C. 77a–aa] (''Securities Act''); and amendments to Schedule 14A [17 CFR 240.14a–101] under the Securities Exchange Act of 1934 [15 U.S.C. 78a–mm] (''Exchange Act'').

Table of Contents

Executive Summary

The board of directors of an investment company (''fund'') has significant responsibilities to protect investors under state law, the Investment Company Act, and many of our exemptive rules. Independent directors, in particular, serve as ''independent watchdogs,'' guarding investor interests. These interests are paramount, for it is investors who own the funds and for whose benefit they must be operated.

We recently hosted a Roundtable on the Role of Independent Investment Company Directors, which highlighted the significance of those directors in protecting the interests of fund shareholders. After reviewing corporate governance issues and the recommendations of participants at our Roundtable, we are proposing a number of rule and form changes to enhance the independence and effectiveness of fund boards of directors and provide investors with greater information about fund directors.

First, we are proposing to require that, for funds relying on certain exemptive rules:

- Independent directors constitute either a majority or a super-majority (two-thirds) of the fund's board of directors;
- Independent directors select and nominate other independent directors; and
- Any legal counsel for the fund's independent directors be an independent legal counsel.

Second, we are proposing rules and rule amendments that would:

- Prevent qualified individuals from being unnecessarily disqualified from serving as independent directors;
- Protect independent directors from the costs of legal disputes with fund management;
- Permit us to monitor the independence of directors by requiring

funds to keep records of their assessments of director independence;

• Temporarily suspend the independent director minimum percentage requirements if a fund falls below a required percentage due to an independent director's death or resignation; and

• Exempt funds from the requirement that shareholders ratify or reject the directors' selection of an independent public accountant, if the fund establishes an audit committee composed entirely of independent directors.

Finally, we are proposing to require funds to provide better information about directors, including:

• Basic information about the identity and business experience of directors;

• Fund shares owned by directors;

• Information about directors' potential conflicts of interest; and

• The board's role in governing the fund's operations.

In addition, today we are publishing a companion release that sets forth the views of the Commission and the Commission's staff on a number of interpretive matters.[1] This release provides guidance on certain discrete issues related to independent directors.

Together, these initiatives are designed to reaffirm the important role that independent directors play in protecting fund investors, strengthen their hand in dealing with fund management, reinforce their independence, and provide investors with greater information to assess the directors' independence.

I. Background

Today, millions of Americans rely on mutual funds to save and invest for their families' futures.[2] More than 77 million individual investors own shares of mutual funds, which hold over $5.5 trillion in assets—an increase of over 580 percent from ten years ago.[3] Investments in mutual funds are a significant part of retirement plans and college savings plans, as well as many traditional brokerage accounts.[4] Money market funds, which alone have over $1 trillion in assets,[5] often serve as a substitute for checking accounts and provide an important vehicle for cash management for individual investors as well as many institutions and businesses.[6] International and global funds give investors easy access to foreign markets.[7]

Mutual funds are formed as corporations or business trusts under state law and, like other corporations and trusts, must be operated for the benefit of their shareholders.[8] Mutual funds are unique, however, in that they are ''organized and operated by people whose primary loyalty and pecuniary interest lie outside the enterprise.'' [9] As described below, this ''external management'' of virtually all mutual funds presents inherent conflicts of interest and potential for abuses.

An investment adviser typically organizes a mutual fund and is responsible for its day-to-day operations. The adviser generally provides the seed money, officers, employees, and office space, and usually selects the initial board of directors. In many cases, the investment adviser sponsors several funds that share administrative and distribution systems as part of a ''family of funds.'' As a result of this extensive involvement, and the general absence of shareholder activism, investment advisers typically dominate the funds they advise.[10]

Investment advisers to mutual funds are generally organized as corporations, which have their own shareholders. These shareholders may have an interest in the mutual fund that is quite different from the interests of the fund's shareholders. For example, while fund shareholders ordinarily prefer lower fees (to achieve greater returns), shareholders of the fund's investment adviser might want to maximize profits through higher fees. And while fund shareholders might prefer that advisers use brokers that charge the lowest possible commissions, advisers might prefer to use brokers that are affiliates of the adviser. These types of conflicts (and others) resulted in the pervasive abuses that led Congress in 1940 to enact legislation regulating the activities of mutual funds.[11]

The Investment Company Act establishes a comprehensive regulatory scheme designed to protect fund investors by addressing the conflicts of interest between funds and their investment advisers or other affiliated persons. The Act strictly regulates some of the most serious conflicts. For example, the Act prohibits certain transactions between a fund and its affiliates, including the investment adviser, unless approved by the

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[1] Interpretive Matters Concerning Independent Directors of Investment Companies, Investment Company Act Release No. 24083 (Oct. 14, 1999) [''Interpretive Release'']. [2] For simplicity, this release focuses on mutual funds (*i.e.,* open-end funds). Our proposed rule amendments, however, would apply to all management investment companies, except where noted.

[3] *See* Investment Company Institute, Mutual Fund Fact Book 3 (1999) [''1999 Mutual Fund Fact Book'']. Total assets of mutual funds were $5.525 trillion at the end of 1998, compared to $809.4 billion in 1988. In 1998, an estimated 44 percent of U.S. households owned mutual funds, up from 5.7 percent in 1980 and 24.4 percent in 1988. *Id.* at 45. As of December 31, 1998, an estimated 77.3 million individuals owned shares of mutual funds. *Id.* at 41. At the end of 1998, assets of all funds (open-end funds, closed-end funds, and unit investment trusts) totaled $5.778 trillion. *See id.* at 3 (stating that assets of open-end funds totaled $5.525 trillion at the end of 1998); Lipper Inc., Lipper Closed-End Fund Performance Analysis 1–2 (Jan 1999) (stating that assets of closed-end funds totaled $158 billion at the end of 1998); Investment Company Institute, Release No. 99–36 (stating that assets of unit investment trusts totaled $94.54 billion at the end of 1998).

[4] At the end of 1998, assets totaling approximately $1.9 trillion, or 35 percent of all mutual fund assets, were held in retirement accounts, up from $348 billion at the end of 1991. 1999 Mutual Fund Fact Book, *Supra* note 3, at 47–48; *see also* Jennifer Karchmer, *Planning for Retirement Has Given Mutual Fund Assets a Steady Boost,* Bond Buyer, May 24, 1999, at 6.

[5] At the end of 1998, money market fund assets totaled approximately $1.352 trillion. *See* 1999 Mutual Fund Fact Book, *supra* note 3, at 4.

[6] *See generally* Investment Company Institute, Money Market Mutual Funds (1990).

[7] Assets in funds investing primarily in foreign securities totaled over $448.5 billion at the end of 1998. *See* Investment Company Institute, Release No.99–07 (stating that assets of open-end funds investing primarily in foreign securities totaled $416.5 billion at the end of 1998); Lipper Inc., Lipper Closed-End Fund Performance Analysis—Fourth Quarter 1998 Report (stating that assets of closed-end funds investing primarily in foreign securities totaled $32 billion at the end of 1998).

[8] *See generally* James M. Storey & Thomas M. Clyde, Mutual Fund Law Handbook § 7.2 (1998); Allan S Mostoff & Oliver P. Adler, *Organizing an Investment Company—Structural Considerations* § 2.4 *in* The Investment Company Regulation Deskbook (Amy L. Goodman ed., 1997).

[9] Division of Investment Management, SEC, Protecting Investors; A Half Century of Investment Company Regulation 251 (''1992 Protecting Investors Report''); *see also* 1 Tamar Frankel, Regulation of Money Managers 10 (1978).

[10] *See* SEC. Report on the Public Policy Implications of Investment Company Growth, H.R. Rep. No. 2337, 89th Cong., 2d. Sess. 12 127, 148 (1966) [''Public Policy Report''] (stating that funds generally are formed by their advisers and remain under their control, and that advisers' influence permeates fund activities); Wharton School of Finance and Commerce, a Study of Mutual Funds, H.R. Rep. No. 2274, 87th Cong., 2d Sess. 463 (1962) [''Wharton Report''] (discussing the dominant position of advisers in the control of funds and the infrequency with which funds have a separate existence from their advisers); *see also* Clarke Randall, *Fiduciary Duties of Investment Company Directors and Management Companies Under the Investment Company Act of 1940,* 31 Okla. L. Rev. 635, 636 (1978) (''The adviser's control and influence over the fund is very nearly total.''); In the Matter of Steadman Security Corporation, Investment Company Act Release No. 9830 [1977 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 81,243, at n.81 (Jun. 29, 1977) (''[T]he investment adviser almost always controls the fund.'').

[11] *See* section 1(b)(2) of the Act [15 U.S.C. 80a–1(b)(2)]; SEC, Report on Investment Trusts and Investment Companies, Part III (1939); *see also Storey & Clyde, supra* note 8, at § 2.2 Joseph F,. Krupsky, *The Role of Investment Company Directors,* 32 Bus. Law. 1733, 1737–40 (1977); William J. Nutt, *A Study of Mutual Fund Independent Directors,* 120 U. PA. L. Rev. 179, 181 (1971).

Commission.[12] The Act also relies on fund boards of directors to police conflicts of interest.

Under state law, directors are generally responsible for the oversight of all of the operations of a mutual fund.[13] In addition, the Investment Company Act assigns many specific responsibilities to fund boards. For example, fund boards must evaluate and approve a fund's advisory contract and any assignment of the contract, and may unilaterally terminate the contract.[14] Directors also approve the fund's principal underwriting contract,[15] select the fund's independent accountant,[16] and value certain securities held by the fund.[17] In addition, under the Act and our rules, directors have responsibility for evaluating the reasonableness of advisory and distribution-related fees charged the fund [18] and managing certain operational conflicts. Just recently, for example, we clarified that boards must assume oversight responsibility for personal securities transactions by employees of the fund and its adviser.[19]

The Act requires that independent directors constitute at least 40 percent of a fund's board,[20] and sets the standards for when a person will be disqualified from being an independent director (*i.e.*, will be considered an ''interested person'' under the Act).[21] These independent directors play an important role in representing and guarding the interests of investors. As has been stated many times, Congress intended these directors to be the ''independent watchdogs'' [22] for investors and to ''supply an independent check on management.'' [23]

Many requirements of the Act and our rules that protect investors from conflicts of interest specifically rely on action by these independent directors. The Act, for example, requires independent directors to separately evaluate and approve the fund's contract with an investment adviser or principal underwriter.[24] Our rules have permitted innovative types of funds, more efficient fund operations, and new distribution arrangements by exempting funds from prohibitions related to conflicts of interest. While these rules have provided important flexibility to allow mutual funds to meet the changing needs of investors, they also rely on approval, oversight, and monitoring by independent directors to protect investors.[25]

Earlier this year we held a two-day public Roundtable discussion on the role of independent directors of mutual funds.[26] Participants in the Roundtable included independent directors, investor advocates, executives of fund advisers, academics, corporate governance experts, and experienced legal counsel. They examined the activities and responsibilities of independent directors and reviewed the nature of their independence. Participants also discussed various ways that the Commission might promote greater effectiveness of independent directors.

We endorse the sentiments of the Roundtable participants who favor enhancing the effectiveness and independence of fund boards of directors. While those sentiments can be fully achieved only through amendments to the Investment Company Act, we are impressed by the consensus of the participants concerning the importance of the role of independent directors and the conditions they believe are necessary to enhance the effectiveness of those directors. We therefore are proposing rule amendments designed to reaffirm the important role that independent directors play in protecting fund investors, strengthen their hand in dealing with fund management, reinforce their independence, and provide investors with better information to assess the independence of directors.

II. Discussion

A. Enhancing the Independence of Fund Boards of Directors

Panelists at our recent Roundtable discussed a number of possible ways to enhance the independence and effectiveness of fund boards. Most participants agreed that independent directors can best fulfill their responsibilities when they constitute a substantial majority of the board.

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[12] Section 17(a) of the Act [15 U.S.C. 80a–17(a)].

[13] *See* Jean Gleason Stromberg, *Governance of Investment Companies, in* The Investment Company Regulation Deskbook §§ 4.1–.2 (Amy L. Goodman, ed. 1997).

[14] *See* section 15(a) of the Act [15 U.S.C. 80a–15a)] (requiring annual approval of the advisory contract by the funds's board of directors or shreholders and requiring that the contract empower the board to terminate the contract); section 15(c) of the Act [15 U.S.C. 80a–15(c)] (requiring that a fund's independent directors separately evaluate and approve any advisory contract with the fund).

[15] *See* Section 15(b) of the Act [15 U.S.C. 80a–15(b)] (requiring approval of the principal underwriting contract by the fund's board or shareholders); section 15(c) of the Act (requiring that a fund's independent directors separately evaluate and approve the fund's contract with its principal underwriter).

[16] *See* section 32(a)(1) of the Act [15 U.S.C. 80a–31(a)(1)] (requiring that a fund's independent directors select the fund's independent public accountant).

[17] *See* section 2(a)(41) of the Act [15 U.S.C. 80a–2(a)(41)] (requiring, in effect, that any security for which no market quotation is readily available be valued at fair value as determined in good faith by the board of directors).

[18] *See* sections 15 (a)–(c) of the Act (board review of fees paid to a fund's adviser and principal underwriter); rule 12b–1 under the Act [17 CFR 270.12b–1] (board review of asset-based distribution fees paid pursuant to a ''rule 12b–1 plan'').

[19] *See* Personal Investment Activities of Investment Company Personnel, Investment Company Act Release No. 23958 (Aug. 20, 1999) [64 FR 46821 (Aug. 27, 1999)] (adopting amendments to rule 17j–1 under the Act [17 CFR 270.17j–1]).

[20] Section 10(a) of the Act [15 U.S.C. 80a-10(a)] (prohibiting more than 60 percent of a fund's directors from being interested persons of the fund). We refer to directors who are not ''interested persons'' of the fund as ''independent directors.'' *See also* section 10(b)(2) of the Act [15 U.S.C. 80a-10(b)(2)] (requiring, in effect, that independent directors comprise a majority of a fund's board if the fund's principal underwriter is an affiliate of the fund's investment adviser); section 15(f)(1) of the Act [15 U.S.C. 80a-15(f)(1)] (providing a safe harbor for the sale of an advisory business if directors who are not interested persons of the investment adviser constitute at least 75 percent of a fund's board for at least three years following the assignment of the advisory contract).

[21] Section 2(a)(19) of the Act [15 U.S.C. 80a–2(a)(19)] (defining ''interested person''); *see infra* note 170 (discussing the elements of the definition of ''interested person'').

[22] *See* Burks v. Lasker, 441 U.S. 471, 484 (1979) (quoting Tannenbaum v. Zeller, 552 F.2d 402, 406 (2d Cir. 1977)).

[23] S. Rep. No. 184, 91st Cong., 2d Sess. 31 (1969).

[24] *See* section 15(c) of the Act.

[25] *See, e.g.*, rule 10f-3 [17 CFR 270.10f-3] (permitting funds to purchase securities in a primary offering when an affiliated broker-dealer is a member of the underwriting syndicate if the fund's board, including a majority of its independent directors, (i) approves procedures regulating purchases of these securities and (ii) determines at least quarterly that the purchases complied with the board-approved procedures). In addition, we have eliminated certain rule provisions that arguably required directors to ''micro-manage'' fund operations. *See* Custody of Investment Company Assets Outside the United States, Investment Company Act Release No. 22658 (May 12, 1997) [62 FR 26923 (May 16, 1997)] (amending rule 17f-5 to permit fund directors to delegate certain responsibilities related to foreign custody arrangements and eliminating the requirement that directors annually review those arrangements); Revision of Certain Annual Review Requirements of Investment Company Boards of Directors, Investment Company Act Release No. 19719 (Sept. 17, 1993) [58 FR 49919 (Sept. 24, 1993)] (eliminating certain annual board review requirements of rules 10f-3, 17a-7, 17e-1, 17f-4, and 22c-1). *See also* Investment Company Institute, SEC No-Action Letter (Jun. 15, 1999) (revising the staff's previous position to permit a fund's adviser, rather than the fund's board, to evaluate the creditworthiness of repurchase agreement counterparties and otherwise assume primary responsibility for monitoring and evaluating the fund's use of repurchase agreements).

[26] *See* SEC, Notice of Sunshine Act Meetings (Feb. 18, 1999) [64 FR 8632 (Feb. 22, 1999)]; *see also* Transcripts from the Roundtable on the Role of Independent Investment Company Directors, February 23–24, 1999 [''Roundtable Transcripts'']. The Roundtable Transcripts are available to the public in the Commission's public reference room and the Commission's Louis Loss Library. They also are available on the Commission's Internet web site <http://www.sec.gov/offices/invmgmt/roundtab.htm>.

Participants also recommended that the selection of new independent directors be entrusted to existing independent directors and that independent directors have independent legal counsel.[27] An industry advisory group organized by the Investment Company Institute recently made similar recommendations in a ''best practices'' report (''ICI Advisory Group Report'').[28]

The recommendations of the Roundtable participants have led us to review our exemptive rules that provide funds and advisers relief from various statutory prohibitions designed to prevent the most egregious conflicts of interest. Roundtable participants repeatedly noted that one of the most important functions of independent directors is to oversee conflicts of interest.[29] Although the rules that we have adopted over the years have expanded the responsibilities of boards, the rules generally do not contain conditions designed to enhance the independence and effectiveness of fund boards, with two notable exceptions.[30]

Upon reflection, and in light of the recommendations of the Roundtable participants, we believe that our exemptive rules that rely on fund boards to approve and oversee arrangements or transactions that involve conflicts of interest and are otherwise prohibited by the Act also should contain provisions designed to enhance director independence and effectiveness. We therefore are proposing amendments to certain exemptive rules under the Investment Company Act to enhance the independence of fund directors who are charged with overseeing the fund's activities and transactions covered by those rules. These amendments would require, for funds that rely (or whose affiliated persons rely) on the rules, that: (i) independent directors constitute either a majority or a super-majority (two-thirds) of their boards; (ii) independent directors select and nominate other independent directors; and (iii) any legal counsel for the independent directors be an independent legal counsel.

Our proposals to enhance board independence would amend ten rules under the Investment Company Act. We have selected those rules that (i) exempt funds or their affiliated persons from provisions of the Act, and (ii) have as a condition the approval or oversight of independent directors. For convenience, we will refer to these rules as the ''Exemptive Rules.''[31] The Exemptive Rules typically relieve funds from statutory prohibitions that preclude certain types of transactions or arrangements that would involve serious conflicts of interest.[32] In one case, a rule permits the board to approve an interim advisory agreement without a shareholder vote that otherwise would be required.[33] Based on these criteria, we propose to amend the following rules:

- Rule 10f–3 (permitting funds to purchase securities in a primary offering when an affiliated broker-dealer is a member of the underwriting syndicate);
- Rule 12b–1 (permitting use of fund assets to pay distribution expenses);
- Rule 15a–4 (permitting fund boards to approve interim advisory contracts without shareholder approval);
- Rule 17a–7 (permitting securities transactions between a fund and another client of the fund's adviser);
- Rule 17a–8 (permitting mergers between certain affiliated funds);
- Rule 17d–1(d)(7) (permitting funds and their affiliates to purchase joint liability insurance policies);
- Rule 17e–1 (specifying conditions under which funds may pay commissions to affiliated brokers in connection with the sale of securities on an exchange);
- Rule 17g–1(j) (permitting funds to maintain joint insured bonds);
- Rule 18f–3 (permitting funds to issue multiple classes of voting stock); and
- Rule 23c–3 (permitting the operation of interval funds by enabling closed-end funds to repurchase their shares from investors).

The Commission requests comment on the criteria that we have used to select these rules. Are there additional rules that we should similarly amend? Conversely, should any of the Exemptive Rules not be amended?

Although the Commission urges all funds to adopt these measures to strengthen the independence of their boards, we are *not* proposing to require all funds to adopt these measures. Funds that do not rely on any of the Exemptive Rules will not be subject to these requirements. They may continue, for example, to have only 40 percent of their boards consist of independent directors.

As discussed above, an advisory group organized by the Investment Company Institute (''ICI Advisory Group'') has issued a report containing a set of ''best practices'' for ''enhancing a culture of independence and effectiveness'' of fund directors.[34] These best practices generally include some of the practices that our proposed rule amendments would require boards to adopt in order to rely on the Exemptive Rules. We applaud the initiative, but, as the report acknowledges, many of the ''best practices'' may be impracticable or unnecessary for all funds to adopt. Moreover, it may not be appropriate for us to address many of the

[27] *See infra* notes 41, 63, and 76 (citing testimony of Roundtable participants). We discuss the merits of each of these recommendations below.

[28] Investment Company Institute, Report of the Advisory Group on Best Practices for Fund Directors: Enhancing A Culture of Independence and Effectiveness (June 24, 1999). On July 7, 1999, the Board of Governors of the Investment Company Institute unanimously endorsed the recommended ''best practices.'' *See* ''ICI Board Adopts Resolution Urging Fund Industry to Strengthen Governance,'' at <http://www.ici.org/issues/dtrs__best__prac.htm>.

[29] *See, e.g.,* Roundtable Transcript of Feb. 24, 1999 at 174 (statement of John C. Coffee, Jr.) (stating that the need for activism by independent directors is most evident in the context of conflicts of interest); *id.* at 197 (statement of Richard M. Phillips) (''[T]he focal point of independent directors is conflicts of interest.'').

[30] Rule 12b–1, one of the exceptions, permits the use of fund assets to pay for distribution of fund shares, but only if the fund's independent directors select and nominate other independent directors. *See* rule 12b–1(c) under the Act [17 CFR 270.12b–1(c)]. In adopting this requirement, we stated our view that ''as a general proposition disinterested directors should not be entrusted with a decision on the use of fund assets for distribution without receiving the benefit of measures designed to enhance their ability to act independently.'' Bearing of Distribution Expenses by Mutual Funds, Investment Company Act Release No. 11414 (Oct. 28, 1980) [45 FR 73898 (Nov. 7, 1980)] [''Rule 12b–1 Adopting Release''], at text following n.50. Rule 23c–3, the other exception, permits the creation of so-called ''interval funds'' (i.e., closed-end funds that periodically offer to repurchase their securities from investors), but only if independent directors constitute a majority of the board, and select and nominate other independent directors. Rule 23c-3(b)(8) under the Act [17 CFR 270.23c–3(b)(8)]. These requirements were included in the rule to ''ensure that the board of directors provides independent decisions or scrutiny for actions or decisions that may involve a conflict of interest between the adviser and [the fund's] shareholders.'' Repurchase Offers by Closed-End Management Investment Companies, Investment Company Act Release No. 19399 (Apr. 7, 1993) [58 FR 19330 (Apr. 14, 1993)] [''Rule 23c–3 Adopting Release''], at Section II.D.

[31] A number of the Exemptive Rules exempt fund affiliates, rather than the fund, from certain statutory prohibitions. For ease of reference, this Release generally refers to *funds* that rely on the Exemptive Rules, rather than reiterating that funds or their affiliated persons may be relying on the rules.

[32] These rules also require boards of funds relying on the rules to exercise vigilance in protecting funds and their investors. *See, e.g.,* Exemption for the Acquisition of Securities During the Existence of an Underwriting or Selling Syndicate, Investment Company Act Release No. 22775 (July 31, 1997) [62 FR 42401 (Aug. 7, 1997)], at n.52 and accompanying text (the fund's board should be ''vigilant'' not only in reviewing the fund's compliance with the procedures required by rule 10f–3, but also ''in conducting any additional reviews that it determines are needed to protect the interests of investors'').

[33] *See* rule 15a–4 [17 CFR 270.15a–4]. Under section 15(a) of the Act, shareholders generally must approve a fund's contract with its adviser.

[34] ICI Advisory Group Report, *supra* note 28.

recommendations through rulemaking.[35] Thus, we are not at this time proposing to require that funds relying on the Exemptive Rules follow all of these practices. Nonetheless, we believe that fund boards should give serious consideration to the recommendations of the ICI Advisory Group. We request comment whether we should amend the Exemptive Rules, or other rules, to require funds relying on them to follow any of these ''best practices.'' Commenters who favor any of these practices also should address the benefits and burdens of amending the Exemptive Rules in this manner.

1. Independent Directors as a Majority of the Board

(a) Proposed Board Composition Requirements. We believe that a fund board that has at least a majority of independent directors is better equipped to perform its responsibilities of monitoring potential conflicts of interests and protecting the fund and its shareholders.[36] By virtue of its independence, and its ability to act without the approval of the investment adviser (whose employees often serve as interested, or ''inside,'' directors on fund boards), such a board is better able to exert a strong and independent influence over fund management.[37] This is particularly important in circumstances where the fund's interests conflict with those of the adviser.[38]

Today most, but not all, mutual funds have boards with at least a simple majority of independent directors.[39] When our Division of Investment Management studied mutual fund governance in 1992 it recommended that, as a requirement for all funds, independent directors constitute at least a majority of a fund's board.[40] Many of the Roundtable participants stated that, based on their experience, a fund board generally is more effective if independent directors represent a substantial majority of the board.[41] Similarly, the ICI Advisory Group Report recently endorsed boards having a ''super-majority'' of independent directors. The Report concluded that a *two-thirds* majority of independent directors on a board ''will be more effective than a simple majority in enhancing the authority of independent directors.''[42]

We take the conclusions of the ICI Report as a serious recommendation reflecting the collective experience and wisdom of the Advisory Group, which consisted of prominent members of the mutual fund industry.[43] Although the Report did not address whether Congress or the Commission should adopt a two-thirds majority as a regulatory requirement, it recommended the standard as a ''best practice'' for all funds to consider.[44] It is unclear, however, why a super-majority standard as a ''best practice'' would be appropriate for some fund boards and not others.

A simple majority requirement would permit, under state law, the independent directors to control the ''corporate machinery,'' *i.e.*, to elect officers of the fund, call meetings, solicit proxies, and take other actions without the consent of the adviser. Such a provision would require few funds to change the current composition of their boards, but would bring those that must change into conformity with the better practice. A two-thirds requirement, on the other hand, could change the dynamics of board decision-making in favor of the interests of investors, but may require many funds to change the composition of their boards.

In light of the potential benefits to funds, their boards, and shareholders, we are proposing to amend the Exemptive Rules to require funds relying on them to have boards with *at*

[35] In addition, because our rules apply to all funds (or, in the case of the Exemptive Rules, all funds that rely on those rules), we have designed our amendments by considering, among other things, the costs, benefits, and paperwork burdens for funds and investors (including small entities) that may result from the changes. *See, e.g., infra* Section III (cost-benefit analysis); Section IV (Paperwork Reduction Act analysis); Section V (Regulatory Flexibility Act analysis). In each area of consideration, we have requested comment on the costs, benefits, and burdens of the proposed rule amendments.

[36] *See* 1992 Protecting Investors Report, *supra* note 9, at 267 (''[A]n increased measure of independence is necessary to allow independent directors to perform these responsibilities appropriately.''). In the context of business development companies, Congress has recognized that having a majority of independent directors is particularly important ''where board approval is made expressly a substitute for Commission review or for a per se restriction.'' H.R. Rep. No. 1341, 96th Cong., 2d Sess. 25 (1980). *See also* S. Rep. No. 75, 94th Cong., 1st Sess. 71 (1975) (stating that the requirement in section 15(f) that 75 percent of a fund's board consist of directors who are not interested persons of the adviser for three years following the sale of an advisory contract is a ''safeguard [ ] to protect the investment company and its shareholders'').

[37] The original Senate bill that culminated in the Investment Company Act would have required a majority of a fund's directors to be independent from management. *See* S. 3580, 76th Cong., 3d Sess. § 10(a) (1940). That requirement was changed to 40 percent out of concern that a board with an independent majority would repudiate the recommendations of the investment adviser, depriving fund shareholders of those recommendations. *See Investment Trusts and Investment Companies: Hearings on H.R. 10065 Before the House Subcomm. on Interstate and Foreign Commerce,* 76th Cong., 3d Sess. 109–10 (1940) (statement of David Schenker). Experience has shown that this concern was unfounded. *See* 1992 Protecting Investors Report, *supra* note 9, at 267. Rather, we believe that an independent majority enhances board oversight without unnecessarily impeding fund operations or significantly increasing costs.

[38] We expressly recognized this when we adopted rule 23c–3. We included the requirements that independent directors constitute a majority of the board and select and nominate their successors to ''ensure that the board of directors provides independent decisions or scrutiny for actions or decisions that may involve a conflict of interest between the adviser and [fund] shareholders.'' Rule 23c–3 Adopting Release, *supra* note 30; *cf.* Peter Tufano & Matthew Sevick, *Board Structure and Fee-setting in the U.S. Mutual Fund Industry,* J. FiN. ECON. 321, 350 (1997) (''[T]he salutary benefits of * * * a higher fraction of independent directors [on a fund's board] should be *most visible* when management's and shareholders' interests are most at odds.'').

[39] *See* ICI Advisory Group Report, *supra* note 28, at 5 (''The vast majority of fund boards today consist of a majority of independent directors.''); Investment Company Institute, Understanding the Role of Mutual Fund Directors 5 (1998) (noting that most fund boards have a majority of independent directors). In some cases, fund boards have an independent majority in order to comply with certain requirements of the Act and our rules. *See, e.g.,* section 10(b)(2) (requiring, in effect, that independent directors comprise a majority of a fund's board if the fund's principal underwriter is an affiliate of the fund's investment adviser); section 15(f)(1) (providing a safe harbor for the sale of an advisory business if directors independent of the adviser constitute at least 75 percent of a fund's board for at least three years following the assignment of the advisory contract); rule 6e–3(T)(b)(15) [17 CFR 270.6e–3(T)(b)(15)] (exempting certain funds underlying insurance products from various Investment Company Act provisions provided that independent directors constitute a majority of the boards of those funds); rule 23c–3(b)(8) (permitting the operation of interval funds if, among other conditions, independent directors comprise a majority of the board).

[40] *See* 1992 Protecting Investors Report, *supra* note 9, at 267 (Division recommended that Investment Company Act be amended to require that independent directors constitute more than 50 percent of a fund's board); *see also* Wharton Report, *supra* note 10, at 35 (increasing the proportion of unaffiliated directors may enhance the value of those directors as a check on management).

[41] *See* Roundtable Transcript of Feb. 24, 1999 at 241 (statement of Aulana L. Peters) (''My experience * * * dictates that for a board to have a chance of operating truly independently * * * there should be at least two independent [ ] [directors] to one [inside director].''); *id.* at 265 (statement of Gerald C. McDonough) (recommending that fund boards be required to have ''a certain majority, 60, 66 percent, * * * certainly a clear majority of truly independent [directors]''); Roundtable Transcript of Feb. 23, 1999 at 136 (statement of Faith Colish) (endorsing a ''substantial majority'' of independent directors as a positive corporate governance feature for fund boards). *See also* Tufano & Sevick, *supra* note 38 (using empirical analysis to suggest that funds with boards that have a larger fraction of independent directors tend to have lower fees).

[42] *See* ICI Advisory Group Report, *supra* note 28, at 11.

[43] As noted above, the Board of Governors of the ICI also unanimously endorsed the recommendations of the ICI Advisory Group Report. *See supra* note 28.

[44] The Report also noted that, while many funds already have a two-thirds majority of independent directors, the practice is ''far from universal.'' ICI Advisory Group Report, *supra* note 28, at 11.

least a majority of independent directors. Comment is requested on whether we should adopt a simple majority requirement, as the staff recommended in 1992, or the two-thirds super-majority requirement recommended by the ICI Advisory Group Report. We also request comment whether we should adopt an even higher percentage requirement (*e.g.*, 75 percent or 100 percent).[45]

We note that the charters [46] of some funds may contain provisions that require the approval of greater than a majority of a fund's board for some matters, and, in light of our proposed amendments, other funds may amend their charters to provide that a board may act only upon the vote of greater than a simple (or two-thirds) majority of its members. Would the existence of these super-majority voting provisions in fund charters undercut the effectiveness of a board with a majority of independent directors by requiring the consent of the ''inside'' directors and thus, in many cases, give the adviser a veto over board votes? We request comment regarding the prevalence and potential effect of these voting provisions in fund charters.

If we adopt the proposed amendments, we expect to delay the compliance date for one year to allow funds to bring their boards into compliance with the majority independence condition to the Exemptive Rules.[47] As of the compliance date, any fund relying on an Exemptive Rule would be required to have a board with the requisite percentage of independent directors. We request comment on this transition period.

(b) Suspension of Board Composition Requirements. If the death, disqualification, or bona fide resignation of an independent director causes the representation of independent directors on the board to fall below that required under the Investment Company Act, section 10(e) of the Act suspends the percentage requirement for a short time to allow the vacancy to be filled.[48] Under section 10(e), the relevant percentage requirement is suspended for 30 days if the board may fill the vacancy,[49] or for 60 days if the vacancy must be filled by a shareholder vote.[50] Section 10(e) also authorizes the Commission to set a longer period for filling a board vacancy in these circumstances.[51]

In our experience, the time provided by section 10(e) is insufficient for most funds to select and nominate qualified independent director candidates, and, if necessary, hold a shareholder election. Many funds address this problem by avoiding the need to rely on the section—they have a greater percentage of independent directors than is required by the Act. This approach may become more difficult if, as we propose, funds relying on the Exemptive Rules must have a majority or a super-majority of independent directors.[52] Moreover, the consequence of a fund falling below the minimum required percentage of independent directors would be more severe and more immediate because the fund would lose the availability of the Exemptive Rules.[53]

The Commission is proposing new rule 10e–1 to address these concerns. Proposed rule 10e–1 would suspend the board composition requirements of the Act, and of the rules under the Act, for 60 days if the board of directors may fill the vacancy or 150 days if a shareholder vote is required.[54] We believe these longer time periods are appropriate in light of the need to select, nominate, and elect qualified candidates for service as independent directors.[55]

We request comment whether the proposed 60-day and 150-day periods are adequate to provide funds and their independent directors with the time needed to approve new independent directors. Commenters who believe that a longer or shorter period is appropriate should explain why, and specify the number of days they believe would be adequate.

2. Selection and Nomination of Independent Directors

Independent directors who are truly independent are more effective in their roles as ''watchdogs'' for fund shareholders. While the Investment Company Act precludes independent directors from having certain affiliations or relationships with the fund's adviser or principal underwriter,[56] no law can

[45] *See, e.g.*, section 15(f)(1) of the Act (providing a safe harbor for the sale of an advisory business if directors who are independent of the adviser constitute at least 75 percent of a fund's board for at least three years following the assignment of the advisory contract). The ICI Advisory Group Report discussed, but did not recommend at a best practice, having fund boards comprised exclusively of independent directors. *See* ICI Advisory Group Report, *supra* note 28, at 11–12. As a result of the Glass-Steagall Act, most bank-sponsored funds have boards comprised entirely of independent directors. *See* section 32 of the Glass Steagall Act [12 U.S.C. 78] (prohibiting directors of any entity issuing securities, such as a fund, from simultaneously serving as an officer, director, or employee of a national bank); *see also* Roundtable Transcript of Feb. 24, 1999 at 111 (statement of Richard J. Herring, independent director of a family of bank-related mutual funds and business school professor of international banking) (noting that a bank-related fund board comprised entirely on independent directors ''works quite well'').

[46] We use the term ''charters'' generally to include the organizational documents of a fund—typically articles of incorporation or declarations of trust, and corporate by-laws.

[47] There are several methods by which funds could affect the transition to majority independent representation on their boards. For instance, funds could (i) increase the size of their boards and elect new independent board members; (ii) decrease the size of their boards and allow some inside directors to resign; or (ii) allow some inside directors to resign and replace them with independent board members. A fund's ability to alter the composition of its board without holding a shareholder vote will be determined by state law and by section 16(a) of the Act [15 U.S.C. 89a–16(a)], which states that a fund's board may fill a board vacancy without a shareholder vote if, after the new director takes officer, at least two-thirds of the board has been elected by shareholders. Section 16(a) further requires a shareholder meeting to elect directors if the number of shareholder-elected board members decreases to less than half of the board. Newly organized funds could begin operations during the one-year transition period without a majority of independent directors and still rely on the Exemptive Rules, but they, like other funds, would be required to have boards with a majority of independent directors if they rely on any of the Exemptive Rules after the compliance date for the amendments.

[48] Various provisions of the Investment Company Act require a particular percentage or minimum number of independent directors. *See* sections 10(a), 10(b)(2), 10(d) [15 U.S.C. 80a–10(d)], and 15(f)(1); *see also supra* notes 20, 39, and 45 (discussing sections 10(a), 10(b)(2), and 15(f)(1) and their percentage requirements). Section 10(e) [15 U.S.C. 80a–10(e)] similarly suspends the board composition requirements of sections 10(d)(1), 10(b)(3), and 10(c) [15 U.S.C. 80a–10(b)(1), –10(b)(3), and –10(c)]. For convenience, we refer to all of the above requirements as ''percentage requirements.''

[49] *See* section 16(a) of the Act (permitting directors to fill a board vacancy if, after the new director takes officer, at least two-thirds of the board has been elected by shareholders, but requiring a shareholder meeting to elect directors if the number of shareholder-elected board members decreases to less then half of the board).

[50] Section 10(e)(1) and (2) [15 U.S.C. 80a–10(e)(1) and (2)].

[51] Section 10(e)(3) [15 U.S.C. 80a–10(e)(3)].

[52] *See supra* Section II.A.1.a.

[53] Currently, the loss of an independent director that causes a fund to fall below a statutorily required percentage of independent directors does not result in immediate consequences for a fund. Issues arise only when the fund's next board vote is required. Under the proposed amendments to the Exemptive Rules, however, the fund would be unable, for example, to offer multiple classes of shares, pay distribution fees under rule 12b–1, engage in securities transactions with fund affiliates, or participate in a joint liability insurance policy from the date of the loss of the independent director until the fund replaces the independent director.

[54] *See* proposed rule 10e–1.

[55] *See infra* Section II.A.2 (discussing the selection and nomination of independent directors by other independent directors); *cf.* Temporary Exemption for Certain Investment Advisers, Investment Company Act Release No. 23325 (July 22, 1998) [63 FR 40231 (July 28, 1998)] (proposing amendments to rule 15a–4 in part to extend, from 120 days to 150 days, the period of time funds are permitted to operate with an interim advisory contract that has not been approved by shareholders to allow funds more time to seek shareholder approval of an advisory contract).

[56] *See* section 2(a)(19)(B) [15 U.S.C. 80a–2(a)(19)(B)] (outlining the types of affiliations and

Continued

guarantee that an independent director will be vigilant in protecting fund shareholders. Fund shareholders therefore must depend on the character, ability, and diligence of persons who serve as fund directors to protect their interests.[57]

One recognized method of enhancing the independence of directors is to commit the selection and nomination of new independent directors to the incumbent independent directors.[58] Independent directors who are selected and nominated by other independent directors, rather than by the fund's adviser, are more likely to have their primary loyalty to shareholders rather than the adviser.[59] In addition, when independent directors are self-selecting and self-nominating, they are less likely to feel beholden to the adviser. Thus, they may be more willing to challenge the adviser's recommendations when the adviser's interests conflict with those of the shareholders.[60]

Two comprehensive studies that addressed mutual fund governance recognized that the selection and nomination of independent directors by other independent directors could enhance their independence.[61] In its guidebook for fund directors, the American Bar Association's Section of Business Law has endorsed this practice,[62] as did several participants at our Roundtable.[63] The recent ICI Advisory Group report also recommended the self-selection and self-nomination of independent directors.[64] As noted above, two of our rules currently require funds to have self-selecting and self-nominating independent directors,[65] and many fund groups have adopted this practice.[66]

We are proposing to amend each of the Exemptive Rules to require that funds relying on those rules have boards whose independent directors select and nominate any other independent directors.[67] Funds that have adopted distribution plans under rule 12b–1, which already contains this requirement, would be unaffected by the proposal.[68] Funds whose independent directors were not nominated in this manner would not immediately lose their ability to rely on the Exemptive Rules. Rather, if we adopt the proposed amendments, these funds would be required to adopt the practice before the compliance date for the amendments, and the fund's incumbent independent directors subsequently would select and nominate all independent directors of the fund.[69]

We understand that committing the selection and nomination of independent directors to a board committee composed entirely of independent directors might, in some cases, conflict with applicable state law.[70] We believe that a fund could comply with our proposed amendments in those circumstances if the fund's independent directors choose the candidates and then present their recommendations to the full board. We

relationships that render a director an ''interested person'' of a fund's adviser or principal underwriter).

[57] *See* Bearing of Distribution Expenses by Mutual Funds, Investment Company Act Release No. 10862 (Sept. 7, 1979) [44 FR 54014 (Sept. 17, 1979)] (proposing rule 12b–1) (''[P]roper fulfillment of directors' duties depends primarily on the character, ability, and diligence of directors.''); William G. Bowen, Inside the Boardroom: Governance by Directors and Trustees 47 (1994) (''Effective governance by any board surely depends, most of all, on having an outstanding group of members.''); Roundtable Transcript of Feb. 23, 1999 at 14–15 (statement of Arthur Levitt, Chairman, SEC) (''[B]oard independence does not come from a specific legal structure * * * I believe passionately in boards made up of men and women of good, sound independent judgment. Board independence comes from directors who do their jobs aggressively.'').

[58] Selection and nomination refers to the process by which board candidates are researched, recruited, considered, and formally named. Some funds establish a nominating committee of the board that is comprised entirely of independent directors to select and nominate directors.

[59] *See* ICI Advisory Group Report, *supra* note 28, at 14 (''[I]ndependent directors are uniquely qualified to evaluate whether a present or prospective director is likely to contribute to the continuing independence and effectiveness of the independent directors as a group.'').

[60] *See* ICI Advisory Group Report, *supra* note 28, at 14 (''[C]ontrol of the nominating process by the independent directors helps dispel any notion that the directors are 'hand picked' by the adviser and therefore not in a position to function in a true spirit of independence.'')

[61] *See* 1992 Protecting Investors Report, *supra* note 9, at 266–67 (recommending that the Act be amended to require that independent directors be self-nominating); Wharton Report, *supra* note 10, at 465–66 (noting that the selection of unaffiliated directors by management limits those directors' independence).

[62] *See* A.B.A., Section of Business Law, Fund Director's Guidebook 27 (1996) [''Fund Director's Guidebook''] (''The independence of a fund's independent directors is enhanced by providing that persons nominated by the board for election as independent directors be nominated by a committee of the fund's incumbent independent directors.'').

[63] *See* Roundtable Transcript of Feb. 24, 1999 at 182 (statement of John C. Coffee, Jr.) (''[W]e should have'' independent nominating committees.); Roundtable Transcript of Feb. 23, 1999 at 136 (statement of Faith Colish) (''a very good idea''); Roundtable Transcript of Feb. 24, 1999 at 63 (statement of Dawn-Marie Driscoll) (''I'm a great believer in independent directors choosing other independent directors who the adviser does not know. * * * The more ways you can ensure independence, the better the process will be.''); *id.* at 148 (statement of Ronald J. Gilson) (''A nominating committee made up of independent directors makes an enormous amount of sense.''); *id.* at 215 (statement of John R. Haire) (''[Self-selection and self-nomination are] very helpful in the process of seeing that * * * independent directors * * * bring to the board a diversity of skills that are useful * * * in the role of overseeing management.''); *id.* at 243 (statement of Aulana L. Peters) (''[I]t is not a good idea to have the adviser or the CEO of the adviser * * * be the sole decisionmaker on who should serve as a disinterested member of the board.''). *But see id.* at 245 (statement of Aulana L. Peters) (stating that the involvement of a fund's adviser in the selection and nomination of independent directors may facilitate increasing diversity on a fund's board).

[64] *See* ICI Advisory Group Report, *supra* note 28, at 14–16.

[65] Rule 12b–1 permits the use of fund assets to pay for distribution of fund shares, but only if the fund's independent directors select and nominate other independent directors. *See supra* note 30 (discussing rule 12b–1). In discussing our decision to include this condition in the rule, we noted that ''the likelihood that a decision will be in the best interests of a fund and its shareholders will be increased if the disinterested directors are genuinely independent of management,'' and that ''formal independence will breed an atmosphere in which actual independence will develop.'' Rule 12b–1 Adopting Release, *supra* note 30, at discussion of ''Independence of Directors.'' See also *supra note* 30 (discussing rule 23c–3, which permits the operation of interval funds if independent directors are self-selecting, self-nominating, and comprise a majority of the board). The Act also requires independent directors to select and nominate individuals to fill independent director vacancies for a period of three years following the sale of an investment advisory contract. Section 16(b) [15 U.S.C. 80a–16(b)].

[66] *See* ICI Advisory Group Report, *supra* note 28, at 15 (noting that funds with rule 12b–1 plans, which are required to have self-selecting and self-nominating independent directors, represent a majority of all mutual funds and that many funds without rule 12b–1 plans also assign to independent directors the selection and nomination of other independent directors); Joel H. Goldberg & Gregory N. Bressler, *Revisiting Rule 12b–1 Under the Investment Company Act*, 31 Rev. Sec. & Commodities Reg. 147, 147 (1998) (since the adoption of rule 12b–1 in 1980, over 7,000 mutual funds have adopted rule 12b–1 plans).

[67] *See* proposed rules 10f–3(b)(11)(i); 15a–4(c)(1); 17a–7(f)(1); 17a–8(c)(1); 17d–1(d)(7)(v)(A); 17e–1(c)(1); 17g–1(j)(3)(i); 18f–3(e)(1). In addition, we are proposing to amend rules 12b–1 and 23c–3 to conform their current language regarding the self-selection and self-nomination of independent directors to the language of the proposed amendments. Proposed rules 12b–1(c)(1) and 23c–3(b)(8)(i).

[68] Our proposals to amend rules 12b–1 and 23c–3 to conform their language regarding self-selection and self-nomination to the language of our proposed amendments are not intended to have any substantive effect on the operation of those rules. *See* proposed rules 12b–1(c)(1), 23c–3(b)(8)(i).

[69] Our proposed amendments would have no impact on the initial selection of an organizing fund's directors because, at the time of organization, the fund would not yet be registered under the Investment Company Act and therefore would not be relying on our Exemptive Rules. Any organizing fund that intends to rely on the Exemptive Rules, however, should adopt a self-selection and self-nomination practice, and once the fund begins operations, independent directors should select and nominate other independent directors as board vacancies occur.

[70] *See, e.g.*, ICI Advisory Group Report, *supra* note 28, at n.28 (discussing Md. Code Ann., Corps. & Ass'ns § 2–411(a)(2), which prohibits the bylaws of a Maryland corporation from authorizing the board to delegate to a committee the power to recommend to stockholders any action that requires stockholder approval). Section 2–411(a)(2) may have a greater effect on closed-end funds, which, unlike mutual funds, generally must hold annual meetings of shareholders at which shareholders elect directors.

request comment whether this approach adequately addresses any potential conflicts between state law and our proposed amendments regarding self-selection and self-nomination of independent directors.

Moreover, our proposals regarding the self-selection and self-nomination of independent directors are not intended to limit the abilities of public shareholders to nominate independent directors. To the extent permitted under state law, shareholders may participate in the nomination process.[71]

We request comment whether we should further amend the Exemptive Rules to require that independent directors, rather than the entire board, elect other independent directors in those instances when a shareholder vote is not required.[72] Commenters should discuss the effect state law would have on a fund board's ability to delegate its authority to elect directors to a subset of the board.

3. Independent Legal Counsel

Another recognized method of enhancing the independence and effectiveness of independent directors is to provide them with independent counsel.[73] Because mutual funds are highly regulated and their boards frequently are called upon to protect fund shareholders from conflicts of interest, independent counsel can be particularly helpful to independent directors of funds.[74] Experienced counsel can help to identify potential conflicts of interest and other compliance issues. They can assist directors in ''marshal[ling] arguments to balance those presented by management in matters involving conflicts of interest,'' and evaluating legal issues with an independent and critical eye.[75] Often, independent counsel can draw on their experience and knowledge to identify best practices of other funds that might be appropriate for directors to adopt for their fund.

We believe counsel who does not also represent the fund's adviser can best provide zealous representation of independent directors. Several of our Roundtable participants made this point,[76] as have many legal commentators over the years.[77] The recent ICI Advisory Group Report recommended that independent directors have qualified counsel who is independent from the fund's adviser and other service providers.[78] Courts too have recognized that independent legal counsel improves the deliberative process of fund independent directors.[79] As a result, independent directors of many funds retain legal counsel who does not also represent the adviser and, in some cases, does not represent the fund.

We are aware, however, that in some cases counsel has regularly represented the fund, the fund's adviser, and the independent directors. We have no doubt that such representation has been in conformity with applicable codes of legal ethics, which permit a lawyer to represent clients with conflicting interests after full disclosure and client consent.[80] We nevertheless are troubled by such conflicts and how they affect the ability of independent directors to carry out their responsibilities under the Act and the Exemptive Rules. We are particularly concerned when lawyers represent both the independent directors and management organizations in the negotiation of the advisory contract, distribution arrangements (*e.g.*, 12b–1 plans), and other matters of fundamental importance to a fund and its shareholders. Lawyers representing

[71] *See* Item 7(e)(2) of Schedule 14A (requiring that any proxy sent to shareholders for the purpose of electing directors state whether a registrant's nominating committee will consider nominees recommended by shareholders and describe the procedures to be followed by shareholders submitting nominee recommendations); *see also infra* note 224 and accompanying text.

[72] The ICI Advisory Group Report recommends that, to the extent permitted by state law, fund boards delegate to a fund's incumbent independent directors the authority to elect independent directors in the absence of a shareholder vote. *See* Advisory Group Report, *supra* note 28, at 15–16; *see also supra* note 47 (discussing section 16(a) of the Act and the circumstances under which fund directors may elect a board member without holding a shareholders vote).

[73] *See generally* Grover C. Brown, Michael J. Maimone, and Joseph C. Schoell, *Director and Advisor Disinterestedness and Independence Under Delaware Law,* 23 Del. J. Corp. L. 1157 (1998).

[74] *See* ICI Advisory Group Report, *supra* note 28, at 18 (''[Independent] counsel can help to ensure that the directors understand their responsibilities, ask the pertinent questions, and receive the information necessary to carry out those responsibilities.''); *What's the Job of Your Fund Counsel?,* Fund Directions, Nov. 1995, at 4, 5 (Independent directors ''look to their lawyer for assistance in resolving and acting upon any matters where the adviser potentially has a conflict of interest with the shareholders.' '') (quoting Edward T. O'Dell, partner, Goodwin, Procter & Hoar LLP).

[75] Joel H. Goldberg, *Disinterested Directors, Independent Directors and the Investment Company Act of 1940,* 9 Loy. U. Chi. L.J. 565, 585 (1978).

[76] *See* Roundtable Transcript of Feb. 24, 1999 at 178 (statement of John C. Coffee, Jr.) (''[T]he central lesson from corporate governance generally is that independent directors can function well as a committee if an probably only if they have the effective assistance of a truly independent legal counsel who does not generally represent the investment adviser and who does not have any other conflict.''); *id.* at 190–97 (statement of Leslie L. Ogg) (discussing the important role of service providers, including separate counsel, to fund independent directors); *id.* at 52 (statement of David M. Butowsky) (stating that independent directors should be counseled by someone ''who is completely independent of any affiliation with management when reviewing found reorganizations following the acquisition of an adviser); *id.* at 67 (statement of Joseph Hankin) (noting that retaining counsel separate from fund management is ''absolutely a prudent step'' when reviewing fund mergers and advisory contracts); *see also id.* at 222–23 (statement of David A. Sturms) (reviewing various structures of legal representation of a fund, its independent directors, and its adviser).

[77] *See, e.g.,* Martin Lipton, *Directors of Mutual Funds: Special Problems,* 31 BUS. LAW. 1259, 1262 (1976) (''[M]utual funds should have separate counsel. Either the independent directors of a fund should have separate counsel or the fund itself should have separate counsel. That is, separate counsel from counsel for the management company. Independent counsel plays a very important role.''); Goldberg, *supra* note 75, at 585 (''[T]he value of [independent] counsel in helping to ensure independent consideration of issues by disinterested directors is beyond dispute * * *.''); Jean W. Gleason, Mutual Fund Governance: Independent Directors—Their Role and Incentives and Tools for Fulfilling It, VI–A–9, VI–A–16 (1994) (material prepared for the 1994 Mutual Funds and Investment Management Conference) (''Access to, and use of, outside experts [such as independent legal counsel] can provide increased independence and allow for informed judgments [by independent directors] * * *.''). *See also* Public Policy Report, *supra* note 10, at 130–31 (listing the absence of separate legal counsel as one of the factors contributing to the relative ineffectiveness of unaffiliated directors).

[78] *See* ICI Advisory Group Report, *supra* note 28, at 18–20. The Advisory Group concluded that ''[c]ounsel to the independent directors must be independent from the adviser and other fund service providers in order to render objective advice on areas of potential conflict between the fund and its service providers.'' *Id.* at 18. *See also* Fund Director's Guidebook, *supra* note 62, at 23 (''[G]enerally it is important that the independent directors have ready access to counsel who views the board and the fund, not the adviser, as the client.'').

[79] *See* Tannenbaum v. Zeller, 552 F.2d 402, 428 (2d Cir. 1977) (stating that it would have been preferable if the fund's independent directors received advise from an independent counsel, rather than counsel who also represented the fund, the fund's adviser, and the fund's distributor); Fogel v. Chestnutt, 533 F.2d 731, 750 (2d Cir. 1975) (''It would have been * * * better to have the investigation of recapture methods and their legal consequences performed by disinterested counsel furnished to the independent directors.''); Schuyt v. Rowe Price Prime Reserve Fund, Inc., 663 F. Supp. 962, 965, 982, 986 (S.D.N.Y.) (noting that ''[d]uring all relevant times, the independent directors * * * had their own counsel'' who was an ''important resource'' and who advice ''the record indicates the directors made every effort to keep in mind as they deliberated''), *aff'd,* 835 F.2d 45 (2d Cir. 1987); Cartenberg v. Merill Lynch Asset Management, Inc., 528 F. Supp. 1038, 1064 (S.D.N.Y. 1981) (noting that the ''non-interested Trustees were represented by their own independent counsel * * * who acted to give them conscientious and competent advice''), *aff'd, 694 F.2d 923 (2d Cir. 1982). See also* Palilsky v. Berndt, [1976–1977 Transfer Binder] Fed. Sec. L. Rep. (CCH) ¶ 95,627, 15 90,133 (S.D.N.Y. June 24, 1976) (noting that a law firm, in advising both a fund and the fund's adviser, ''was counseling people with contrary interests. * * * The effect of the inadequate advice was to discourage any independent inquiry by * * * [the] Board.'').

[80] *See* American Bar Association, Center for Professional Responsibility, Model Rules of Professional Conduct [''ABA Model Rules''], Rule 1.7 (1998); *see also* Del. Prof. Cond. R. 1.7 (1998); MASS. SUP. JUD. CT.R. 3:07, R.P.C. 1.7 (1999); Md. Rule 1.7 (1998).

fund management may not suggest courses of action to independent directors that are opposed by their management clients. Thus, we are proposing to amend the Exemptive Rules to require that counsel for a fund's independent directors not also act as counsel to the fund's adviser, principal underwriter, or administrator (or their control persons).[81]

We are not, however, proposing at this time to *require* independent directors to retain legal counsel. Although we believe that independent directors are in the best position to fulfill the roles assigned to them by the Exemptive Rules if they have the assistance of independent counsel, the services of counsel do not come without cost.[82] We are hesitant to propose a rule that might result in the engagement of legal counsel simply to fulfill a legal requirement. Moreover, we believe that a likely result of our proposed amendments would be that fund directors will seek independent counsel. Comment is requested whether we should amend the Exemptive Rules to require independent directors of funds relying on those rules to retain independent legal counsel. Would this requirement impose substantial costs on small fund groups? If we adopt this condition to the Exemptive Rules, should we provide for an exception for smaller fund groups? If so, what factors should determine which fund groups are small?

Under the proposed amendments, reliance on each of the Exemptive Rules would be conditioned on any legal counsel for a fund's independent directors being an ''independent legal counsel.''[83] A person would be an ''independent legal counsel'' if the fund reasonably believes the person and his law firm, partners, and associates[84] have not acted as legal counsel for the fund's investment adviser, principal underwriter, administrator[85] (collectively, ''management organizations''), or any of their control persons[86] at any time since the beginning of the fund's last two completed fiscal years.[87] The independent directors could make an exception and permit a person to serve as independent legal counsel even if the person has a remote or minor conflict of interest because the person has provided legal advice to management organizations or their control persons.[88]

(a) Independent of Fund Management Organizations. The proposed amendments would treat as fund management organizations, fund advisers (including sub-advisers), principal underwriters, and fund administrators.[89] We are proposing to include fund administrators because, in some fund complexes, an administrator performs many of the management functions traditionally performed by a fund's adviser, and thus may have the same types of conflicts as an investment adviser sponsoring a fund.[90] The limitations on dual representation also would extend to *control persons* of fund management organizations: persons who directly or indirectly control, are controlled by, or are under common control with the adviser, principal underwriter, or fund administrator.[91] Counsel to both a parent company of the fund's adviser and a fund's independent directors, for example, may face the same conflicts as those faced by counsel to the fund's adviser and the fund's independent directors.[92] We request comment whether the amendments should extend to other types of service providers in addition to management organizations,[93] and to persons other than control persons (*e.g.*, affiliated persons of a management organization).

Under the proposed amendments, a person could be an independent legal counsel to a fund's independent directors regardless of the nature and amount of legal services he or she provides to the fund itself. A person acting as both fund counsel and independent director counsel ordinarily should not have the types of conflicts of interest that would diminish the counsel's ability to provide zealous

[81] Our proposals are not intended to regulate the practice of law, but rather to delimit the ability of independent fund directors to waive certain conflicts of interest. In other contexts, fiduciaries have been similarly restricted in their ability to waive conflicts. *See, e.g.*, section 327 of the U.S. Bankruptcy Code [11 U.S.C. 327] (bankruptcy trustee generally cannot employ a counsel who represents an interest adverse to the estate in bankruptcy, and any counsel employed by the trustee must be a disinterested person); Md. Regs. Code tit. 13 § 105 (attorney to a receiver or assignee in bankruptcy must meet prescribed independence standards, including that the attorney does not represent an interest adverse to the estate). *See also* rule 116.5 of the Bureau of Indian Affairs [25 CFR 116.5] (no person with a personal, financial, or business connection to a trustee of restricted Indian property may act as an appraiser of that property in connection with loans made from the trust).

[82] In the 1992 Protecting Investors Report, the staff of the Division of Investment Management considered, but did not recommend, requiring funds to provide independent directors with their own counsel. While the staff recognized the benefits of separate counsel for independent directors, it was concerned about the costs associated with requiring separate counsel in all cases. *See* 1992 Protecting Investors Report, *supra* note 9, at 268.

[83] *See* proposed rules 10f–3(b)(11)(ii); 12b–1(c)(2); 15a–4(c)(2); 17a–7(f)(2); 17a–8(c)(2); 17d–1(d)(7)(v)(B); 17e–1(c)(2); 17g–1(j)(3)(ii); 18f–3(e)(2); 23c–3(b)(8)(ii).

[84] The proposed definition of an independent legal counsel would apply to a ''person.'' *See* proposed rule 0–1(a)(6)(i). The term ''person'' would have the same meaning as in section 2(a)(28) of the Act [15 U.S.C. 80a–2(a)(28)] and, in addition, would include a partner, co-member, or employee of any person. *See* proposed rule 0–1(a)(6)(ii)(A). The term ''co-member'' is intended to address law firms organized as limited liability companies. The interest-holders of limited liability companies generally are called ''members.''

[85] *See infra* note 89.

[86] *See infra* note 91 and accompanying text.

[87] *See* proposed rule 0–1(a)(6)(i)(A). We intend that the phrase ''act as legal counsel'' as used in the proposed definition of ''independent legal counsel'' will have the same meaning that it has for purposes of section 2(a)(19)(B)(iv) [15 U.S.C. 80a–2(a)(19)(B)(iv)]. The staff has interpreted the phrase ''acts as legal counsel'' broadly. *See* 399 Fund, SEC No-Action Letter (Sept. 2, 1973) (fund directors would be an ''interested person'' because his firm had entered an appearance on behalf of certain officers and directors of the fund's adviser in litigation unrelated to the fund); Alpha Investors Fund, Inc., SEC No-Action Letter (Jan. 9, 1972) (fund director would be an ''interested person'' because his firm had performed two small legal projects for a company that owned a 50 percent share of an adviser to a fund).

In some cases, ethics rules permit counsel to accept payment for legal services from a non-client third party. *See* ABA Model Rules, *supra* note 79, rule 1.8(f) (1998) (counsel may accept compensation from a third party if (i) the client consents after consultation, (ii) there is no interference with counsel's independence of professional judgment or with the attorney-client relationship, and (iii) counsel maintains client confidentiality); *see also id.* Rule 1.7 cmt. 10 (''Interest of Person Paying for a Lawyer's Service''). Under our proposed amendments, we would not view a lawyer as ''acting as legal counsel'' to a fund's investment adviser merely because the lawyer accepts payment of fees from the adviser for legal services performed on behalf of the fund or its independent directors as permitted by relevant professional ethics rules.

[88] *See infra* Section 11.A.3(d) ''Exception''; proposed rule 0–1(a)(6)(i)(B).

[89] We are proposing to define ''administrator'' as any person who provides significant administrative or business affairs management services to a fund. Proposed rule 0–1(a)(5). This definition is substantially similar to, and has the same meaning as, the definition of administrator contained in Item 22(a)(1)(i) of Schedule 14A and Item 15(h)(1) of Form N–1A.

[90] Funds are increasingly turning to third-party fund administrators to provide an array of services, including shareholder servicing, recordkeeping, accounting, and fund distribution. *See* Jackie Cohen, *Priming the Pump for Better Mutual Fund Sales*, Bank Tech. News, June 1998, at 43; Katharine Fraser, *Fund Administrators Vie for Megabank Pacts*, Am. Banker, May 27, 1998, at 10. As of December 31, 1998, third-party fund administrators had approximately $527 billion in assets under administration. *See generally* Lipper Inc., Lipper Directors' Analytical Data: Executive Summary (1st ed. 1999) (providing estimates of fund assets administered by entities other than funds, from which estimates of fund assets administered by entities unaffiliated with the fund may be derived).

[91] The definition of ''control person'' would exclude funds. This exclusion enables the same counsel to represent a fund and its independent directors. *See* proposed rule 0–1(a)(6)(ii)(B); *see also infra* note 94 and accompanying text.

[92] This could be the case even if the legal work performed for the control person is unrelated to the fund or its operations.

[93] *See* ICI Advisory Group Report, *supra* note 28, at 19 (recommending counsel for the independent directors who is independent from all of the fund's service providers).

representation of independent directors.[94] Similarly, our proposal would not preclude counsel from representing the independent directors of multiple funds affiliated with the same management organization. We request comment on this provision.

(b) Two-Year Period. Section 2(a)(19) of the Act prevents any person who has acted as legal counsel to a fund's adviser or principal underwriter during the last two years from serving as an independent director of the fund.[95] This section reflects Congress's belief that acting as counsel to fund management organizations creates conflicts that may affect a person's ability to represent shareholder interests. Based upon similar considerations, the proposed amendments would (subject to the exception discussed below) preclude a person from acting as counsel for independent directors for two years after having acted as legal counsel to a fund management organization or its control person. As in section 2(a)(19), the disqualification would apply to any partner or employee of a person who acted as legal counsel to the management organization or its control person.[96]

(c) Reasonable Belief. The proposed amendments would require the fund to have a ''reasonable belief'' that counsel to the independent directors meets the requirements of the independent legal counsel definition. If, despite the fund's reasonable belief, counsel does not actually meet the requirements, the fund would not lose the ability to rely on any of the Exemptive Rules. A fund could form a reasonable belief based on a representation from counsel. If the fund relies on counsel's representation, the fund also should obtain an undertaking that the counsel will inform the fund and the independent directors if it begins to act as legal counsel to the fund management organizations or any of their control persons.

(d) Exception. As discussed above, these proposed amendments are intended to assure that independent directors have the benefit of counsel who is free from the types of conflicts that may affect the advice provided to independent directors. The scope of the proposed limitation, described above, is broad and covers direct and indirect conflicts. As a result, the proposed amendments might preclude a person from serving as counsel to a fund's independent directors because of a remote or minor conflict involving, for example, a law-firm partner who represented an affiliate of the fund's adviser in a minor real estate transaction. Therefore, the proposed definition of ''independent legal counsel'' includes an exception that would permit the independent directors to retain the counsel if they determine that the counsel's representation was ''so limited that it would not adversely affect the counsel's ability to provide impartial, objective, and unbiased legal counsel to the [independent] directors.'' [97]

The exception would not permit waivers in all instances, but only in circumstances where the nature or extent of the conflict is minor. We would expect that the independent directors, in making a determination under the exception, would consider all relevant factors. These factors could include whether the representation presented a direct and ongoing conflict with the fund, the amount of legal fees generated by the representation, and the nature and the extent of the affiliation between a control person and a fund management organization. The basis for any determination under this provision also must be recorded in board meeting minutes.[98]

We request comment on the approach we have taken. Should independent directors who engage legal counsel under the exception to the general rule be required to make findings different from those proposed? For example, the Blue Ribbon Committee on Improving the Effectiveness of Corporate Audit Committees recommended that a director who does not meet proposed independence standards be allowed to serve as a member of a company's audit committee if the board, under exceptional and limited circumstances, determines that membership on the committee is required by the best interests of the company and its shareholders, and the board discloses, in the next annual proxy statement, the reasons why the director does not meet the independence standards and the reasons for the board's determination.[99] Should we also require public disclosure of the independent directors' determination regarding their counsel's conflict and the nature of that conflict? If so, in what document should the disclosure be made?

(e) Transition Period. If we adopt the proposals after the comment period, counsel for the independent directors of funds relying on any of the Exemptive Rules would not be required to be ''independent legal counsel'' until the compliance date established in the adopting release. We believe that independent directors of most fund groups would not be required to seek new counsel. In some cases, however, they may. Comment is requested on the transition time that independent directors would need to hire new counsel.

B. Limits on Coverage of Directors Under Joint Insurance Policies

The oversight responsibilities that the Act assigns to independent directors [100] may create tensions between those directors and the fund's adviser [101] that can lead to disputes.[102] A dispute among these parties that escalates to the level of a lawsuit can result in significant legal expenses for the independent directors.[103]

Funds typically purchase ''errors and omissions'' insurance policies (''D&O/E&O policies'') [104] to cover expenses

[94] *See id.* at 18–19 (''The Adisory Group believes that counsel for the independent directors also may serve as fund counsel because, in virtually every situation except possibly litigation, the interests of the fund and its directors are aligned.''). *But see* Roundtable Transcript of Feb. 24, 1999 at 179 (statement of John C. Coffee, Jr.) (noting that counsel to a fund invariably works closely with, and generally receives work requests from, personnel of the adviser who manages the fund, and that the close association with the adviser that results from representing the fund could influence the counsel's representation of the independent directors).

[95] Section 2(a)(19)(B)(vi). Section 2(a)(19)(A)(iv) of the Act [15 U.S.C. 80a–2(a)(19)(A)(iv)] also precludes a person who has acted as *fund* counsel from serving as an independent director of that fund for at least two years. As discussed above, our proposal would not preclude counsel to a fund from serving as counsel to a fund's independent directors. *See supra* note 94 and accompanying text.

[96] *See* proposed rule 0–1(a)(6)(ii)(A); *see also supra* note 84.

[97] *See* proposed rule 0–1(a)(6)(i)(B).

[98] *See id.*

[99] *See* Report and Recommendations of the Blue Ribbon Committee on Improving the Effectiveness of Corporate Audit Committees 11 (1999) [''Blue Ribbon Committee Report''].

[100] *See supra* notes 12–24 and accompanying text; *see also* section 36(a) of the Act [15 U.S.C. 80a–35(a)] (enabling federal lawsuits to be brought against fund directors for breaches of fiduciary duty involving personal misconduct).

[101] *See* Roundtable Transcript of Feb. 24, 1999 at 234 (statement of Gerald C. McDonough) (''The adversarial role * * * of independent [directors] and fund advisers is a healthy and desirable one.'').

[102] *See* David A. Sturms, The Debate: The System is Broken—Fix It or Scrap It vs. The System Works—Don't Fix What Isn't Broken 4–7 (materials prepared for SEC Roundtable on the Role of Independent Investment Company Directors, Feb. 23–24, 1999) (discussing recent disputes between independent directors of funds and the funds' advisers).

[103] *See* ICI Advisory Group Report, *supra* note 28, at 26 (''[L]itigation [involving independent directors] can be extremely expensive and may even carry with it a potential for personal financial ruin.'').

[104] D&O/E&O policies generally insure directors and officers of an insured entity (*e.g.*, a fund) for claims made against them for their designated acts, errors, or omissions. *See generally* Spiro K. Bantis, ''What Mutual Fund D&O/E&O Policies Don't Cover''; Ellen Metzger, Mutual Fund D&O/E&O Insurance: Considerations in Selecting and

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incurred by directors and officers in the event of litigation.[105] Often these policies are joint policies that cover numerous funds within a fund family as well as the adviser and principal underwriter of those funds. Although the Investment Company Act and our rules generally prohibit joint transactions and other joint arrangements involving a fund and its affiliates,[106] rule 17d–1(d)(7) permits the purchase of joint D&O/E&O policies.[107]

Joint D&O/E&O policies historically have excluded claims in which the parties under the policy sue each other.[108] A policy that insures both a fund's investment adviser and its independent directors therefore may not cover the independent directors' expenses of litigation with the fund's adviser. Without this coverage, independent directors face substantial personal legal expenses in the event of a lawsuit.[109]

The exclusion of coverage under joint policies creates a potential threat to directors' personal assets, which can hamper directors' willingness to question management and weaken their resolve to protect fund shareholders in the event of a conflict with the adviser. Because we are concerned about the effect that these exclusions may have on the ability of independent directors to carry out their statutory responsibilities, we propose to amend rule 17d–1(d)(7) to make the rule available only for joint liability insurance policies that do not exclude coverage for litigation between the independent directors and the fund's adviser.[110] These proposals are intended to allow independent directors to engage in the good faith performance of their statutory responsibilities without concern for their personal financial security.[111]

We request comment on the proposed amendments to rule 17d-1(d)(7) concerning the purchase of joint D&O/E&O policies. The ICI Advisory Group Report recommended more broadly that fund boards should consider obtaining D&O/E&O insurance policies and/or indemnification from the fund ''that is adequate to ensure the independence and effectiveness of independent directors.'' [112] The proposed amendments do not require that funds obtain insurance coverage or indemnification for independent directors, so that funds will have the latitude to determine which arrangements are appropriate for their circumstances. We request comment whether we should further amend rule 17d-1(d)(7) to require that joint insurance polices purchased under the rule be in an amount adequate to ensure that independent directors can perform their duties in an independent and effective manner, and what that amount might be.

C. Exemption From Ratification of Independent Public Accountant Requirement for Funds With Independent Audit Committees

The Investment Company Act requires that a fund's independent directors select the fund's independent public accountant.[113] The Act further requires that the selection of the fund's independent public accountant be submitted to shareholders for ratification or rejection at their next annual meeting.[114]

We have observed that shareholders rarely contest votes over the ratification of the selection of a fund's independent accountant. Many believe shareholder ratification has become perfunctory. This may have occurred because of the growth of funds,[115] their organization into large complexes, the increased complexity of accounting issues, or the consolidation of accounting firms, which have made it impracticable for shareholders to evaluate the qualifications and independence of fund auditors. We are proposing, therefore, to exempt funds from the shareholder ratification requirement if the auditor is subject to the oversight and direction of an audit committee consisting entirely of independent directors.

Today, in many corporations and fund complexes, audit committees play an important and growing role in assuring the integrity of financial statements.[116] The current listing

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Maintaining a Policy; Natalie Shirley, Claims—What to Do When the Unthinkable Happens; Daniel T. Steiner, Selected Issues Regarding Basic Policy Forms (collected materials from 1995 Mutual Funds and Investment Management Conference, Mutual Fund D&O/E&O Insurance 101).

[105] Under the Act, a fund's organizational documents cannot contain any provision protecting a director or officer of the fund from any liability to the fund or its shareholders to which he is subject by reason of willful misfeasance, bad faith, gross negligence, or reckless disregard of the duties involved in the conduct of his office. *See* section 17(h) of the Act [15 U.S.C. 80a–17(h)]; *see also* Interpretive Release, *supra* note 1, Section II.C (discussing section 17(h) and providing guidance regarding when a fund may pay an advance of legal fees to its directors).

[106] *See* section 17(d) [15 U.S.C. 80a–17(d)] (prohibiting an affiliated person of a fund from effecting a joint transaction with the fund in contravention of Commission rules); rule 17d–1 [17 CFR 270.17d–1] (prohibiting a fund affiliate from participating in any joint enterprise, joint arrangement, or profit-sharing plan with a fund without first obtaining a Commission order, except in certain designated circumstances); *see also* Interpretive Release, *supra* note 1, Section II.B (discussing section 17(d) and rule 17d–1 and explaining the view of the staff that actions taken by fund directors within the scope of their duties for the fund generally would not be joint transactions under section 17(d) and rule 17d–1).

[107] 17 CFR 270.17d–1(d)(7). Reliance on rule 17d–1(d)(7) currently is conditioned on a fund's board, and a majority of its independent directors, annually determining that the joint policy is in the best interests of the fund and that the proportion of the policy's premium allocated to the fund is fair and reasonable.

[108] *See* ICA Advisory Group Report, *supra* 28, at 26. The general purpose of these standard ''insured versus insured'' exclusions is to prevent collusion among insureds.

[109] *See* Paul H. Dykstra and Paulita Pike-Bokhari, *The Yacktman Battle: Manager Bites the Watchdogs*, Investment Law., Nov./Dec. 1998, at 1, 9–10 (discussing the effect of an ''insured versus insured'' exclusion of insurance coverage on independent directors of the Yacktman Fund).

[110] Proposed rule 17d–1(d)(7)(iii). The proposed amendments would prohibit exclusions for bonafide (*i.e.*, non-collusive) claims made against any independent director by another person insured under the joint insurance policy. The proposed amendments also would prohibit exclusion of coverage for the fund if it is a co-defendant with an independent director in a claim brought by a co-insured. We believe that the ability of fund directors to perform their duties may be further impaired if an adviser's lawsuit poses a threat to fund assets as well as to director's personal assets.

[111] Earlier this year, Chairman Levitt expressed concern about standard ''insured versus insured'' exclusions. *See* Arthur Levitt, Keeping Faith with the Shareholder Interest: Strengthening the role of Independent Directors of Mutual Funds (remarks at the Mutual Funds and Investment Management Conference, Palm Springs, CA, Mar. 22, 1999), available at <http://www.sec.gov/news/speeches/spch259.htm>. In response, the ICI Mutual Insurance Company (''ICI Mutual''), which insures funds representing approximately 70 percent of all mutual fund assets, recently announced that it has revised its D&O/E&O policies to clarify that these types of claims are covered under its standard insurance policy. *See* Aaron Lucchetti, *Direct and Protect*, Wall St. J., April 2, 1999, at C23. ICI Mutual now makes available a standard policy endorsement that permits independent directors to recover defense costs, settlements, and judgments in ''insured versus insured'' claims otherwise covered under the policy. This change by ICI Mutual is a significant step toward ensuring the ability of independent directors to vigorously fulfill their duties under the Act without concerns of personal liability. We believe, however, that all independent directors who serve on funds that obtain joint liability insurance policies should have the benefit of protections similar to those provided by ICI Mutual.

ICI Advisory Group Report, *supra* note 28, at 26. the Report also noted that independent directors may need to be covered by insurance after their service on the board has ended for claims involving their service as directors. *Id.* at 26–27.

[113] Section 32(a)(1).

[114] Section 32(a)(2) [15 U.S.C. 80a–31(a)(2)].

[115] *See supra* note 3 and accompanying test.

[116] *See generally* A.B.A., Section of Business Law, Corporate Director's Guidebook 27–32 (2d ed. 1994) [''1994 Corporate Director's Guidebook'']; *See also* Investment Company Institute, Understanding the Role of Mutual Fund Directors 7 (1998) (noting that although not required by law, it is common practice for mutual funds to have an audit committee oversee the financial reporting and internal controls of the fund and stating that the results of a 1998 survey conducted by Management Practice Inc. indicated that 100 percent of fund boards surveyed had an audit committee); Fund Director's Guidebook, *supra* note 62, at 26 (stating that the audit committees of many funds are comprised of all of the fund's independent directors).

requirements of the primary U.S. securities exchanges require publicly traded companies to have audit committees,[117] and many commentators have recognized the value of independent audit committees and the significance of their function in a corporate governance structure.[118] Recently, the Blue Ribbon Committee on Improving the Effectiveness of Corporate Audit Committees emphasized the important role of audit committees and recommended enhanced responsibilities, membership standards, and methods of operation designed to strengthen their oversight function.[119] The ICI Advisory Group Report, furthermore, recommended that fund boards establish audit committees comprised entirely of independent directors.[120]

We believe that the ongoing oversight provided by an independent audit committee can provide greater protection to shareholders than the current requirement for shareholder ratification of a fund's independent auditors. We therefore are proposing a rule that would exempt a fund from the Act's requirement that shareholders ratify or reject the selection of the fund's independent public accountant if the fund has an audit committee comprised wholly of independent directors.[121] In order for a fund to rely on the proposed exemption, (i) the audit committee must be responsible for overseeing the fund's accounting and auditing processes,[122] (ii) the fund's board of directors must adopt an audit committee charter setting forth the committee's structure, duties, powers, and methods of operation,[123] and (iii) the fund must maintain a copy of the charter.[124]

We request comment regarding the conditions of the proposed rule. Should the exemption require that the charter set forth certain specific responsibilities and methods of operation? Should funds relying on the exemption be required to provide a copy of their audit committee charter as an exhibit to their registration statement, and should the board be required to review the charter on an annual basis? Should the exemption require fund audit committees to obtain an annual representation from the fund's independent public accountant certifying its independence, as the ICI Advisory Group suggested?[125] Should the exemption include other conditions that are similar to the recommendations of the ICI Advisory Group and Blue Ribbon Committee on Improving the Effectiveness of Corporate Audit Committees?

The proposed rule assumes that the appropriate form for the instrument governing an audit committee is a charter. Should the rule explicitly recognize that the audit committee provisions could be included in a document other than the charter, such as the fund's by-laws, articles of incorporation, or declaration of trust?

D. Qualification as an Independent Director

In addition to the amendments to enhance the independence of fund boards, we are proposing amendments to prevent qualified individuals from being unnecessarily disqualified from serving as independent directors. The Investment Company Act sets standards for who may be considered an independent director.[126] While these standards are meant to exclude individuals with affiliations or business interests that can impair their independence, there are circumstances in which the standards may cause certain individuals to be unnecessarily disqualified from serving as an independent director. For this reason, Congress directed the Commission to apply the standards ''in a flexible manner'' and adopt appropriate exemptions.[127] Today we are proposing (i) to amend the rule that permits directors to be considered independent directors even if they are affiliated with a broker-dealer, and (ii) a new rule that would prevent directors from being disqualified as independent directors solely because they own shares of index funds that hold limited interests in their fund's adviser or principal underwriter.

1. Affiliation With a Broker-Dealer

Section 2(a)(19) of the Act provides that no person can be an independent director if he is, or is affiliated with, a registered broker-dealer.[128] This provision is designed to prevent independent directors from being influenced by a business relationship with broker-dealers.[129] Rule 2a19–1 under the Act provides relief from this provision under certain conditions, but only if no more than a minority of a

[117] *See e.g.,* New York Stock Exchange Listed Company Manual ¶ 303.00.

[118] *See, e.g.,* Roundtable Transcript of Feb. 23, 1999 at 236 (statement of Manuel H. Johnson) (noting that an audit committee comprised entirely of independent directors serves as a check and balance); 1994 Corporate Director's Guidebook, *supra* note 116, 27 (''The Audit Committee should be composed solely of independent directors.''); Fund Director's Guidebook, *supra* note 62, at 25–26 (noting that the boards of many public companies, including funds, have established audit committees at the urging of many governmental and non-governmental institutions that have determined that audit committees can play a meaningful role in ensuring corporate accountability), *The Role and Composition of the Board of Directors of the Large Publicly Owned Corporation: Statement of the Business Roundtable,* 33 Bus. Law. 2083, 2108, 2109 (1978) (''[W]e believe it highly desirable * * * that the board be served by an Audit Committee.'' THe audit committee should be ''composed entirely of non management directors.'') Report of the National Commission on Fraudulent Financial Reporting 12 (Oct. 1987) [''Treadway Report''] (''The audit committee on the board of directors plays a role critical to the integrity of the company's financial reporting. [We] recommend[] that all public companies be required to have audit committees composed entirely of independent directors.''); Advisory Panel on Auditor Independence, Strengthening the Professionalism of the Independent Auditor 14 (Sep. 13, 1994) (Special Report to the Oversight Board of the SEC Practice Section, AICPA [''Kirk Panel Report''] (noting that it is important that companies have audit committees of independent directors).

[119] Blue Ribbon Committee Report, *supra* note 99. With respect to independence of audit committee members, the Blue Ribbon Committee Report states:

[I]t is widely recognized that each member of the audit committee should be an independent director. Several recent studies have produced a correlation between audit committee independence and two desirable outcomes: a higher degree of active oversight and a lower incident of financial statement fraud. In addition, common sense dictates that a director without any financial, family, or other material personal ties to management is more likely to be able to evaluate objectively the propriety of management's accounting internal control and reporting practices.

Id. at 22.

[120] ICI Advisory Group Report, *supra* note 28, at 22–23.

[121] *See* proposed rule 32a–4(b). A closed-end fund listed on a stock exchange also is subject to the exchange's listing requirements regarding audit committees. *See, e.g., Supra* note 117 and accompanying text.

[122] Proposed rule 32a–4(a).

[123] Proposed rule 32a–4(c).

[124] Proposed rule 32a–4(d). Under the current requirements of rule 31a–1(b)(4) [17 CFR 270.31a–1(b)(4)], funds also would be required to maintain minute books of the audit committee's meetings.

[125] *See* ICI Advisory Group Report, *supra* note 28, at 22–23. *Cf.* Independence Standards Board Standard No. 1: Independence Discussions with Audit Committees (Jan. 1999) (requiring, for all funds with fiscal years ending after July 19, 1999, that a fund's auditor provide an annual representation of the auditor's independence).

[126] For example, the Act provides that no person can be an independent director to a fund if he is affiliated with the fund itself, or with the fund's investment adviser or principal underwriter. Section 2(a)(19)(A)(i), (A)(iii), (B)(i) [15 U.S.C. 80a–2(a)(19)(A)(i), (A)(iii), (B)(i)]. *See generally infra* note 170.

[127] *See* H.R. Rep. No. 1382, 91st Cong., 2d Sess. 15 (1970).

[128] Section 2(a)(19)(A)(v), (B)(v) [15 U.S.C. 80a–2(a)(19)(A)(v), (b) (v)].

[129] *See* The First Australia Fund, Inc., SEC No-Action Letter, at n.8 and accompanying text (Oct. 8, 1987) (''The broad scope of section 2(a)(19) with respect to brokers and dealers appears to have been prompted by the many subtle relationships that exist between persons who are active in the securities markets.'') (citing Public Policy Report, *supra* note 10, at 162–88). Congress also may have adopted this broad prohibition reaction to the nature of fund brokerage arrangements when fixed commission rates were prevalent. *See* Certain Persons Not Deemed Interested Persons; Definition of Regular Broker or Dealer, Investment Company Act Release No. 13920 (May 2, 1984) [49 FR 19519 (May 8, 1984)] at n.1 [''Rule 2a19–1 Proposing Release'']

fund's independent directors are broker-dealers or affiliated with broker-dealers.[130] When we proposed this condition in 1984, we explained that allowing all of the fund's independent directors to be affiliated with broker-dealers would be inconsistent with Congress's intent to separate independent directors from the brokerage industry.[131]

In recent years, some directors have been unable to qualify as independent directors due to the condition that no more than a minority of a fund's independent directors may be affiliated with a broker-dealer. This condition has been especially troublesome for funds with small boards of directors. For example, if a three-member board has only two independent directors, neither director can rely on rule 2a19–1 because it would result in more than a minority of the independent directors relying on the rule. In these types of circumstances, the Commission has granted exemptions from this condition of the rule.[132]

We are proposing to amend rule 2a19–1 to provide that no more than *one-half* of a fund's independent directors may be broker-dealers or their affiliates.[133] This condition should make the rule more flexible for funds with small boards of directors, while continuing to ensure that not all of a fund's independent directors are broker-dealers or their affiliates.[134] We seek comment on whether rule 2a19–1 should be expanded further.

2. Ownership of Index Fund Securities

Section 2(a)(19) disqualifies an individual from being considered an independent director if he knowingly has any direct or indirect beneficial interest in a security issued by the fund's investment adviser or principal underwriter, or by a controlling person of the adviser or underwriter.[135] A fund director, for example, who owns securities issued by the fund's adviser (or its parent company) could not be an independent director. This provision was designed to ensure that an independent director does not have a financial interest in the organizations that are closely associated with the fund or that would benefit from payments that the independent director is charged with scrutinizing.[136]

If a director owns securities of an index fund [137] that seeks to replicate a securities market index that includes securities of the fund's adviser (or principal underwriter or a controlling person of the adviser or principal underwriter), an issue could arise whether the director knowingly has an indirect beneficial interest in the securities of the adviser (or principal underwriter or controlling person).[138] We believe that this attenuated interest in the adviser's or underwriter's securities is not the type of interest Congress intended to prohibit independent directors from owning when it adopted section 2(a)(19). An index fund's investment decision-making process is dictated by the goal of mirroring the performance of a market index, and thus is largely mechanical.[139] Because index fund portfolios typically are spread among a large number of issuers, ownership of their shares is unlikely to have a material effect on the independent judgment of a fund director.

In order to resolve concerns that may have arisen about the status of independent directors who own index funds, we are proposing a new rule that would conditionally exempt an individual from being disqualified as an independent director merely because he owns shares of an index fund that invests in the adviser or underwriter of the fund, or their controlling persons.[140] The exemption would be available if the value of securities issued by the adviser or underwriter (or controlling person) does not exceed five percent of the value of any index tracked by the index fund.[141] The purpose of this condition is to assure that an independent director's indirect interest in the adviser's securities will not be substantial enough to impair his independence and create a conflict of interest.

The proposed rule would define an ''index fund'' as a fund with an investment objective to replicate the performance of a securities index or indices.[142] We request comment on the proposed definition of index fund. Does it encompass the types of funds for which relief is appropriate? Should other types of investment vehicles be included in the proposed rule? We also request comment on the proposed limit on the percentage of the value of securities of the adviser or principal underwriter (or their controlling persons) represented in any index tracked by the fund. Should the rule allow an independent director to own index fund shares when the value of the securities issued by the adviser or underwriter (or their controlling persons) in the index constitutes more than five percent of the value of any index tracked by the fund? Should the limit be less than five percent?

[130] Rule 2a19–1(a)(3) [17 CFR 270.2a19–1(a)(3]. Rule 2a19–1 also requires that the broker-dealer not execute any portfolio transactions for, engage in any principal transactions with, or distribute shares for, the fund's ''complex,'' and that the board determine that the fund and its shareholders will not be adversely affected if the broker-dealer does not perform those functions for the fund. Rule 2a19–1(a)(1), (2) [17 CFR 270.2a19–1(a)(1), (2)]. The rule defines ''complex'' to the fund on whose board the director serves, its investment adviser and principal underwriter, and other funds having the same adviser or principal underwriter. Rule 2a19–1(b) [17 CFR 270.2a19–1(b).

[131] *See* Rule 2a19–1 Proposing, *supra* note 129, at n.36 and accompanying text.

[132] *See* Bergstrom, Capital Corporation, Investment Company Act Release Nos. 23629 (Dec. 31, 1998) [64 FR 1035 (Jan. 7, 1999)] (notice) and 23666 (Jan. 26, 1999) [68 SEC Docket 3501 (Feb. 23 1999)] (order); Counsellors Tandem Securities Fund, Inc. and Warburg, Pincus Counsellors, Inc., Investment Company Act Release Nos. 15636 (Mar. 24, 1987) [52 FR 10278 (Mar. 31, 1987)] (notice) and 15697 and 15697 (Apr. 22, 1987) [38 SEC Docket 318 (May 5, 1987)] (order).

[133] Proposed amendment to rule 2a19–1(a)(3).

[134] We also are proposing to amend the title of rule 2a19–1 to refer specifically to broker-dealers, the subject of the rule.

[135] Section 2(a)(19)(B)(iii) [15 U.S.C. 80a–2(a)(19)(B)(iii)].

[136] *See* H.R. Rep. No. 1382, 91st Cong., 2d Sess. 13–14 (1970) (expressing policy concerns about the use of ''affiliated person'' in the Act because, among other things, it permitted a director to be classified as ''unaffiliated'' even though he had substantial business relationships with the fund, its adviser, or its underwriter); Public Policy Report, *supra* note 10, at 332–34 (same); *see also* section 15(c) of the Act (requiring independent directors to scrutinize and approve the fund's contracts with investment advisers and principal underwriters).

[137] An index fund is a type of fund that selects the securities in its portfolio in an effort to replicate the investment performance of the securities in a market index. Nearly 20 percent of the index funds registered with the Commission track the performance of the Standard & Poor's 500 Composite Stock Price Index.® For a discussion of other types of indexes, *see* John Waggoner, *Index Funds Race Into New Venues; Investors Can Track Europe or Racing Firms*, USA Today, Nov. 27, 1998, at 3B.

[138] *Cf.* The Massachusetts Company, SEC No-Action Letter (Jan. 29, 1972) (fund director who serves as a trustee of an irrevocable trust that holds shares of a controlling person of the fund's adviser and underwriter would be an interested person of the fund under section 2(a)(19)(B)(iii)).

[139] *Cf., e.g.,* The Victory Stock Index Fund, SEC No-Action Letter (Feb. 7, 1995) (staff would not recommend enforcement action under section 12(d)(3) or rule 12d3–1 when an index fund purchased securities of an affiliated person of the fund's adviser or principal underwriter, because, among other things, the ''non-volitional nature of the index fund's purchases'' made it unlikely that the fund's portfolio securities would be selected in the interest of the fund's adviser or principal underwriter, rather than the fund's shareholders).

[140] The proposed rule would not address an independent director's ownership of securities of an *actively* managed fund. The holdings of this type of fund can vary from day to day without the knowledge of the fund's shareholders, and periodic disclosure of fund holdings may be out of date by the time an investor receives them. We therefore believe it is clear that an independent director who owns shares of an actively managed fund ordinarily would not ''knowingly'' have an indirect beneficial interest in the issuers of securities the fund holds.

[141] Proposed rule 2a19–3.

[142] *Id.*

E. Disclosure of Information About Fund Directors

Participants at the Roundtable agreed that independent directors can vigilantly represent the interests of mutual fund shareholders only when they are truly independent of those who operate and manage the fund.[143] We agree with the Roundtable participants and believe that the effectiveness of fund boards of directors is enhanced by a high degree of independence of each independent director.

We believe that shareholders have a significant interest in knowing who the independent directors are, whether the independent directors' interests are aligned with shareholders' interests, whether the independent directors have any conflicts of interest, and how the directors govern the fund. This information helps a mutual fund shareholder to evaluate whether the independent directors can, in fact, act as an independent, vigorous, and effective force in overseeing fund operations.

The Commission has long recognized the importance of providing mutual fund shareholders with relevant information about fund directors and has required funds to provide shareholders with certain information about fund directors. Currently, information about directors is available in fund registration statements and proxy statements for the election of directors. Generally, funds are required to provide basic information about directors in the statement of additional information (''SAI'') and proxy statements, including name and age; positions with the fund; principal occupations during the past five years; and compensation from the fund and fund complex.[144] Moreover, funds are required to disclose in proxy statements for the election of directors a director's positions with, interests in, and transactions with, the fund and certain persons related to the fund.[145]

For some time, however, we have been concerned that mutual fund investors do not in all cases have access to significant information about fund directors when they need it. When we adopted our recent comprehensive revisions to the mutual fund prospectus, we noted that mandating more information about fund directors than is available under our existing rules may be appropriate in light of independent directors' role as ''watchdogs'' for fund shareholders.[146] Critics have charged that shareholders do not know the very people who are entrusted with safeguarding their interests.[147] Some have complained that fund shareholders do not know whether the interests of independent directors are aligned with shareholders or with fund management.[148]

We have reevaluated our disclosure requirements in light of these criticisms and have concluded that, while our fundamental approach is sound, there are several gaps in the information that shareholders currently receive about directors. Historically, the primary vehicle for providing information about mutual fund directors was the proxy statement prepared in connection with shareholder meetings. In recent years, the proxy statement has become an ineffective vehicle for communicating information to fund shareholders on a regular basis because funds generally are no longer required to hold annual meetings.[149]

In addition, although mutual funds are required to disclose certain information that bears on a director's potential conflicts, the SAI requirements and proxy rules do not require disclosure of other circumstances that could raise similar conflict of interest concerns, such as those involving a director's immediate family members. The current rules also do not require disclosure of information that may show

[143] *See, e.g.,* statement of Bruce K. MacLaury, Roundtable Transcript of Feb. 23, 1999, at 42 (''It should be apparent that boards work best when the possibilities for conflict of interest are minimized so that truly independent directors can exercise their best judgment on behalf of the interest of the shareholders.''); statement of Dawn-Marie Driscoll, Roundtable Transcript of Feb. 24, 1999, at 63 (''[I]ndependence is one of the most important characteristics of an independent director. The more ways that you can ensure independence the better the process will be.''); statement of Thomas R. Smith, Jr., Roundtable Transcript of Feb. 24, 1999, at 253 (''There is something beyond what is in the statute that you consider when you pick new directors. You've got to look at material business relationships, and, quite frequently, in the selection process you will rule somebody out, although technically they are independent, because of relationships.'').

[144] Items 13(b) and (d) of Form N–1A; Items 18.1 and 18.4 of Form N–2; Items 20(a) and (c) of Form N–3; Items 401(a) and (e) of Regulation S–K, through Item 22(b)(4) of Schedule 14A.

Funds also are required to disclose for each director the positions held with affiliated persons or principal underwriters of the fund. Item 13(c) of Form N–1A; Item 18.2 of Form N–2; Item 20(b) of Form N–3. Funds also must provide the percentage of the fund's equity securities owned as a group by all officers, directors, and advisory board members. Item 14(c) of Form N–1A and Item 19.3 of Form N–2. *See also* Items 23(f) and 25 of Form N–1A; Items 24.2.i and 29 of Form N–2; Items 21(a)(ii) and (f)(ii), 28(b)(10), and 32 of Form N–3.

[145] *See* Item 22(b)(1) of Schedule 14A (requiring disclosure of director's positions with the investment adviser and a director's securities holdings or material interest in the investment adviser and any person controlling, controlled by, or under common control with the investment adviser); Item 401 of Regulation S–K, through Item 22(b)(4) of Schedule 14A (requiring disclosure of director's positions with the fund); Item 22(b)(2) of Schedule 14A (requiring disclosure of any material interests of a director in the fund's principal underwriter or administrator); Item 22(b)(3) of Schedule 14A (requiring disclosure of any material interests of a director in any material transactions with the fund, the investment adviser, the principal underwriter, or the administrator, and any person controlling, controlled by, or under common control with the investment adviser, principal underwriter, or administrator); Item 404(a) of Regulation S–K, through Item 22(b)(4) of Schedule 14A (requiring disclosure of a director's material interests in transactions with the fund involving amounts over $60,000). Funds also must disclose in proxy statements a director's holdings in the fund. Item 403(b) of Regulation S–K, through Item 6(d) of Schedule 14A. *See also* Items 5, 7(e), (f), and (g), and 22(b)(5) and (b)(6) of Schedule 14A (requiring other information about directors).

[146] Registration Form Used by Open-End Management Investment Companies, Investment Company Act Release No. 23064 (Mar. 13, 1998) [63 FR 13916, 13931 (Mar. 23, 1998)] (''1998 Form N–1A Release'').

[147] John Markese, president of the American Association of Individual Investors, discussed his view that there is a ''disconnect'' between shareholders and the independent directors at our recent Roundtable. Roundtable Transcript of Feb. 23, 1999, at 48–49. *See also* Paul J. Lim, *Despite Plan to Fortify Independent Directors, Shareholders Must be Their Own Watchdogs,* L.A. Times, Mar . 28, 1999, at C3; Russ Wiles, ''Fund Directors Losing Clout,'' The Arizona Republic D1 (Mar. 28, 1999).

[148] *See, e.g.,* Edward Wyatt, *Empty Suits In the Board Room; Under Fire, Mutual Fund Directors Seem Increasingly Hamstrung,* N.Y. Times, June 7, 1998, at C1; Steven D. Kaye, *Whose board is it?,* U.S. News & World Rep., Feb. 2, 1998, at 64; Jason Zweig, *How Funds Can Do Better,* MONEY, Feb. 1998, at 42.

[149] *See* John Nuveen & Co., Inc. SEC No-Action Letter (Nov. 18, 1986) (''Nuveen Letter'') (annual meetings to elect directors not required by Investment Company Act). The Nuveen Letter took the position that annual meeting requirements generally are a question of state law.

For historical and other reasons, most funds are organized under the laws of Massachusetts or Maryland. The organizational and operational requirements of Massachusetts business trusts are not specified by statute, and a fund's essential structure is contained in the trust agreement, which generally includes a provision eliminating the need for annual shareholder meetings to elect directors. *See generally* Jones, Moret and Storey, *The Massachusetts Business Trust and Registered Investment Companies,* 13 DEL. J. CORP. L. 421 (1988). Under Maryland corporate law, fund charters or by-laws are not required to provide that annual meetings be held in any year in which election of directors is not required by the Investment Company Act. MD. CODE ANN., CORPS. & ASS'NS Code § 2–501(b) (1999). In addition, Delaware, Minnesota, and California also have business trust or special corporate law structures that have the effect of not requiring shareholder meetings other than those required by the Investment Company Act. DEL. CODE ANN. tit. 12, § 3806 (1999); Minn. Stat. § 302A.431 (1999); CAL. CORP. CODE § 600(b) (West 1999).

Closed-end funds registered on national securities exchanges, however, are required to hold an annual meeting to elect directors under the rules of the exchanges. *See, e.g.,* American Stock Exchange Listing Standards, Policies, and Requirements § 704; New York Stock Exchange Listed Company Manual § 302.00. Closed-end fund shareholders therefore generally would receive annual proxy statements.

that a director's interests are aligned with shareholder interests, including a director's securities holdings in funds in the fund complex.

Therefore, we are proposing amendments to our disclosure rules to close these gaps. Our proposals would require mutual funds to:

- Provide basic information about directors to shareholders annually so that shareholders will know the identity and experience of their representatives;
- Disclose to shareholders fund shares owned by directors to help shareholders evaluate whether directors' interests are aligned with their own;
- Disclose to shareholders information about directors that may raise conflict of interest concerns; and
- Provide information to shareholders on the board's role in governing the fund.

These proposals would supplement the information that currently is available in the mutual fund SAI and in proxy statements. For ease of reference, we have attached as Appendix A a table cross-referencing the proposed disclosure requirements in the proxy rules and the SAI of Form N–1A with existing requirements.[150]

1. Basic Information About Directors

(a) Location of Information. The Commission is proposing to require mutual funds to disclose basic information about directors in an easy-to-read tabular format.[151] We are proposing to combine in one table certain information currently required for directors in the SAI and proxy statements.[152] This new table would be required in three places: the fund's annual report to shareholders, SAI, and proxy statement for the election of directors. This would ensure that the information is available to prospective investors upon request. It also would ensure that mutual fund shareholders receive basic information about the identity and experience of their directors both annually and whenever they are asked to vote to elect directors.

We are not proposing to require that basic information about directors be included in the prospectus. We considered, and rejected, this idea during our recent top-to-bottom overhaul of the mutual fund prospectus.[153] At the time of our prospectus overhaul, however, we directed the Division of Investment Management to consider whether information about directors should be included in fund annual reports, and we have now concluded that it should.[154]

Our proposals would, for the first time, require that basic information about mutual fund directors be included in the annual report to shareholders.[155] Because the proxy statement is no longer received by most fund shareholders annually, we are proposing to include basic information about directors in the annual report to ensure that shareholders will receive it regularly. We also are proposing to require funds to include in the annual report a statement that the SAI includes additional information about fund directors and is available without charge upon request.[156] The statement must include a toll-free (or collect) telephone number for shareholders to call for additional information.

We request comment on the appropriate location for basic information about mutual fund directors. Please address whether basic information should be included in the prospectus, SAI, annual report, and/or proxy statement. Should we, for example, reconsider our decision not to include any of the basic information about directors in the prospectus?

(b) Required Information. The proposed table would require for each director: (1) Name, address, and age; (2) current positions held with the fund; (3) term of office and length of time served; (4) principal occupations during the past five years; (5) number of portfolios overseen within the fund complex; and (6) other directorships held outside of the fund complex.[157] The table also would require for each ''interested'' director, as defined in section 2(a)(19) of the Act, a description of the relationship, events, or transactions by reason of which the director is an interested person.[158]

Currently, mutual funds must disclose the number of other registered investment companies in the fund complex that a director oversees.[159] The Commission now is proposing to require disclosure of the total number of portfolios, rather than registered investment companies, that a director oversees.[160] In today's environment, where a complex may choose between organizing a single series company with multiple portfolios or multiple investment companies each with a single portfolio, we believe that requiring disclosure of the number of portfolios that a director oversees would provide a more accurate picture of the director's responsibilities.

The Commission seeks comment on whether the proposed basic information would provide shareholders with sufficient information about the directors who are charged with protecting shareholder interests. If the disclosure would not achieve this purpose, is there other basic information about directors that should be required? If proposed disclosure of any item is not necessary or useful to investors, please explain the reason why. Should the same basic information be included in the SAI, annual report, and proxy statement?

2. Ownership of Equity Securities in Fund Complex

As discussed above, some have complained that shareholders do not know whether directors' interests are

[150] Form N–1A is the registration form used by open-end management investment companies to register under the Investment Company Act and to offer their shares under the Securities Act. We also are proposing parallel changes to Forms N–2 (closed-end funds) and N–3 (managed separate accounts offering variable annuity contracts).

[151] Proposed Item 22(b)(1) of Schedule 14A; proposed Items 13(a)(1) and 22(b)(5) of Form N–1A; proposed Item 18.1 and Instruction 4.e. to Item 23 of Form N–2; proposed Item 20(a) and Instruction 4(v) to Item 27 of Form N–3. For convenience in discussing the proposed requirements, we are not specifically referring to nominees for election as directors. The proposed requirements, however, would be applicable to nominees in proxy solicitations for the election of directors. The disclosure requirements in Item 22 of Schedule 14A also are applicable to information statements prepared in accordance with Regulation 14C and Schedule 14C [17 CFR 240.14c–101].

[152] *See* Item 13(b) of Form N–1A; Item 18.1 to Form N–2; Item 20(a) of Form N–3; Items 401(a) and (e) of Regulation S–K, through Item 22(b)(4) of Schedule 14A. As currently required, funds would continue to include in the table information about officers and advisory board members of the fund, as well as directors. *See* Items 13(b) of Form N–1A; Item 18.1 of Form N–2; Item 20(a) of Form N–3; Items 401(b) and (e) of Regulation S–K, through Item 22(b)(4) of Schedule 14A.

[153] *See* 1998 Form N–1A Release, *supra* note 146, at 13930–13931.

[154] *See Id.*

[155] Proposed Item 22(b)(5) of Form N–1A; proposed Instruction 4.e. to Item 23 of Form N–2; proposed Instruction 4(v) to Item 27 of Form N–3.

[156] Proposed Item 22(b)(6) of Form N–1A; proposed Instruction 4.e. to Item 23 of Form N–2; proposed Instruction 4(vi) to Item 27 of Form N–3.

[157] As is currently required, the fund also would be required to explain any family relationship between the persons listed in the table. *See* current Item 401(d) of Regulation S–K, through Item 22(b)(4) of Schedule 14A; Item 13(b) of Form N–1A; Item 18.1 of Form N–2; Item 20(a) of Form N–3; proposed Item 22(b)(1) of Schedule 14A; proposed Item 13(a)(1) of Form N–1A; proposed Item 18.1 of Form N–2; proposed Item 20(a) of Form N–3.

[158] Proposed Instruction 4 to Item 22(b)(1) of Schedule 14A; proposed Instruction 2 to Item 13(a)(1) of Form N–1A; proposed Instruction 2 to Item 18.1 N–2; proposed Instruction 2 to Item 20(a) of Form N–3.

[159] *See* Item 401(e)(2) and Instruction to Item 401(e)(2) of Regulation S–K, through Item 22(b)(4) of Schedule 14A; Item 13(c) and Instruction to Item 13(c) of Form N–1A; Item 18.2 and Instruction to Item 18.2 of Form N–2; Item 20(b) and Instruction to Item 20(b) of Form N–3.

[160] Proposed Item 22(b)(1) of Schedule 14A; proposed Item 13(a)(1) of Form N–1A; proposed Item 18.1 of Form N–2; proposed Item 20(a) of Form N–3.

aligned with those of shareholders.[161] Although a director need not necessarily hold securities of funds in a fund complex to be an effective advocate for shareholders, the interests of a director who holds shares in the complex will tend to be aligned with the interests of other shareholders.[162] We are therefore proposing to require disclosure of the aggregate dollar amount of equity securities of funds in the fund complex owned beneficially and of record by each director.[163]

We are not proposing to require separate disclosure of a director's holdings of equity securities in the fund itself. We are concerned that this information might have limited meaning because of the many reasons that a director could have for not holding shares of any specific fund, *e.g.*, that its investment objective did not fill a need in the director's portfolio.

Funds would provide information on director holdings in an easy-to-read tabular format including: (1) Name of director; (2) identity of fund complex; and (3) aggregate dollar amount of equity securities owned of funds in the complex. The information, as of the most recent practicable date, would be provided in the fund's SAI and in any proxy statement relating to the election of directors. This would ensure that the information is available to prospective investors upon request and is provided to shareholders whenever they are asked to vote to elect directors.[164]

''Fund complex'' is currently defined in the proxy rules as two or more funds that (1) hold themselves out to investors as related companies for purposes of investment and investor services; or (2) have a common investment adviser or an investment adviser that is an affiliated person of the investment adviser of any of the other funds.[165] The Commission is proposing to use this definition to determine a director's holdings in a fund complex.[166]

We request comment on whether information on director holdings of shares in a fund complex would be useful to shareholders. If so, should the Commission use the definition of ''fund complex'' that is currently contained in the proxy rules? Or should the Commission use another definition, such as ''family of investment companies'' used in Form N–SAR?[167] Should disclosure of director holdings be limited to holdings in the fund itself, the group of funds overseen by a director, or some other group of funds? The Commission also requests comment on whether there is other information that bears on the alignment of interests of shareholders and directors and should be disclosed.

3. Conflicts of Interest

(a) Statutory Scheme Governing Conflicts of Interest. As described above, Congress provided that at least 40 percent of the board of directors of an investment company must be independent and assigned a special role to the independent directors—to supply a check on management and act as independent watchdogs for investors.[168] Under the Investment Company Act, an independent director is an individual who is not an ''interested person'' of the fund.[169]

In section 2(a)(19) of the Act, Congress enumerated individuals who are ''interested persons'' of a fund and who, therefore, are not considered independent directors. These individuals include: (1) Any affiliated person of the fund, (2) any member of the immediate family of any natural person who is an affiliated person of the fund, (3) any interested person of any investment adviser of or principal underwriter for the fund, (4) any person or partner or employee of any person who at any time since the beginning of the last two completed fiscal years of the fund has acted as legal counsel for the fund, and (5) any broker or dealer registered under the Exchange Act or any affiliated person of a broker or dealer.[170]

Congress also gave the Commission authority to determine by order that a director is an interested person even though he is not covered by the categories enumerated in the statute.[171] The Commission may determine that a natural person is an interested person of a fund by reason of having had, at any time since the beginning of the last two completed fiscal years of the fund, a material business or professional relationship with the fund, the principal executive officer of the fund, any other investment company having the same investment adviser or principal underwriter, or the principal executive officer of the other investment

[161] *See supra* note 148 and accompanying text.

[162] *See* Peter McKenna, *Mutual Funds Are Built to Last With Embedded Checks, Balances,* Investor's Business Daily, May 1, 1998, at B4 (quoting fund industry consultant Geoffrey H. Bobroff) (''It's useful to see how many shares are owned by members of the board. * * * Most investors like board members to share the fund's risk and possible reward.'').

[163] Proposed Item 22(b)(4) of Schedule 14A; proposed Item 13(b)(4) of Form N–1A; proposed Item 18.7 of Form N–2; proposed Item 20(f) of Form N–3.

[164] As noted earlier, *supra* note 149, closed-end funds are not required to update their registration statements annually; however, shareholders would receive the information annually in proxy statements for the election of directors.

[165] *See* Item 22(a)(1)(v) of Schedule 14A.

[166] *See* proposed Instruction 1(a) to Item 13 of Form N–1A; proposed Instruction 1.b. to Item 18 of Form N–2; proposed Instruction 1.a. to Item 20 of Form N–3. The proposed definition of ''fund complex'' also would apply to the proposed disclosure requirement for basic information about directors. *See supra* note 157 and accompanying text (proposing to require disclosure for each director of the number of portfolios overseen within the fund complex and other directorships held outside of the fund complex).

[167] *See* Item H of Form N–SAR [17 CFR 274.101] (defining ''family of investment companies'' to mean any two or more investment companies that share the same investment adviser or principal underwriter and hold themselves out to investors as related companies for purposes of investment and investor services); *see also* Rule 11a–3 under the Act [17 CFR 270.11a–3] (defining ''group of investment companies'' to mean any two or more open-end investment companies that hold themselves out to investors as related companies for purposes of investment and investor services and that either (1) have a common investment adviser or principal underwriter or (2) the investment adviser or principal underwriter of one of the companies is an affiliated person of the investment adviser or principal underwriter of each of the other companies).

[168] *See supra* notes 20, 22, and 23 and accompanying text.

[169] *See* section 10(a) of the Act.

[170] Sections 2(a)(19)(A)(i)–(v) of the Act [15 U.S.C. 80a–2(a)(19)(A)(i)–(v)]. Section 2(a)(3) of the Act [15 U.S.C. 80a–2(a)(3)] defines affiliated person of another person to mean: (1) any person directly or indirectly owning, controlling, or holding with power to vote, 5 per centum or more of the outstanding voting securities of such other person; (B) any person 5 per centum or more of whose outstanding voting securities are directly or indirectly owned, controlled, or held with power to vote, by such other person; (C) any person directly or indirectly controlling, controlled by, or under common control with, such other person; (D) any officer, director, partner, copartner, or employee of such other person; (E) if such other person is an investment company, any investment adviser thereof or any member of an advisory board thereof; and (F) if such other person is an unincorporated investment company not having a board of directors, the depositor thereof.

Section 2(a)(19) of the Act [15 U.S.C. 80a–2(a)(19)] defines immediately family member to mean any parent, spouse of a parent, child, spouse of a child, spouse, brother, or sister, and includes step and adoptive relationships.

Sections 2(a)(19)(B)(i)–(v) of the Act [15 U.S.C. 80a–2(a)(19)(B)(i)–v] define an interested person of an investment adviser or principal underwriter of a fund to include: (1) Any affiliated person of the investment adviser or principal underwriter; (2) any member of the immediate family of any natural person who is an affiliated person of the investment adviser or principal underwriter; (3) any person who knowingly has any direct or indirect beneficial interest in, or who is designated as trustee, executor, or guardian of any legal interest in, any security issued either by the investment adviser or principal underwriter or by a controlling person of the investment adviser or principal underwriter; (4) any person or partner or employee of any person who at any time since the beginning of the last two completed fiscal years of the fund has acted as legal counsel for the investment adviser or principal underwriter; and (5) any broker or dealer registered under the Exchange Act or any affiliated person of a broker or dealer.

[171] *See* H.R. Rep. No. 1382, 91st Cong., 2d Sess. 14–15 (1970).

company.[172] We also may determine that a natural person is an interested person of an investment adviser or principal underwriter of a fund (and therefore of the fund itself) by reason of having had, at any time since the beginning of the last two completed fiscal years of the fund, a material business or professional relationship with the investment adviser or principal underwriter or with the principal executive officer or any controlling person of the investment adviser or principal underwriter.[173] For example, in appropriate circumstances, the Commission may find that a director who was an employee of a fund's investment adviser within the past two years is an ''interested person'' under section 2(a)(19)(B)(vi) of the Act by reason of having a material business or professional relationship with the investment adviser.[174]

(b) Need for Disclosure Changes. The proxy rules currently require significant information about conflicts of interest of directors.[175] The proxy rules require disclosure of positions held with the investment adviser and any securities holdings or material interests in the investment adviser and any person controlling, controlled by, or under common control with the investment adviser.[176] A mutual fund also must disclose any material interests of a director in the fund's principal underwriter or administrator.[177] In addition, a fund must disclose any material interests of a director in any material transactions with the fund, the investment adviser, the principal underwriter, the administrator, or any person controlling, controlled by, or under common control with the investment adviser, principal underwriter, or administrator.[178]

We are proposing to enhance the disclosure required in the proxy rules because we believe that there are other situations that could involve conflicts of interest. We also are proposing to include the proposed conflicts disclosure about directors in the SAI because mutual funds no longer prepare proxy statements on a regular basis.[179]

We believe disclosure of directors' potential conflicts of interest would serve three purposes. First, this disclosure would bring to the attention of shareholders circumstances that may affect the directors' allegiance to shareholders. With this information, shareholders may decide for themselves whether an independent director has any potential conflicts of interest that could affect the director's ability to protect the interests of shareholders.

Second, disclosure would provide the public, including the press and other third-party information providers, access to information about directors' potential conflicts of interest. The resulting public dissemination may discourage the selection of independent directors who have relationships or engage in activities that raise questions about their independence.

Third, the information would assist the Commission in evaluating whether it should exercise its authority to determine that a director is ''interested'' under section 2(a)(19)(A)(vi) or (B)(vi) of the Act even though he is not within one of the categories of ''interested persons'' specifically enumerated by Congress in other provisions of section 2(a)(19).[180] The legislative history of section 2(a)(19) states that the Commission could issue an order determining that a director is an interested person if the Commission found that a director's ''business or professional relationship [with certain related persons] was material in the sense that it might tend to impair the independence of such director.'' [181] In providing the Commission with this authority, Congress contemplated that the Commission would look at each situation on a case-by-case basis.[182] The proposed disclosure would assist the Commission in determining whether it would be appropriate to make a further inquiry into a director's independence.

We believe that the proposed disclosure would give shareholders the tools to help determine how effectively the directors serve their interests and encourage the selection of directors that are independent in the spirit intended by Congress. We first discuss our general approach to the disclosure requirements and then discuss the specific requirements.

(c) General Approach to Disclosure—(1) Circumstances Raising Potential Conflicts of Interest. The Commission is proposing to require disclosure of three types of circumstances that could affect the allegiance of mutual fund directors to their shareholders: positions, interests, and transactions and relationships of directors. In specifying the circumstances where disclosure is required, we have drawn on the current proxy rules, which require disclosure of positions, interests, and transactions of directors.[183]

The Commission is proposing to require disclosure of positions held by a director with the fund and persons related to the fund.[184] A director who holds such a position may be influenced to act in the interest of persons related to the fund rather than the interest of fund shareholders. We also are proposing to require disclosure of directors' interests, including securities holdings, in entities related to the fund.[185] A director who holds an

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[172] Section 2(a)(19)(A)(vi) of the Act [15 U.S.C. 80a–2(a)(19)(A)(vi)]. The statute also provides that no person shall be deemed an interested person of a fund solely by reason of being a member of its board of directors or advisory board or an owner of its securities, or his membership in the immediate family of any person who is a member of the fund's board of directors or advisory board or an owner of its securities. *Id.*

[173] Section 2(a)(19)(B)(vi) of the Act [15 U.S.C. 80a–2(a)(19)(B)(vi)].

Section 2(a)(9) of the Act [15 U.S.C. 80a–2(a)(9)] defines control to mean the power to exercise a controlling influence over the management or policies of a company, unless such power is solely the result of an official position with such company. Any person who owns beneficially, either directly or through one or more controlled companies, more than 25 percent of the voting securities of a company shall be presumed to control such company. Any person who does not own more than 25 percent of the voting securities of any company shall be presumed not to control such company.

[174] *See* Interpretive Release, *supra* note 1.

[175] *See supra* note 145 and accompanying text.

[176] *See* Item 22(b)(1) of Schedule 14A.

[177] *See* Item 22(b)(2) of Schedule 14A.

[178] *See* Item 22(b)(3) of Schedule 14A, and Item 404(a) of Regulation S–K, through Item 22(b)(4) of Schedule 14A.

[179] *See supra* note 149 and accompanying text.

[180] *See supra* note 170 and accompanying text.

[181] *See* H.R. Rep. No. 1382, 91st Cong., 2d Sess. 14–15 (1970). Ordinarily, a business or professional relationship would not be deemed to impair independence where the benefits flow from the director of an investment company to the other party to the relationship. *Id.*

[182] *Id.* Over the years, Division of Investment Management staff analyzed issues arising under sections 2(a)(19)(A)(vi) or (B)(vi) of the Act on the particular facts of each case to determine whether a director's relationships might tend to impair the independence of the director. *See, e.g., Travelers Equities Fund Inc.*, SEC No-Action Letter (Jan. 11, 1982); *Securities Groups*, SEC No-Action Letter (Apr. 20, 1981); *Equitable of Iowa Variable Annuity Account A*, SEC No-Action Letter (Jan. 6, 1980); *American Medical Association*, SEC No-Action Letter (Dec. 5, 1979); *American Medical Association Tax-Exempt Income Fund, Inc.*, SEC No-Action Letter (Jun. 18, 1978); *Cal-Western Separate Account A*, SEC No-Action Letter (Mar. 8, 1976); *Southwestern Investors, Inc.*, SEC No-Action Letter (Jun. 13, 1971).

Beginning in 1984, the staff stated that it did not believe that it was appropriate for the staff to consider no-action requests under section 2(a)(19)(A)(vi) or (B)(vi) as a matter of policy. *Capital Supervisors Helios Fund, Inc.*, SEC No-Action Letter (Jun. 13, 1984); *see also Daniel Calabria*, SEC No-Action Letter (Sept. 12, 1984). *See also* Interpretive Release, *supra* note 1.

[183] *See* Items 22(b)(1) (positions with the interests in the investment adviser), 22(b)(2) (interests in the principal underwriter or administrator), 22(b)(3) (interests in transactions with the investment adviser, principal underwriter, or administrator), and 22(b)(4) (interests in transactions with the fund) of Schedule 14A.

[184] Proposed Item 22(b)(3) of Schedule 14A; proposed Item 13(b)(3) of Form N–1A; proposed Item 18.6 of Form N–2; proposed Item 20(e) of Form N–3.

[185] Proposed Items 22(b)(5) and (6) of Schedule 14A; proposed Items 13(b)(5) and (6) of Form N–

interest in an entity related to the fund may be tempted to place his financial interest in the entity ahead of shareholders' interests in the fund. Finally, we are proposing to require disclosure of directors' transactions and relationships with the fund and persons related to the fund.[186] A director who is involved in a transaction or relationship with the fund or related persons may have financial or other interests that compete with those of fund shareholders.

The Commission requests comment on whether disclosure of directors' positions, interests, and transactions and relationships is appropriate. Are there other types of circumstances that also raise conflict of interest concerns and should be disclosed?

(2) Persons Covered by Disclosure Requirements; Directors and Immediate Family Members. The Commission is proposing to follow the approach taken in the current proxy rules and require conflicts of interest disclosure about all directors, both interested and independent.[187] The Commission requests comment on whether this approach is appropriate, or whether there are any proposed requirements that should apply only to independent directors. If so, which requirements should apply only to independent directors?

The Commission also proposes to extend the disclosure requirements to the immediate family members of directors because the involvement of family members with the fund or persons related to the fund could raise the same conflicts of interest for a director as if the director was involved directly in the situation. The Commission proposes to define ''immediate family member'' to mean any spouse, parent, child, sibling, mother- or father-in-law, son- or daughter-in-law, or sister- or brother-in-law, including step and adoptive relationships.[188] This definition is similar to the definition of immediate family member in the current proxy rules.[189] We are proposing to add step and adoptive relationships, based on the definition of ''immediate family member'' in section 2(a)(19) of the Act. Our proposed definition would be slightly broader than the definition in section 2(a)(19) of the Act, which does not include mother- or father-in-law or sister- or brother-in-law relationships. We request comment on whether the proposed definition is appropriate, or whether it should be expanded or narrowed.

Related Persons. The Commission is proposing to require disclosure about circumstances involving directors, on the one hand, and the fund and persons related to the fund, on the other. We looked to the Act for guidance in determining which related persons should be covered by our disclosure requirements. The Commission's statutory authority to determine that a director is an ''interested person'' is based on finding a relationship with the fund; its investment adviser, principal underwriter, or a person controlling the investment adviser or principal underwriter; another investment company with the same investment adviser or principal underwriter; or the principal executive officer of the fund, its investment adviser or principal underwriter, or another investment company with the same investment adviser or principal underwriter.[190]

We are proposing to require disclosure with respect to circumstances involving these persons and other persons that we have concluded may pose similar conflicts of interest. The additional persons include: (1) a fund's administrator or a person directly or indirectly controlling the administrator; (2) a person directly or indirectly controlled by or under common control with the fund's investment adviser, principal underwriter, or administrator; (3) any other investment company with the same administrator as the fund; (4) any other investment company with an investment adviser, principal underwriter, or administrator that directly or indirectly controls, is controlled by, or is under common control with an investment adviser, principal underwriter, or administrator of the fund; and (5) any officer of (i) the fund; (ii) the investment adviser, principal underwriter, or administrator of the fund; (iii) a person directly or indirectly controlling, controlled by, or under common control with the fund's investment adviser, principal underwriter, or administrator; (iv) an investment company with the same investment adviser, principal underwriter, or administrator as the fund; or (v) an investment company with an investment adviser, principal underwriter, or administrator that directly or indirectly controls, is controlled by, or is under common control with an investment adviser, principal underwriter, or administrator of the fund.[191]

We are following the approach of the current proxy rules in proposing to require disclosure regarding directors' relationships with mutual fund administrators. As administrators take on an increasing role in the operations of funds, the relationships of independent directors with these entities may affect the directors' ability to safeguard the interests of fund shareholders.[192]

As in the current proxy rules, we are proposing to require mutual funds to disclose circumstances involving the director and persons controlling, controlled by, or under common control with some parties related to the fund.[193] We believe that situations involving a director and persons controlled by or under common control with persons related to the fund could pose conflicts of interest that are similar to situations involving controlling persons, which are referenced in section 2(a)(19) of the Act. We are concerned that the burden on mutual funds of expanding disclosure beyond these persons, however, may outweigh the value of the information to investors. The Commission requests comment on whether it should extend the proposed disclosure requirements beyond persons controlling, controlled by, or under common control with parties related to the fund, or limit the proposed disclosure requirements to

1A; proposed Items 18.8 and 18.9 of Form N–2; proposed Items 20(g) and (h) of Form N–3.

[186] Proposed Items 22(b)(7) and (8) of Schedule 14A; proposed Items 13(b)(7) and (8) of Form N–1A; proposed Items 18.10 and 18.11 of Form N–2; proposed Items 20(i) and (j) of Form N–3.

[187] *See* Items 22(b)(1) (positions and interests); 22(b)(2) (interests); 22(b)(3) (transactions); and 22(b)(4) (transactions) of Schedule 14A.

[188] Proposed Item 22(a)(1)(vi) of Schedule 14A; proposed Instruction 1(b) to Item 13 of Form N–1A; proposed Instruction 1.b. to Item 18 of Form N–2; proposed Instruction 1.b. to Item 20 of Form N–3.

[189] *See* Instruction 2 to Item 404(a) of Regulation S–K, through Item 22(b)(4) of Schedule 14A.

[190] *See* sections 2(a)(19)(A)(vi) and (B)(vi) of the Act [15 U.S.C. 80a–2(a)(19)(A)(vi) and (B)(vi)].

[191] Separate accounts offering variable insurance products that are registered as management companies also would be required to disclose circumstances involving the insurance company that sponsors the separate account. We are proposing to define ''sponsoring insurance company'' in the proxy rules to mean the insurance company that establishes and maintains the separate account and that owns the assets of the separate account. Proposed Item 22(a)(1)(x) of Schedule 14A.

[192] *See supra* notes 89–90 and accompanying text.

[193] *See* Items 22(b)(1) of Schedule 14A (requiring funds to disclose directors' ownership of any securities and any other material direct or indirect interest in the investment adviser or any person controlling, controlled by, or under common control with the investment adviser unless the director is a general partner or director of the investment adviser) and 22(b)(3) of Schedule 14A (requiring funds to disclose any material interest, direct or indirect, of any director or nominee for election as director in any material transactions or any proposed material transactions to which the investment adviser, principal underwriter, the administrator, or a person controlling, controlled by, or under common control with those entities (other than a fund) was or is to be a party).

controlling persons as specified in section 2(a)(19) of the Act.

As noted above, we also are proposing to require disclosure of circumstances involving any officer of (1) the fund; (2) the investment adviser, principal underwriter, or administrator of the fund; (3) a person directly or indirectly controlling, controlled by, or under common control with the fund's investment adviser, principal underwriter, or administrator; (4) an investment company with the same investment adviser, principal underwriter, or administrator as the fund; or (5) an investment company with an investment adviser, principal underwriter, or administrator that directly or indirectly controls, is controlled by, or is under common control with an investment adviser, principal underwriter, or administrator of the fund. We are proposing to require disclosure for all officers who perform policy-making functions, not only the principal executive officer as referred to in sections 2(a)(19)(A)(vi) and (B)(vi) of the Act, because we believe that situations involving a director and other officers may raise conflict of interest concerns that are similar to those involving a director and the principal executive officer. Form N–1A defines ''officer'' to mean president, vice-president, secretary, treasurer, controller, or any other officer who performs policy-making functions.[194] We are proposing to add this definition to the proxy rules.[195]

The Commission requests comment on the scope of its general approach to disclosure outlined above, including whether there are any other circumstances that could raise potential conflicts of interest that should be disclosed, and whether the scope of persons covered by the disclosure requirements is appropriate. Having discussed the general concepts of our proposal, we now turn to the specific proposed requirements for disclosure in the SAI and proxy statements for the election of directors.

(d) Specific Disclosure in the Proxy Rules and SAI—(1) Positions. The Commission is proposing to require disclosure of any positions, including as an officer, employee, director, or general partner, held during the past five years by directors and their immediate family members with: (1) the fund; (2) an investment company having the same investment adviser, principal underwriter, or administrator as the fund or an investment adviser, principal underwriter, or administrator that controls, is controlled by, or is under common control with the fund's investment adviser, principal underwriter, or administrator;[196] (3) an investment adviser, principal underwriter, administrator, or affiliated person of the fund; or (4) any person controlling, controlled by, or under common control with the fund's investment adviser, principal underwriter, or administrator.[197]

We request comment on the proposed disclosure of director positions. Should we limit the disclosure required to certain positions, such as managerial or policy-making positions? Have we appropriately specified the entities with respect to which positions should be disclosed? Should any entities be added to or eliminated from the required disclosure? Should disclosure be required for five years as proposed consistent with the current proxy rules, or for a longer or shorter period?[198]

(2) Interests. The Commission is proposing to require disclosure of securities currently owned, and material direct or indirect interests held during the past five years, by each director and his immediate family members in (i) an investment adviser, principal underwriter, or administrator of the fund; or (ii) a person (other than a registered investment company) directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, or administrator.[199] Information about securities owned would be provided in a table, including the value of the securities and percent of each class owned.[200] The value of the securities and percent of each class owned would be provided in the aggregate for each director and his immediate family members.[201] This information would be provided as of the most recent practicable date.[202]

We request comment on the proposed disclosure of director interests. Have we appropriately defined the scope of the interests required to be disclosed? Should disclosure be required of current securities ownership, and of material interests for the past five years, as in the current proxy rules, or should longer or shorter periods be used? Should securities ownership be aggregated or presented separately for a director and his immediate family members? Should the Commission establish any *de minimis* threshold for the disclosure of material interests? If so, what should it be, *e.g.*, interests exceeding $5,000, $10,000, $50,000, or some other amount?

(3) Transactions and Relationships

Transactions and Relationships Generally. The Commission is proposing to require disclosure of transactions and relationships of directors with the fund and parties related to the fund. The parties related to the fund that would be covered by this requirement are: (i) an officer of the fund; (ii) an investment company

[194] Instruction 1 to Item 13(b) of Form N–1A; *see also* Instruction 1 to Item 18.1 of Form N–2 and Instruction 1 to Item 20(a) of Form N–3.

[195] Proposed Item 22(a)(1)(vii) of Schedule 14A; proposed Instruction 1(c) to Item 13 of Form N–1A; proposed Instruction 1.c. to Item 18 of Form N–2; proposed Instruction 1.c. to Item 20 of Form N–3.

[196] This category would include a foreign fund (*i.e.*, an investment company that is organized under the laws of a jurisdiction other than the United States). The proposed rule also would require disclosure of positions with a person that would be an investment company but for the exclusions provided by sections 3(c)(1) and 3(c)(7) of the Investment Company Act. *See* proposed Item 22(b)(3)(ii) of Schedule 14A; proposed Item 13(b)(3)(ii) of Form N–1A; proposed Item 18.6(b) of Form N–2; proposed Item 20(e)(ii) of Form N–3.

[197] Proposed Item 22(b)(3) of Schedule 14A; proposed Item 13(b)(3) of Form N–1A; proposed Item 18.6 of Form N–2; proposed Item 20(e) of Form N–3. *Cf.* Item 13(b) of Form N–1A, Item 18.1 of Form N–2, and Item 20(a) of Form N–3 (requiring disclosure of directors' positions with the fund); Item 13(c) of Form N–1A, Item 18.2 of Form N–2; and Item 20(b) of Form N–3 (requiring disclosure of directors' positions with affiliated persons of the fund and the principal underwriter); Item 22(b)(1) of Schedule 14A (requiring the fund to identify each director or nominee who is, or was during the past five years, an officer, employee, director, general partner, or shareholder of the investment adviser); and Item 401(a) and (b) of Regulation S–K, through Item 22(b)(4) of Schedule 14A (requiring disclosure of directors' and executive officers' positions and offices with the fund). We have proposed to include disclosure of positions with affiliated persons of the fund consistent with current SAI requirements.

Separate accounts offering variable insurance products that are registered as management companies also would be required to disclose directors' positions with the insurance company that sponsors the separate account. *See supra* note 191.

[198] *See* Item 22(b)(1) of Schedule 14A.

[199] Separate accounts offering variable insurance products that are registered as management companies also would be required to disclose directors' interests in the insurance company that sponsors the separate account. *See supra* note 191.

[200] Proposed Items 22(b)(5) and (6) of Schedule 14A; proposed Items 13(b)(5) and (6) of Form N–1A; proposed Items 18.8 and 18.9 of Form N–2; proposed Items 20(g) and (h) of Form N–3. *Cf.* Item 22(b)(1) of Schedule 14A (generally requiring disclosure of directors' current ownership of securities, and material interests during the past five years, in the investment adviser or any person controlling, controlled by, or under common control with the investment adviser); Item 22(b)(2) of Schedule 14A (requiring disclosure of director's material interests during the past five years in a fund's principal underwriter and administrator).

[201] Proposed Instruction 4 to Item 22(b)(5) of Schedule 14A; proposed Instruction 4 to Item 13(b)(5) of Form N–1A; proposed Instruction 4 to Item 18.8 of Form N–2; proposed Instruction 4 to Item 20(g) of Form N–3.

[202] Proposed Instruction 1 to Item 22(b)(5) of Schedule 14A; proposed Instruction 1 to Item 13(b)(5) of Form N–1A; proposed Instruction 1 to Item 18.8 of Form N–2; proposed Instruction 1 to Item 20(g) of Form N–3.

having the same investment adviser, principal underwriter, or administrator as the fund or having an investment adviser, principal underwriter, or administrator that directly or indirectly controls, is controlled by, or is under common control with an investment adviser, principal underwriter, or administrator of the fund;[203] (iii) an officer of an investment company described in (ii); (iv) an investment adviser, principal underwriter, or administrator of the fund; (v) an officer of an investment adviser, principal underwriter, or administrator of the fund; (vi) a person directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, or administrator of the fund; or (vii) an officer of a person directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, or administrator of the fund (together ''Related Parties'').[204]

We are proposing to require disclosure of any material interest, direct or indirect, of any director or his immediate family member in any material transaction, or material series of similar transactions, since the beginning of the last two completed fiscal years (or currently proposed), to which the fund or a Related Party was or is to be a party.[205] Transactions would include loans, lines of credit, and other indebtedness.

For material interests in material transactions, a mutual fund would be required to state the name of the director or family member whose interest is described, the nature of the circumstances by reason of which the interest is required to be described, the nature of the interest, the approximate dollar amount involved in the transaction, and, where practicable, the approximate dollar amount of the interest.[206] For indebtedness, a mutual fund would be required to indicate the largest aggregate amount of indebtedness outstanding at any time during the period, the nature of the indebtedness and the transaction in which it was incurred, the amount outstanding as of the latest practicable date, and the rate of interest paid or charged.[207]

We also are proposing to require disclosure of any material relationship, direct or indirect, of any director or his immediate family member that exists, or has existed at any time since the beginning of the last two completed fiscal years, or is currently proposed, with the fund or a Related Party. Relationships would include payments for property or services, provision of legal or investment banking services, and any consulting or other relationship that is substantially similar in nature and scope to any of the foregoing relationships.[208]

For material relationships, a fund would be required to state the name of the director or family member whose relationship is described, the nature of the circumstances by reason of which the relationship is required to be described, the nature of the relationship, and the amount of business done between the director or family member and the fund or Related Party since the beginning of the last two completed fiscal years or proposed to be done during the current fiscal year.[209]

A fund would not be required to disclose routine, retail transactions and relationships between directors or immediate family members and the fund or Related Parties. For example, a mutual fund need not disclose that a director holds a credit card or bank or brokerage account with a fund or Related Party, unless the director is accorded special treatment, such as preferred access to initial public offerings.[210]

Indirect, as well as direct, material interests in material transactions and material relationships would be required to be disclosed. A director or family member who has a position or a relationship with, or interest in, a company that engages in a transaction or has a relationship with a fund or Related Party may have an indirect interest in the transaction or an indirect relationship by reason of the position, relationship, or interest.[211] The interest in the transaction or the relationship of the director or family member, however, would not be deemed material if the interest or the relationship arises solely from the holding of an equity interest (excluding a general partnership interest) or a creditor interest in a company that engages in a transaction or has a relationship with the fund or Related Party if the transaction or the relationship is not material to the company.

We request comment on the proposed disclosure of director transactions and relationships. Have we appropriately defined the scope of transactions and relationships to be disclosed? Should disclosure be required for the period since the beginning of the last two completed fiscal years, as proposed based on the time period specified in section 2(a)(19) of the Act,[212] or only since the beginning of the most recently completed fiscal year as required in the

[203] This category would include a foreign fund (*i.e.*, an investment company that is organized under the laws of a jurisdiction other than the United States). The proposed rule also would require disclosure of transactions with a person that would be an investment company but for the exclusions provided by sections 3(c)(1) and 3(c)(7) of the Investment Company Act. *See* proposed Item 22(b)(7)(iii) of Schedule 14A; proposed Item 13(b)(7)(iii) of Form N–1A; proposed item 18.10(c) of Form N–2; proposed Item 20(i)(iii) of Form N–3.

[204] Proposed Items 22(b)(7) and (8) of Schedule 14A; proposed Items 13(b)(7) and (8) of Form N–1A; proposed Items 18.10 and 18.11 of Form N–2; proposed Items 20(i) and (j) of Form N–3. *Cf.* Item 22(b)(3) of Schedule 14A (generally requiring disclosure of directors' material interests in material transactions since the beginning of the most recently completed fiscal year, or proposed material transactions, to which the investment adviser, principal underwriter, administrator, or a person controlling, controlled by, or under common control with those entities was or is to be a party). *See also* Item 404(a) of Regulation S–K [17 CFR 229.404(a)], through Item 22(b)(4) of Schedule 14A (requiring disclosure of transactions since the beginning of the last fiscal year, or proposed transactions, to which the fund was or is to be a party, in which any director or immediate family member had, or will have, a material interest and which the amount involved exceeds $60,000).

Separate accounts offering variable insurance products that are registered as management companies also would be required to disclose directors' transactions with the insurance company that sponsors the separate account. *See supra* note 191.

[205] Proposed Item 22(b)(7) of Schedule 14A; proposed Item 13(b)(7) of Form N–1A; proposed Item 18.10 of Form N–2; proposed Item 20(i) of Form N–3.

[206] Proposed Instructions 1 and 2 to Item 22(b)(7) of Schedule 14A; proposed Instructions 1 and 2 to Item 13(b)(7) of Form N–1A; proposed Instructions 1 and 2 to Item 18.10 of Form N–2; proposed Instructions 1 and 2 to Item 20(i) of Form N–3.

[207] Proposed Instruction 9 to Item 22(b)(7) of Schedule 14A; proposed Instruction 9 to Item 13(b)(7) of Form N–1A; proposed Instruction 8 to Item 18.10 of Form N–2; proposed Instruction 8 to Item 20(i) of Form N–3.

[208] Proposed Item 22(b)(8) of Schedule 14A; proposed Item 13(b)(8) of Form N–1A; proposed Item 18.11 of Form N–2; proposed Item 20(j) of Form N–3.

[209] Proposed Instructions 1 and 2 to item 22(b)(8) of Schedule 14A; proposed Instructions 1 and 2 to Item 13(b)(8) of Form N–1A; proposed Instructions 1 and 2 to Item 18.11 of Form N–2; proposed Instructions 1 and 2 to item 20(j) of Form N–3.

[210] Proposed Instruction 10 to Item 22(b)(7) and Instruction 8 to Item 22(b)(8) of Schedule 14A; proposed Instruction 10 to Item 13(b)(7) and Instruction 8 to Item 13(b)(8) of Form N–1A; proposed Instruction 9 to Item 18.10 of and instruction 7 to Item 18.11 of Form N–2; proposed Instruction 9 to Item 20(i) and Instruction 7 to Item 20(j) of Form N–3. *See* H.R. Rep. No. 1382, 91st Cong., 2d Sess. 14–15 (1970) (''[A] director ordinarily would not be considered to have a material business relationship with the investment adviser simply because he is a brokerage customer who is not accorded special treatment.''); Interpretive Release, *supra* note 1.

[211] Proposed Instruction 7 to Item 22(b)(7) and Instruction 5 to Item 22(b)(8) of Schedule 14A; proposed Instruction 7 to Item 13(b)(7) and Instruction 5 to Item 13(b)(8) of Form N–1A; proposed Instruction 6 to Item 18.10 and Instruction 4 to Item 18.11 of Form N–2; proposed Instruction 6 to Item 20(i) and Instruction 4 to Item 20(j) of Form N–3.

[212] *See* sections 2(a)(19)(A)(vi) and 2(a)(19)(B)(vi) of the Act.

current proxy rules, or for some other time period?

We also request comment on whether we should specify a minimum dollar amount involved in a transaction or relationship that would trigger the disclosure requirements rather than simply requiring disclosure of ''material'' transactions or relationships. If so, what should the threshold be, *e.g.*, transactions exceeding $60,000, or some other amount?[213] Similarly, should we require disclosure of transactions or relationships only when the interest of a director or his immediate family member is greater than a specified dollar amount? If so, what should the dollar amount be, *e.g.*, interests exceeding $5,000, $10,000, $50,000, or some other amount?

We also request comment on whether we should limit disclosure of transactions or relationships where the interest of a director or his immediate family member arises indirectly through ownership of an interest in a company that is involved in a transaction or relationship with a fund or Related Party. For example, should disclosure of a transaction or relationship not be required when a director and his immediate family members, in the aggregate, have less than a specified threshold interest in a company that is a party to the transaction or relationship with the fund or Related Party?[214] If so, what should the threshold percentage be, *e.g.* 5%, 10%, or some other amount? Or should the Commission set a threshold dollar amount ownership interest in the company? If so, what should the dollar amount be, *e.g.*, $5,000, $10,000, $50,000, or some other amount? In determining whether the threshold is exceeded, should a director's interests be aggregated with those of his immediate family members, other directors or nominees, executive officers, security holders who own more than 5% of any class of the registrant's voting securities, or any other persons?[215]

Cross-Directorships. Finally, the Commission is proposing to require a mutual fund to disclose situations where an officer of an investment adviser, principal underwriter, or administrator of a fund, or an officer of a person directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, or administrator of the fund serves, or has served since the beginning of the last two completed fiscal years of the fund, as a director of a company of which a fund director or his immediate family member is, or was, an officer.[216] The fund would be required to identify (i) the company involved; (ii) the individual who serves or has served as a director of the company and the period of service as director; (iii) the investment adviser, principal underwriter, or administrator, or person controlling, controlled by, or under common control with the investment adviser, principal underwriter, or administrator where the individual named in (ii) holds or held office and the office held; and (iv) the director of the fund or immediate family member who is or was an officer of the company, the office held, and the period of holding office.

We believe that cross-directorships could potentially create a conflict of interest for a director because the position that he or his immediate family member holds in another company could be affected by an officer of the investment adviser, principal underwriter, or administrator, or an officer of a party controlling, controlled by, or under common control with the investment adviser, principal underwriter, or administrator.[217] We request comment on the proposed disclosure of cross-directorships. Have we appropriately defined the scope of the circumstances to be disclosed? Should disclosure be required for a shorter or longer period than since the beginning of the last two completed fiscal years of the fund?

4. Board's Role in Fund Governance

The Commission is proposing to modify disclosure of matters related to the board's role in governing a fund currently required in the proxy rules and the SAI. We believe that this information would help shareholders more readily determine whether the directors are effectively representing shareholders' interests, independent of fund management.

The proxy rules require a mutual fund to discuss in reasonable detail the material factors and conclusions that formed the basis for the board of directors' recommendation that the shareholders approve an investment advisory contract, including a discussion of any benefits derived or to be derived by the investment adviser from the relationship with the fund such as soft dollar arrangements by which brokers provide research to the fund or its investment adviser in return for allocating fund brokerage.[218] We are proposing to require similar disclosure in the SAI so that investors will be able to evaluate the board's basis for approving the renewal of an existing investment advisory contract.[219]

Director responsibility for evaluating and approving a mutual fund's advisory contract is one of the most important fund governance obligations assigned to directors under the Investment Company Act.[220] In approving an investment advisory contract, independent directors must review the level of fees charged to a fund by an investment adviser. Participants at the Roundtable discussed the important role of independent directors in negotiating these fees and expenses.[221] We believe that a discussion of the factors considered by the board in retaining an investment adviser will help investors understand and evaluate the board's basis for that action.

We also are proposing to modify disclosure in the proxy rules and the SAI relating to a fund's committees of the board of directors. The proxy rules currently require mutual funds to disclose information about standing audit, nominating, and compensation committees.[222] In the SAI, mutual funds

[213] *Cf.* Item 404(a) of Regulation S–K, through Item 22 (b)(4) of Schedule 14A (requiring disclosure of a director's or immediate family member's material interest in a transaction with the fund only when the amount involved in the transaction is greater than $60,000).

[214] Currently, Instruction 8(A) of Item 404(a) of Regulation S–K states that a director's interest in a material transaction is not material when he and all other directors, nominees, executive officers, security holders who own more than 5% of any class of the registrant's voting securities, and immediate family members, in the aggregate, own less than a 10% equity interest in another person that is a party to the transaction.

[215] *See supra* note 214 (Instruction 8(A) of Item 404(a) of Regulation S–K.

[216] Proposed Item 22(b)(9) of Schedule 14A; proposed Item 13(b)(9) of Form N–1A; proposed Item 18.12 of Form N–2; proposed Item 20(k) of Form N–3.

Separate accounts offering variable insurance products that are registered as management companies also would be required to disclose cross-directorships involving the insurance company that sponsors the separate account. *See supra* note 191.

[217] *Cf. Report and Recommendations of the Blue Ribbon Committee on Improving the Effectiveness of Corporate Audit Committee* at 11 (1999) (director not independent when he is employed as an executive of another company where any of the corporation's executives serves on that company's compensation committee).

[218] Item 22(c)(11) of Schedule 14A.

[219] Proposed Item 13(b)(10) of Form N–1A; proposed Item 18.13 of Form N–2; proposed Item 20(l) and Form N–3.

[220] *See* sections 15 (a) and (c) of the Investment Company Act [15 U.S.C. 80a–15 (a) and (c)].

[221] *See* Negotiating Fees and Expenses Panel, Roundtable Transcript of Feb. 23, 1999 at 26–91.

[222] The fund must state whether it has a standing audit, nominating, compensation, or similar committee, identify each committee member, state the number of committee meetings held by each committee during the last fiscal year, and describe briefly the functions performed by the committees. Item 7(e)(1) of Schedule 14A. If the fund has a nominating or similar committee, the fund must state whether the committee will consider nominees recommended by security holders and, if

are required to identify members of any executive or investment committee, and provide a concise statement of the duties and functions of each committee.[223]

We are proposing to modify this disclosure to require mutual funds to identify each standing committee of the board in the SAI and proxy statements for the election of directors. As in the current proxy rules, funds would be required to provide a concise statement of the functions of each committee; identify the members of the committee; indicate the number of committee meetings held during the last fiscal year; and state whether its nominating committee will consider nominees recommended by fund shareholders and, if so, describe the procedures for submitting recommendations.[224]

5. Separate Disclosure

Currently, mutual funds must indicate with an asterisk the directors who are interested persons of the fund within the meaning of section 2(a)(19) of the Act for certain disclosure items in the proxy statements and the SAI.[225] To provide more prominent disclosure about independent directors, we are proposing to require funds to present all disclosure for independent directors separately from disclosure for interested directors in the SAI, proxy statements for the election of directors, and annual reports to shareholders.[226] For example, when information is furnished in a table, funds should provide separate tables (or separate sections of a single table) for independent directors and for interested directors. When presenting information in narrative form, funds should clearly indicate, by heading or other means, which directors are interested and which are independent.

6. Technical and Conforming Amendments

The Commission is proposing to clarify that Item 22 of Schedule 14A applies to business development companies.[227] This proposed change reflects current requirements.

The Commission is proposing changes to cross-references in Items 8 and 10 of Schedule 14A to reflect the proposed amendments to Item 22 of Schedule 14A. We also are proposing to amend current Item 22(b)(4) of Schedule 14A. This item requires funds to provide the information required by Items 401, 404(a) and (c), and 405 of Regulation S–K. Because proposed Item 22(b)(7) of Schedule 14A requires much of the information now required by Item 401 of Regulation S–K, we are proposing to modify Item 22(b)(4) of Schedule 14A to require funds to provide the information required by Items 401(f) and (g), 404(a) and (c), and 405 of Regulation S–K.[228]

Because we have defined the term ''officer'' to mean the president, vice-president, secretary, treasurer, controller, or any other officer who performs policy-making functions, we are proposing to change the reference in the compensation table from ''executive officer'' to ''officer.''[229] In addition, we are proposing to amend the definition of ''administrator'' in the proxy rules to conform to the proposed definition of ''administrator'' in rule 0–1(a)(5).[230]

We also are proposing conforming changes to the SAI. Because we are proposing enhanced disclosure about directors' positions, we are proposing to require disclosure of officers' positions, which remains unchanged, as a separate item.[231] We are proposing amendments to the SAI to conform to the proxy rules by requiring a brief description of any arrangement or understanding between a director or officer and any other person pursuant to which he was selected as a director or officer.[232]

We also are proposing changes to rule 30d–1 under the Investment Company Act.[233] Rule 30d–1(d) allows a fund to send to shareholders a copy of its currently effective prospectus or SAI, or both, instead of a shareholder report required by the rule, provided that the prospectus or SAI, or both, include certain financial information and information about directors' compensation. We are proposing to amend the rule to require a prospectus or SAI, or both, serving as a shareholder report to include all the information that would otherwise be required in the shareholder report.[234]

7. Compliance Date

If we adopt the proposed disclosure requirements, we expect to require all new registration statements and post-effective amendments that are annual updates to effective registration statements, proxy statements for the election of directors, and reports to shareholders filed on or after the effective date of the amendments to comply with the proposed amendments. The Commission requests comment on this proposed compliance date.

F. Recordkeeping Regarding Director Independence

To assure that independent directors are able to fully carry out the important

so, describe the procedures to be followed by security holders in submitting such recommendations. Item 7(e)(2) of Schedule 14A.

[223] Instruction 3 to Item 13(b) of Form N–1A; Instruction 3 to Item 18.1 of Form N–2; Instruction 3 to Item 20(a) of Form N–3.

[224] Proposed Item 22(b)(13) of Schedule 14A; proposed Item 13(b)(2) of Form N–1A; proposed Item 18.5 of Form N–2; proposed Item 20(d) of Form N–3. *Cf.* Item 7(e)(1) of Schedule 14A.

Because this proposed disclosure requirement covers information that is similar to that already required for proxy statements in Item 7(e) of Schedule 14A, the Commission is proposing to amend Item 7 to state that investment companies must furnish the information on committees proposed in Item 22(b)(13) in lieu of the information currently required in Item 7(e). *See* proposed Items 7 (d) and (e) of Schedule 14A. We also recently proposed to require additional information about a closed-end fund's audit committee. *See* Audit Committee Disclosure, Securities Exchange Act Release No. 41987 (Oct. 7, 1999) [64 FR 55648 (Oct. 14, 1999)] (proposed Item 7(e)(3) of Schedule 14A).

[225] *See* Instruction 1 to Item 22(b)(4) of Schedule 14A (table containing information about director's background and experience and table containing information about directors' transactions with the fund); Instruction 4 to Item 13(b) of Form N–1A (management information table).

[226] Proposed Instruction 3 to Item 22(b) of Schedule 14A; proposed Instruction 2 to Item 13 of Form N–1A; proposed Instruction 2 to Item 18 of Form N–2; proposed Instruction 2 to Item 20 of Form N–3.

[227] Proposed Item 22(a)(1)(viii) of Schedule 14A. Business development companies are subject to special provisions under the Act designed to accommodate their venture capital investments. *See* sections 54–65 of the Investment Company Act [15 U.S.C. 80a–53 to 80a–64]. Business development companies are required to have a majority of directors who are not ''interested persons.'' *See* section 56 of the Investment Company Act [15 U.S.C. 80a–55].

[228] We also are proposing to redesignate Item 22(b)(4) as Item 22(b)(10). Funds would not be required to provide information for directors, nominees, and their immediate family members as required by Items 404(a) and (c) of Regulation S–K, through Item 22(b)(10) of Schedule 14A, because we are proposing to require the information under Item 22(b)(7) of Schedule 14A. Proposed Instruction to Item 22(b)(10) of Schedule 14A.

[229] Proposed Item 22(b)(12) of Schedule 14A; proposed Item 13(c) of Form N–1A, proposed item 18.14 of Form N–2; proposed Item 20(m) of Form N–3.

[230] *See* Proposed Item 22(a)(1) of Schedule 14A.

[231] *See* Item 13(c) of Form N–1A; Item 18.2 of Form N–2; Item 20(b) of Form N–3; proposed Item 13(a)(2) of Form N–1A; proposed Item 18.2 of Form N–2; proposed Item 20(b) of Form N–3 (requiring disclosure of officers' positions with affiliated persons of the fund and the principal underwriter).

[232] Proposed Item 22(b)(2) of Schedule 14A; proposed Item 13(a)(3) of Form N–1A; proposed Item 18.3 of Form N–2; proposed Item 20(c) of Form N–3. *See* Items 401(a) and 401(b) of Regulation S–K and Instruction 1 to Items 401(a) and 401(b) of Regulation S–K, through Item 22(b)(4) of Schedule 14A.

[233] 17 CFR 270.30d–1.

[234] Proposed rule 30c–1(d) under the Investment Company Act. We also are proposing to amend rule 30d–1(a) to require funds to include in their shareholder reports any information (not just financial statements) required to be included in those reports by the company's registration statement form under the Investment Company Act. Proposed rule 30e–1(a) under the Investment Company Act. We are redesignating rules 30d–1 and 30d–2 as rules 30e–1 and 30e–2 respectively to reflect the National Securities Markets Improvement Act of 1996 amendments to section 30 of the Act. [Pub. L. No. 104–290, 110 Stat. 3416 (1996) (codified in various sections of the United States Code)].

duties assigned to them, the Act and our rules establish standards concerning their financial and other interests.[235] A fund must determine whether the individuals who serve as independent directors in fact satisfy these standards when it prepares certain disclosure documents for investors.[236] The process that a fund uses to make these determinations should reflect diligent efforts to evaluate each director's relevant business and personal relationships that might affect his independent judgment.

We are proposing to amend our rule requiring funds to preserve certain records to enable the Commission to monitor funds' assessments of the independence of their directors. The proposed amendment would require funds to preserve any record of the initial determination that a director qualifies as an independent director, and each subsequent determination of whether the director continues to qualify as an independent director.[237] We propose that funds preserve these documents for a period of six years, the first two years in an easily accessible place.[238]

Because funds already should be collecting relevant information when they make and review their determinations of director independence,[239] we believe that our proposed recordkeeping requirement would not impose substantial costs or other burdens on funds. Comment is requested on the necessity of this information, and on the costs of maintaining these records. We also request comment on the effects that this proposed recordkeeping requirement would have on funds' internal compliance policies and procedures. Are there feasible alternatives to the proposal that would enable the Commission to monitor funds' assessments of the independence of their directors, while minimizing the burdens imposed on funds?[240]

G. General Request for Comments

The Commission requests comment on the new rules, rule amendments, and form amendments proposed in this Release, suggestions for additional provisions or changes to existing rules or forms, and comments on other matters that might have an effect on the proposals contained in this Release. We also request comment whether the proposals, if adopted, would promote efficiency, competition, and capital formation. We will consider those comments in satisfying our responsibilities under section 2(c) of the Investment Company Act, section 2(b) of the Securities Act, and section 3(f) of the Exchange Act.[241] For purposes of the Small Business Regulatory Enforcement Fairness Act of 1996,[242] we also request information regarding the potential effect of the proposals on the U.S. economy on an annual basis. Commenters are requested to provide empirical data to support their views.

As discussed above, the ICI Advisory Group Report recommended several measures that are similar to our proposed amendments as well as several additional practices and policies. We request comment whether we should adopt any of these ''best practices'' recommendations as further measures to enhance the effectiveness of independent directors.[243]

III. Cost-Benefit Analysis

The Commission is sensitive to the costs and benefits imposed by its rules.

A. Proposed Amendments to the Exemptive Rules

The Commission is proposing to amend the Exemptive Rules[244] to require that, for funds relying on those rules: (i) independent directors constitute either a majority or a super-majority (two-thirds) of their boards; (ii) independent directors select and nominate other independent directors; and (iii) any legal counsel for the fund's independent directors be an independent legal counsel. These proposals are designed to enhance the independence and effectiveness of fund directors who are charged with overseeing the fund's activities and transactions that are covered by the Exemptive Rules. Boards that meet these conditions should be more effective at exerting an independent influence over fund management. Their independent directors should be more likely to have their primary loyalty to the fund's shareholders rather than the adviser, and should be better able to evaluate the complex legal issues that are often faced by fund boards with an independent and critical eye. These proposed amendments, therefore, would provide substantial benefits to shareholders by helping to ensure that independent directors are better able to fulfill their role of representing shareholder interests and supplying an independent check on management.

The proposed amendments to the Exemptive Rules may impose some costs on funds that choose to rely on those rules. Funds that do not rely on an Exemptive Rule, however, will not be subject to the proposed conditions, or any costs associated with those conditions. These costs are discussed below.

Independent directors as a majority of the board. First, the Commission is making two alternative proposals regarding the representation of independent directors on fund boards. Under one proposal, funds relying on the Exemptive Rules would be required to have independent directors constitute a simple majority of their boards. Because, as noted above, most mutual funds today have boards with independent majorities,[245] it appears that this proposal would not impose substantial costs on funds as a group. Under the alternative proposal, funds relying on the Exemptive Rules would be required to have independent directors constitute two-thirds of their boards. Because fewer funds currently have boards of which two-thirds of the directors are independent, this alternative proposal could have higher costs for funds as a group.[246]

Under either of these alternative proposals, funds that currently do not have the required percentage of independent directors on their boards (whether a simple majority or two-

[235] *See supra* notes 21, 170 and accompanying text.

[236] A fund must indicate which individuals are independent directors in its registration statement, as well as in proxy statements for the election of directors. *See supra* note 225 and accompanying text.

[237] Proposed rule 31a–2(a)(4). The proposed rule states that these records must include any questionnaire and any other document used to determine that a director qualifies as independent.

[238] *Id.*

[239] *See, e.g.,* ICI Advisory Group Report, *supra* note 28, at 21 (recommending that funds require independent directors to complete a questionnaire each year on business, financial, and family relationships that could affect their independence).

[240] *See* section 31(a)(2) of the Act [15 U.S.C. 80a–30(a)(2)] (requiring Commission to consider and request public comment on minimizing recordkeeping compliance burdens).

[241] Section 2(c) of the Investment Company Act [15 U.S.C. 80a–2(c)], section 2(b) of the Securities Act [15 U.S.C. 77b(b)], and section 3(f) of the Exchange Act [15 U.S.C. 78c(f)] require the Commission, when it engages in rulemaking and is required to consider whether an action is consistent with the public interest, to consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation.

[242] Pub. L. No. 104–121, Title II, 110 Stat. 857 (1996).

[243] *See supra* notes 34–35 and accompanying and following text.

[244] *See supra* text following note 33.

[245] *See supra* note 39 and accompanying text.

[246] *See supra* note 44. As noted above, however, the ICI Advisory Group Report has recommended that independent directors constitute two-thirds of a fund's board. *See supra* note 42 and accompanying text. It is therefore likely that in the future the number of funds following this practice will increase, even absent the Commission's proposal.

thirds) and that would like to rely on the Exemptive Rules may incur some costs. The Commission, however, has no reasonable basis for estimating those costs. Those funds could come into compliance with either alternative proposal in a number of ways. For example, funds could: (i) decrease the size of their boards and allow some inside directors to resign; (ii) maintain the current size of their boards and replace some inside directors with independent directors; or (iii) increase the size of their boards and elect new independent directors.

Where new independent directors are elected, whether to replace inside directors or to fill new positions that expand the size of the board, the fund would incur the costs of preparing a proxy statement and holding a shareholder meeting to elect those independent directors, as well as the costs of compensating those directors.[247] The Commission, however, has no reasonable basis for determining how many funds that currently do not have independent directors as a simple majority of their boards would choose to comply with either proposal through electing new independent directors. Similarly, we have no reasonable basis for determining how many funds that currently have independent directors as a simple majority, but not as a two-thirds majority, would choose to comply with the alternative proposal through electing new independent directors. We also have no reasonable basis for estimating the average compensation that would be paid to those newly elected independent directors, or the costs to those funds of preparing proxy statements and holding shareholder meetings to elect those directors.

We request comment on the potential costs of each of these alternative proposals. Comment is specifically requested on the differences in costs to funds of the two alternatives.

Independent director self-selection and self-nomination. Second, the proposed amendments to the Exemptive Rules would require that independent directors select and nominate any other independent directors. It appears that this proposal would not impose significant new costs on funds, because many funds already have adopted this practice.[248] Although some funds do not currently follow this practice and would need to adopt it in order to rely on the Exemptive Rules, we are not aware of any costs that would result from requiring a fund's incumbent independent directors to select and nominate other independent directors. Comment is requested on the costs associated with independent director self-selection and self-nomination. Are those costs greater than the costs that would otherwise be incurred by a fund in selecting qualified independent directors?

Independent legal counsel. Finally, the proposed amendments to the Exemptive Rules would require that any legal counsel to a fund's independent directors be an independent legal counsel.[249] The proposal would not require independent directors to *retain* legal counsel, but only that any person that does act as counsel to the independent directors qualify as an independent legal counsel. Independent directors who are represented by counsel who does not meet the proposed definition of ''independent legal counsel'' thus would be required to retain different counsel if their fund chooses to rely on any of the Exemptive Rules. The Commission, however, has no reasonable basis for determining whether this substitution of counsel is likely to cause the independent directors' costs of legal counsel to increase. We request comment on the costs associated with this proposal. Do law firms frequently offer fee arrangements that include, for example, discounts for providing services to both a fund's independent directors and the fund's adviser, which could disqualify the firm from serving as an independent legal counsel?

B. Definition of Independent Legal Counsel

Rule 0–1 defines certain terms for purposes of the rules and regulations under the Investment Company Act. The Commission is proposing to amend this rule to add a definition of the term ''independent legal counsel.'' Under the proposed definition, a person is an independent legal counsel if (i) a fund reasonably believes that the person has not acted as legal counsel to the fund's adviser, principal underwriter, administrator,[250] or any of their control persons[251] during the last two years, or (ii) a majority of the fund's independent directors determines that the person's representation of the fund's adviser, principal underwriter, administrator, or a control person is or was so limited that it would not adversely affect the person's ability to provide impartial, objective and unbiased legal counsel to the independent directors. The basis of the independent directors' determination must be recorded in the minutes of the directors' meeting.

The proposed definition of ''independent legal counsel'' should help to ensure that independent directors' counsel is able to provide impartial legal advice concerning the complex legal issues faced by those directors. This proposal thus should benefit both shareholders and independent directors by helping those directors to better fulfill their role as shareholder representatives. Shareholders also would benefit from the requirement that the independent directors' determinations be recorded in the minute books of the fund, because this requirement would make it possible for the Commission staff to review independent directors' determinations that their counsel qualifies as independent legal counsel.

The proposed definition would impose costs on some funds that rely on the Exemptive Rules and thus would be required to use this definition.[252] We assume that approximately 3,200 funds rely on at least one of the Exemptive Rules annually.[253] We further assume that the independent directors of approximately one-third of those funds (1,065) would be required to make the specified determination in order for their counsel to meet the definition of

[247] Under some circumstances a vacancy on the board may be filled by the board of directors. *See* section 16(a) of the Act. In those cases, the fund would only incur the costs of compensating the new independent directors.

[248] *See supra* note 66 and accompanying text.

[249] As discussed above, we are proposing to amend rule 0–1 to include a definition of ''independent legal counsel.'' *See supra* note 87 and accompanying text; *see also infra* notes 250–256 and accompanying text (discussing the costs and benefits of this proposed definition).

[250] In connection with this proposal, we also are proposing to amend rule 0–1 to define an ''administrator'' as any person who provides significant administrative or business affairs management services to a fund. This definition is substantially similar to the definition of administrator that is currently contained in Item 22(a)(1)(i) of Schedule 14A and Item 15(h)(1) of Form N–1A. Adding this definition to rule 0–1 should benefit funds by helping to clarify the scope of the proposed definition of independent legal counsel. We are not aware of any costs that would be associated with this definition of administrator.

[251] We are proposing to amend rule 0–1 to define ''control person'' as any person (other than a registered investment company) directly or indirectly controlling, controlled by or under common control with a fund's investment adviser, principal underwriter, or administrator. This definition should benefit funds by helping to clarify the scope of the proposed definition of independent legal counsel. We are not aware of any costs that would be associated with this definition.

[252] Among other things, the proposed amendments to the Exemptive Rules would require that, for funds relying on those rules, any legal counsel for the independent directors of the fund be an ''independent legal counsel.''

[253] Based on statistics compiled by Commission staff from January 1, 1997 through December 31, 1998, we estimate that there are approximately 3,560 funds that could rely on one or more of the Exemptive Rules. Of those funds, we assume that approximately 90 percent (3,200) actually rely on at least on Exemptive Rule annually.

''independent legal counsel.''[254] We estimate that each of these 1,065 funds would be required to spend, on average, 0.75 hours annually to comply with the proposed requirement that this determination be recorded in the fund's minute books,[255] for a total annual burden of approximately 799 hours. Based on this estimate, the total annual cost to funds of this proposed definition would be approximately $70,505.[256] The Commission is not aware of any other costs that would be associated with this proposal. Comment is requested on these estimated costs.

C. Suspension of Board Composition Requirements

Proposed rule 10e–1 would increase the periods for which the independent director minimum percentage requirements of the Act, and of the rules under the Act, are temporarily suspended if the death, disqualification, or bona fide resignation of an independent director causes the representation of independent directors on the board to fall below that required by the Act or our rules. This proposal would benefit funds by helping to ensure that a fund that dips below the independent director minimum percentage requirements in these circumstances does not immediately face the severe consequences of losing the availability of the Exemptive Rules.

We are not aware of any costs to funds that would result from this proposal. Because we believe that the periods for which the rule would suspend the independent director minimum percentage requirements are consistent with concerns for investor protection, it also appears that this proposal would not have any costs for investors.

D. Limits on Coverage of Directors Under Joint Insurance Policies

Rule 17d–1(d)(7) under the Act permits funds to purchase joint liability insurance policies without first obtaining a Commission order permitting this joint arrangement, provided that certain conditions are met. The Commission is proposing amendments to this rule that would make the rule available only for joint liability insurance policies that do not exclude coverage for independent directors' litigation expenses in the event that they are sued by the fund's adviser. This proposal should benefit shareholders by making it possible for independent directors to engage in the good faith performance of their responsibilities under the Act and our rules without concern for their personal financial security. For the same reasons, the proposal also should benefit independent directors.

Because obtaining this type of coverage may cause the premiums charged by some insurance providers for joint liability insurance policies to increase, this proposed amendment may have some costs for funds.[257] The Commission, however, has no reasonable basis for estimating the possible increase in premiums that may result from this proposal. Comment is requested on these costs.

E. Exemption From Ratification of Independent Public Accountant Requirement for Funds With Independent Audit Committees

Section 32(a)(2) of the Act requires that the selection of a fund's independent public accountant be submitted to shareholders for ratification or rejection. Proposed rule 32a–4 would exempt a fund from this requirement if the fund has an audit committee consisting entirely of independent directors to oversee the fund's auditor. This proposed exemption could provide significant benefits to shareholders. Many believe shareholder ratification of a fund's independent auditor has become a perfunctory process, with votes that are rarely contested. As a consequence, we believe that the ongoing oversight provided by an independent audit committee can provide greater protection to shareholders than shareholder ratification of the choice of auditor.

Proposed rule 32a–4 may impose certain costs on those funds that choose to rely on the exemption. It appears that these costs likely would be minimal and would be justified by the relief provided by the exemption. To rely on the exemption, among other things, a fund's board of directors must adopt an audit committee charter that sets forth the committee's structure, duties, powers, and methods of operation. The fund also must preserve that charter, and any modifications to the charter, permanently in an easily accessible place.[258] We estimate that there are approximately 3,490 investment companies that may rely on the proposed rule.[259] We assume that approximately 15 percent (524) of those funds are likely to rely on the exemption. For each of those funds, we estimate that the adoption of the audit committee charter would require, on average, 2 hours of director time and 2 hours of professional time,[260] for a total one-time burden of approximately 2,096 hours, and a total one-time cost of approximately $655,000.[261] We also estimate that each of the funds relying on the rule would be required to spend approximately 0.2 hours annually to comply with the proposed requirement that they preserve permanently their audit committee charters,[262] for an additional total annual hour burden of 105 hours, and an additional total annual cost of approximately $5,425.[263] We request comment on these estimated costs.

In addition, some funds pay their directors an extra fee for each committee

[254] We assume that the independent directors of the remaining two-thirds of those funds (2,135) either would not have legal counsel, or would have legal counsel who meets the requirements of the first part of the proposed definition, so that no determination by the independent directors would be necessary.

[255] This estimate is based on a staff assessment of the burden associated with this proposed recordkeeping requirement in light of the estimated hour burdens currently associated with other rules under the Act that impose similar collection of information requirements.

[256] To calculate this total annual cost, the Commission staff assumed that two-thirds of the total annual industry hour burden (532 hours) would be incurred by professionals with an average hourly wage rate of $125 per hour, and one-third of that annual hour burden (267 hours) would be incurred by clerical staff with an average hourly wage rate of $15 per hour ((532 × $125/hour) + (267 × $15/hour) = $70,505).

[257] As discussed above, the ICI Mutual Insurance Company (''ICI Mutual''), which insures funds representing approximately 70 percent of all open-end fund assets, recently announced that it is making available to funds a standard policy endorsement that permits independent directors to recover defense costs, settlements, and judgments in ''insured vs. insured'' claims otherwise covered under the policy. *See supra* note 111. According to an ICI Mutual representative, that company is not charging funds any additional premiums for this coverage. It is possible, however, that other insurance providers will charge funds additional premiums for providing this type of coverage.

[258] These conditions are designed to enable the Commission staff to monitor the duties and responsibilities of an independent audit committee formed by a fund relying on the exemption.

[259] This estimate is based on statistics compiled by Commission staff from January 1, 1997 through December 31, 1998.

[260] This estimate is based on a review of the estimated hour burdens currently associated with other rules under the Act that impose similar collection of information requirements.

[261] To calculate this one-time cost, the Commission staff used $500 per hour as the average cost of directors' time and $125 per hour as an average hourly wage for professionals ((2 hours × 524 funds × $500/hour) + (2 hours × 524 funds × $125/hour) = $655,000).

[262] This estimate is based on a review of the estimated hour burdens associated with other rules under the Act that impose similar collection of information requirements.

[263] To calculate the total annual cost of the proposed rule, the Commission staff assumed that one-third of the total annual hour burden (35 hours) would be incurred by professionals with an hourly wage rate of $125 per hour, and two-thirds of that annual hour burden (70 hours) would be incurred by clerical staff with an hourly wage rate of $15 per hour ((35 × $125/hour) + (70 × $15/hour) = $5,425).

on which they serve.[264] Those funds may incur the additional costs of audit committee fees if they establish an audit committee in order to rely on the proposed exemption. Of those funds likely to rely on the exemption, however, we have no basis for determining the number that would pay their independent directors a separate fee for service on the audit committee, or the likely amount of those fees.[265] Comment is requested on these additional costs that may be associated with this proposed exemption.

F. Qualifications as an Independent Director

The proposed amendment to rule 2a19–1 and proposed new rule 2a19–3 should benefit shareholders, funds, and independent directors by working to prevent qualified individuals from being unnecessarily disqualified from serving as independent directors. The proposed amendment to rule 2a19–1 would make the rule more flexible for all funds, particularly funds with small boards of directors. Proposed rule 2a19–3 would benefit both funds and their independent directors by clarifying the status of independent directors who own shares of index funds.

The Commission is not aware of any costs to funds that would result from these proposals. There also should be no costs to investors because, consistent with concerns for investor protection, these proposals would not permit individuals who have affiliations or business interests that could impair their independence to serve as independent directors.

G. Disclosure of Information About Fund Directors

As discussed above, the purpose of the proposed amendments to the proxy rules and Forms N–1A, N–2, and N–3 is to provide fund investors with improved information about directors. Because independent directors are the shareholders' representatives and advocates, shareholders have a significant interest in knowing who the independent directors are, whether the independent directors' interests are aligned with shareholders' interests, whether the independent directors have any conflicts of interest, and how the directors govern the fund. This information would help a fund shareholder to evaluate whether his designated representatives can, in fact, act as independent, vigorous, and effective representatives.

We believe that the proposed amendments would benefit investors in several ways. The proposed requirement that mutual funds disclose basic information about directors in an easy-to-read tabular format in the fund's annual report to shareholders, SAI, and proxy statements for the election of directors would benefit shareholders by ensuring that shareholders receive information about the identity and experience of their directors both annually and whenever they are asked to elect directors. Moreover, this information would benefit prospective investors who may obtain the information upon request.

Our proposal to require disclosure in the SAI of the aggregate dollar amount of equity securities of funds in the fund complex owned beneficially and of record by each director will allow shareholders and prospective investors to better calculate whether the interests of directors are aligned with their interests. In addition, shareholders also would benefit by receiving this information in the proxy statements whenever they are asked to elect directors.

Our proposal to improve the disclosure of possible conflict of interest circumstances for directors will enable investors to decide for themselves whether an independent director would be an effective advocate. Disclosure of this type of information also would result in its public dissemination, bring these circumstances to the attention of fund shareholders, and encourage the selection of independent directors who are independent in the spirit of the Act. Finally, this information would assist the Commission in determining whether to exercise its authority under section 2(a)(19) of the Act to find that a person is an interested person of a fund by reason of having had, at any time since the beginning of the last two completed fiscal years of the fund, a material business or professional relationship with the fund and certain persons related to the fund.

The proposed modifications to the disclosure requirements of matters related to the board's role in governing a mutual fund would benefit shareholders by allowing them to determine more readily whether the directors are effectively representing shareholders' interests, independent of fund management.

The proposed amendments would impose certain costs on the fund industry. The costs associated with the proposed amendments would include the resources expended by funds in determining what information needs to be disclosed about fund directors (in the case of proxy statements, also nominees) and preparing the disclosure documents.

Proxy Statements. The current hour burden for preparing proxy statements is 96.2 hours per proxy statement, and we estimate that approximately ⅓ of those hours—or 32 hours—are expended collecting and disclosing information about directors and nominees.[266] We estimate the additional burden hours that would be imposed by the proposed disclosure requirements to be 10 hours per proxy statement.[267]

We estimate the annual industry cost of the proposed amendments to the proxy statements to be 10,000 hours, or $1.25 million, based on an estimated 1,000 proxy statements that are filed annually.[268]

Registration Statements. Because the information proposed to be disclosed in the registration statement would be the same as in the proxy statements, we believe the hour burden for the proposed amendments per registration statement would be approximately the current hour burden for collecting and disclosing director information under the current proxy rules plus the hour burden for the proposed amendments to the proxy rules. As stated above, we estimate the current hour burden for collecting and disclosing information about directors and nominees in proxy statements to be 32 hours per proxy statement and the burden hours for collecting and disclosing the enhanced information about directors and nominees to be 10 hours per proxy statement, for a total of 42 hours.

[264] In some cases, funds pay these additional committee fees only if the committee meeting is held on a day when a board meeting is not scheduled.

[265] We also have no basis for determining how many funds would choose to avoid those fees by scheduling audit committee meetings for the same day as a board meeting.

[266] This estimate is based on Commission staff assessment of the different types of information currently required to be disclosed in proxy statements.

[267] This estimate is based upon a Commission staff assessment of the proposed amendments in light of the current hour burden and current reporting requirements. As stated above, the additional hours are based on the additional time funds would devote to determining what information needs to be disclosed and preparing the disclosure documents.

[268] The estimated number of proxy statements is based on the approximate number of proxy statements filed with the Commission in calendar year 1998. The total industry cost of the proposed amendments to the proxy statement is calculated by multiplying the annual number of proxy statements (1,000) by the additional hour burden imposed by the proposed amendments (10 hours) by the hourly wage rate ($125). The hourly wage rate is based upon consultations with a sample of filers and represents the Commission's estimate for an appropriate wage rate for the legal, financial, and accounting skills commonly used in preparation of registration statements, shareholder reports, and proxy statements.

Form N–1A. The hour burden for Form N–1A is on a per portfolio basis and not per registration statement filed with the Commission. Based on the Commission staff's experience with Form N–1A, we estimate that there are approximately 1.75 portfolios per registration statement filed on Form N–1A. The average hour burden per portfolio for disclosing the information about directors would be the hour burden per registration statement (42) divided by the average number of portfolios per registrant (1.75), or 24 hours per portfolio.[269] Because mutual funds would only have to update information in post-effective amendments, we expect that the hour burden would be ⅙ of the hours expended for the initial registration statement, or 4 hours per portfolio for post-effective amendments.[270]

We estimate that 280 portfolios file initial registration statements and 7,875 portfolios file post-effective amendments annually on Form N–1A.[271] Thus, we estimate the annual industry cost of the proposed amendments to Form N–1A to be 38,220 hours, or $4.78 million.[272]

Form N–2. The hour burden for Form N–2 is on a per registration statement basis because funds registering on Form N–2 register one portfolio per registration statement. Because the proposed disclosure would be the same for Form N–2 as for Form N–1A, except that it would be for one portfolio per registration statement, we estimate the additional hour burden for the proposed amendments to be 42 hours for each initial registration statement. Because funds would only have to update information in post-effective amendments, we expect that the hour burden would be approximately ⅙ of the hours expended for the initial registration statement, or 7 hours per post-effective amendment.[273]

We estimate that 110 funds file initial registration statements and 20 file post-effective amendments annually on Form N–2.[274] Thus, we estimate annual industry cost of the proposed amendments to Form N–2 to be 4,760 hours, or $595,000.[275]

Form N–3. The hour burden for Form N–3 is on a per portfolio basis and not per registration statement filed with the Commission. Based on the Commission staff's experience with Form N–3, we estimate that there are approximately 4 portfolios per investment company registering on Form N–3. The average hour burden per portfolio for disclosing the information about directors would be the hour burden per registration statement (42) divided by the approximate number of portfolios per registrant (4), or 10.5 hours per portfolio. Because funds would only have to update information in post-effective amendments, we expect that the hour burden would be ⅙ of the hours expended for the initial registration statement, or 1.75 hours per portfolio for post-effective amendments.[276]

We estimate that 20 portfolios file initial registration statements and 40 portfolios file post-effective amendments annually on Form N–3.[277] Thus, we estimate the annual industry cost of the proposed amendments to Form N–3 to be 280 hours, or $35,000.[278]

Shareholder Reports. Because the disclosure of basic tabular information, which is proposed to be required in annual shareholder reports, is a subset of the information that would be required in the initial registration statement of a fund and any post-effective amendments, we expect that the annual burden for complying with the proposed amendments to the shareholder report requirements would be minimal. Based upon the amount of information proposed to be disclosed, we estimate that the hour burden would be one-half hour per investment company for each annual shareholder report. We estimate that there are 3,490 management investment companies that are subject to the annual report requirements.[279] Thus, we estimate the annual industry cost of the proposed amendments for annual shareholder reports to be 1,745 hours, or $218,125.[280]

H. Recordkeeping Regarding Director Independence

The Commission also is proposing to amend rule 31a–2 under the Act, which requires funds to preserve certain records for specified periods of time. The proposed amendments to rule 31a–2 would require funds to preserve for a period of at least six years any record of: (i) the initial determination that a director qualifies as an independent director, and (ii) each subsequent determination of whether the director continues to qualify as an independent director. This proposal would benefit both shareholders and the Commission by enabling the Commission's staff to monitor a fund's assessments of the independence of its directors. This would make it possible for the Commission to ascertain whether a fund's assessments reflect diligent efforts to evaluate each director's relevant business and personal relationships that might affect the director's independent judgment. The proposed amendment would impose certain minimal costs on funds. The Commission staff estimates that each investment company currently spends

[269] Our estimated hour burden may significantly overstate the burden for those portfolios that are part of a fund complex in which multiple registered investment companies have the same board of directors because the burden of collecting and disclosing information about the common board would be spread over a larger number of portfolios.

[270] Although funds would only have to update the information about current directors and add information about new directors, we anticipate that funds would incur some burden hours in regularly collecting information from directors, determining what information needs to be disclosed, and preparing the updated disclosure.

The hour burden for the post-effective amendment to a registration statement filed by an existing fund after the rules take effect generally would be higher than for subsequent post-effective amendments because the fund would need to compile and disclose the required information for the first time.

[271] These estimates are based on filings received in calendar year 1998.

[272] The total annual industry cost is calculated by multiplying he total annual industry hour burden ((280 portfolios × 24 hours) + (7,875 portfolios × 4 hours)) by the hourly wage rate of $125.

[273] Although funds would only have to update the information about current directors and add information about new directors, we anticipate that funds would incur some burden hours in regularly collecting information from directors, determining what information needs to be disclosed, and preparing the updated disclosure.

The hour burden for the first post-effective amendment to a registration statement filed by an existing fund after the rules take effect generally would be higher than for subsequent post-effective amendments because the fund would need to compile and disclose the required information for the first time.

[274] These estimates are based on filings received in calendar year 1998.

[275] The total annual industry cost is calculated by multiplying the total annual industry hour burden ((110 funds × 42 hours) + (20 funds × 7 hours)) by the hourly wage rate of $125.

[276] Although funds would only have to update the information about current directors and add information about new directors, we anticipate that funds would incur some burden hours in regularly collecting information from directors, determining what information needs to be disclosed, and preparing the updated disclosure.

The hour burden for the first post-effective amendment to a registration statement filed by an existing fund after the rules take effect generally would be higher than for subsequent post-effective amendments because the fund would need to compile and disclose the required information for the first time.

[277] These estimates are based on filings received in calendar year 1998.

[278] The total annual industry cost is calculated by multiplying the total annual industry hour burden ((20 portfolios × 10.5 hours) + (40 portfolios × 1.75 hours)) by the hourly wage rate of $125.

[279] This estimate is based on statistics compiled by Commission staff from January 1, 1997 through December 31, 1998.

[280] The industry cost of the proposed annual shareholder reporting requirements is calculated by multiplying the total annual hour burden for the industry (0.5 hours × 3,490 registered management investment companies) by the hourly wage rate of $125.

about 27.8 hours per year complying with the record preservation requirements of rule 31a–2.[281] Approximately 3,490 investment companies would be affected by the proposal to amend the rule to require funds to preserve records regarding the independence of their directors.[282] The Commission staff estimates that each of those investment companies would be required to spend an additional 0.2 hours annually to comply with the proposed amendment,[283] for a total additional burden for all funds of approximately 698 hours. Based on this estimate, the total annual cost for all funds of the proposed amendment to rule 31a–2 would be $36,100.[284] The Commission is not aware of any other costs that would result from the proposed amendments to rule 31a–2. Comment is requested on the costs associated with this proposal.

To assist in the evaluation of the costs and benefits that may result from the proposed rules and rule amendments, the Commission requests that commenters provide views and data relating to any costs and benefits associated with these proposals.

IV. Paperwork Reduction Act

Certain provisions of Forms N–1A, N–2, and N–3, and rules 0–1, 20a–1, 30e–1, 31a–2, and 32a–4 under the Investment Company Act, and Schedule 14A under the Exchange Act contain ''collection of information'' requirements within the meaning of the Paperwork Reduction Act of 1995 [44 U.S.C. 3501–3520].[285] The Commission has submitted those rules and forms to the Office of Management and Budget (''OMB'') for review in accordance with 44 U.S.C. 3507(d) and 5 CFR 1320.11. The titles for the collections of information are: (1) ''Rule 0–1 under the Investment Company Act of 1940, Definition of terms used in this part;'' (2) ''Rule 20a–1 under the Investment Company Act of 1940, Solicitation of Proxies, Consents and Authorizations;'' (3) ''Form N–1A under the Investment Company Act of 1940 and Securities Act of 1933, Registration Statement of Open-End Management Investment Companies;'' (4) ''Form N–2—Registration Statement of Closed-End Management Investment Companies;'' (5) ''Form N–3—Registration Statement of Separate Accounts Organized as Management Investment Companies;'' (6) ''Rule 30e–1 under the Investment Company Act of 1940, Reports to Stockholders of Management Companies;'' (7) ''Rule 31a–2 under the Investment Company Act of 1940, Records to be preserved by registered investment companies, certain majority-owned subsidiaries thereof, and other persons having transactions with registered investment companies;'' and (8) ''Rule 32a–4 under the Investment Company Act of 1940, Exemption from ratification or rejection requirement of section 32(a)(2) for registered investment companies with independent audit committees.'' An agency may not sponsor, conduct, or require response to an information collection unless a currently valid OMB control number is displayed.

Forms N–1A (OMB Control No. 3235–0307), N–2 (OMB Control No. 3235–0026), and N–3 (OMB Control No. 3235–0316) were adopted pursuant to section 8(a) of the Investment Company Act [15 U.S.C. 80a–8] and section 5 of the Securities Act [15 U.S.C. 77e]. Rule 0–1 was adopted pursuant to section 38(a) of the Investment Company Act [15 U.S.C. 80a–37(a)]. Rule 20a–1 (OMB Control No. 3235–0158) and rule 30e–1 (OMB Control No. 3235–0025) were promulgated under sections 20(a) and 30(e) [15 U.S.C. 80a–20 and 80a–29], respectively, of the Investment Company Act. Rule 31a–2 (OMB Control No. 3235–0179) was adopted under sections 31 [15 U.S.C. 80a–30] and 38(a) of the Investment Company Act. Rule 32a–4 is proposed pursuant to sections 6(c) [15 U.S.C. 80a–6(c)] and 38(a) of the Investment Company Act.

Rule 0–1

The proposed amendments to rule 0–1 include collection of information requirements. Rule 0–1 defines certain terms for purposes of the rules and regulations under the Investment Company Act. The proposed amendments would add a definition of the term ''independent legal counsel'' to this rule. Under the proposed definition, a person is an independent legal counsel if (i) a fund reasonably believes that the person has not acted as legal counsel to the fund's adviser, principal underwriter, administrator, or any of their control persons[286] during the last two years, or (ii) a majority of the fund's independent directors determines that the person's representation of the fund's adviser, principal underwriter, administrator, or a control person is or was so limited that it would not adversely affect the person's ability to provide impartial, objective, and unbiased legal counsel to the independent directors. The basis of the independent directors' determination must be recorded in the minutes of the fund. The purpose of this recordkeeping requirement is to make it possible for the Commission staff to review these determinations.

Any fund that relies on an Exemptive Rule would be required to use this proposed definition of independent legal counsel.[287] We assume that approximately 3,200 funds rely on at least one of the Exemptive Rules annually.[288] We further assume that the independent directors of approximately one-third (1,065) of those funds would need to make the required determination in order for their counsel to meet the definition of ''independent legal counsel.''[289] We estimate that each of these 1,065 funds would be required to spend, on average, 0.75 hours annually to comply with the proposed recordkeeping requirement concerning this determination,[290] for a total annual burden of approximately 799 hours.

Compliance with the proposed rule 0–1 definition of independent legal counsel would be necessary to obtain the benefit of relying on the Exemptive Rules. Responses will not be kept confidential.

Rule 20a–1

Rule 20a–1 requires persons soliciting proxies regarding investment companies to comply with the proxy solicitation requirements of Regulation 14A under the Exchange Act, including Schedule 14A, which, with the proposed amendments, contains collection of information requirements. The likely respondents to this information

[281] Commission staff surveyed representatives of several funds to determine the current burden hour estimate for rule 31a–2.

[282] This estimate is based on statistics compiled by Commission staff from January 1, 1997 through December 31, 1998.

[283] This estimate is based on a Commission staff assessment of the hour burden that would be imposed by the proposed amendment in light of the estimated hour burden currently imposed by the requirements of the rule.

[284] In calculating the total annual industry cost of the proposed amendment, the Commission staff assumed that one-third of the total annual industry hour burden (233 hours) would be incurred by professionals with an average hourly wage rate of $125 per hour, and two-thirds of that annual hour burden (465 hours) would be incurred by clerical staff with an average hourly wage rate of $15 per hour ((233×$125/hour)+(465×$15/hour)=$36,100).

[285] Because we are proposing to redesignate rule 30d–1 as rule 30e–1, were refer to the newly designated rule 30e–1 in this section.

[286] The term ''control person'' is defined as any person (other than a registered investment company) directly or indirectly controlling, controlled by, or under common control with a fund's investment adviser, principal underwriter, or administrator.

[287] Among other things, the proposed amendments to the Exemptive Rules would require that, for funds relying on those rules, any legal counsel for the independent directors of the fund be an independent legal counsel.

[288] *See supra* note 253.

[289] *See supra* note 254.

[290] *See supra* note 255 for the basis of this estimate.

collection are investment companies and other persons filing proxy statements for investment companies. We estimate that 1,000 proxy statements are filed annually for investment companies and that the current hour burden for proxy statements is 96.2 hours per statement.[291]

We estimate that the proposed amendments would increase the hour burden per filing of a proxy statement by 10 hours.[292] Thus, we estimate the hour burden per proxy statement would be 106.2 hours, for a total industry annual hour burden of 106,200 hours.

Compliance with the disclosure requirements of rule 20a–1 and Schedule 14A is mandatory. Responses to the disclosure requirements will not be kept confidential.

Form N–1A

Form N–1A, including the proposed amendments, contains collection of information requirements. The likely respondents to this information collection are open-end funds registering with the Commission on Form N–1A. We estimate that 160 initial registration statements are filed annually on Form N–1A, registering 280 portfolios, and that the current hour burden per portfolio per filing is 800 hours, for an annual hour burden of 224,000 hours.[293] We estimate that 4,500 post-effective amendments to registration statements are filed annually on Form N–1A, for 7,875 portfolios, and that the current hour burden per portfolio per post-effective amendment filing is 100 hours, for an annual hour burden of 787,500 hours.[294] Thus, we estimate a current total annual hour burden of 1,011,500 hours for the preparation and filing of Form N–1A.

We estimate that the proposed amendments would increase the hour burden per portfolio per filing of an initial registration statement by 24 hours and would increase the hour burden per portfolio per filing of a post-effective amendment to a registration statement by 4 hours.[295] Thus, if the proposed amendments to Form N–1A are adopted, the total annual hour burden for all funds for preparation and filing of initial registration statements and post-effective amendments on Form N–1A would be 1,049,720 hours.[296]

Compliance with the disclosure requirements of Form N–1A is mandatory. Responses to the disclosure requirements will not be kept confidential.

Form N–2

Form N–2, including the proposed amendments, contains collection of information requirements. The likely respondents to this information collection are closed-end funds registering with the Commission on Form N–2. We estimate that 110 initial registration statements are filed annually on Form N–2, at a current hour burden per filing of 500 hours, for an annual hour burden of 55,000 hours.[297] We estimate that 20 post-effective amendments to registration statements are filed annually on Form N–2, at a current hour burden of 100 hours, for an annual hour burden of 2,000.[298] Thus, we estimate a current total annual hour burden of 57,000 hours for the preparation and filing of Form N–2.

We estimate that the proposed amendments would increase the hour burden per filing of an initial registration statement by 42 hours and would increase the hour burden per filing of a post-effective amendment to a registration statement by 7 hours.[299] Thus, if the proposed amendments to Form N–2 are adopted, the total annual hour burden for all funds for preparation and filing of initial registration statements and post-effective amendments on Form N–2 would be 61,760 hours.[300]

Compliance with the disclosure requirements of Form N–2 is mandatory. Responses to the disclosure requirements will not be kept confidential.

Form N–3

Form N–3, including the proposed amendments, contains collection of information requirements. The likely respondents to this information collection are separate accounts organized as management investment companies registering with the Commission on Form N–3. We estimate that 5 initial registration statements are filed annually on Form N–3, including approximately 20 portfolios, and that the current hour burden per portfolio in a filing is 900 hours, for an annual hour burden of 18,000 hours.[301] We estimate

[291] The estimated number of proxy statements filed is based on the approximate number of proxy statements filed with the commission in calendar year 1998. The current approved Paperwork Reduction Act (''PRA'') hour burden for rule 20a–1 is 96.2 hours.

[292] This estimate is based upon a Commission staff assessment of the proposed amendments in light of the current hour burden and current reporting requirements.

As stated above, the additional hours are based on the additional time funds would devote to determining what information needs to be disclosed and preparing the disclosure documents.

[293] These estimates are based on filings received in calendar year 1998. The current approved PRA hour burden per portfolio for an initial Form N–1A is 800 hours.

[294] These estimates are based on filings received in calendar year 1998. The current approved PRA hour burden per portfolio for post-effectmens amendmends to Form N–1A is 100 hours.

[295] *See supra* 269 and 270 and accompanying text. As stated above, the additional hours are based on the additional time funds would devote to determining what information needs to be dislosed and preparing the disclosure documents.

For post-effective amendments, although funds would only have to update the information about current directors and add information about new directors, we anticipate that funds would incur some burden hours in regularly collecting information from directors, determining what information needs to be disclosed, and preparing the updated disclosure.

The hour burden for the first post-effective amendment to a registration statement filed by an existing fund after the rules take effect generally would be higher than for subsequent post-effective amendments because the fund would need to compile and disclose the required information for the first time.

[296] This total annual hour burden is calculated by adding the hour burden for initial registration statements and the hour burden for post-effective amendments, based on the proposed amendments. The annual hour burden per portfolio for an initial filing would be 824 hours (800 plus 24), for 280 portfolios, for a total of 230,720 hours. The annual hour burden per portfolio for a post-effective amendment would be 104 hours (100 plus 4), for 7,875 portfolios, for a total of 819,000 hours. The total annual hour burden for all funds for preparing and filing of initial registration statements and post-effective amendments on Form N–1A would be 1,049,720 hours (230,720 plus 819,000).

[297] These estimates are based on filings received in calendar year 1998. The current approved PRA hour burden per initial Form N–2 is 500 hours.

[298] These estimates are based on filings received in calendar year 1998. The current approved PRA hour burden per initial Form N–2 is 100 hours.

[299] *See supra* Section III.F. As states above, the additional hours are based on the additional time funds would devote to determining what information needs to be disclosed and preparing the disclosure documents.

For post-effective amendments, although funds would only have to update the information about current directors and add information about new directors, we anticipate that funds would incur some burden hours in regularly collecting information from directors, determining what information needs to be disclosed, and preparing the updated disclosure.

The hour burden for the first post-effective amendment to a registration statement filed by an existing fund after the rules take effect generally would be higher than for subsequent post-effective amendments because the fund would need to compile and disclose the required information for the first time.

[300] This total annual hour burden is calculated by adding the hour burden for initial registration statements and the hour burden for post-effective amendments, based on the proposed amendments. The annual hour burden per initial registration statement would be 542 hours (500 plus 42), for 110 filings, for a total of 59,620 hours. The annual hour burden per post-effective amendment would be 107 hours (100 plus 7), for 20 post-effective amendments, for a total of 2,140 hours. The total annual hour burden for all funds for preparing and filing of initial registration statements and post-effective amendments on Form N–2 would be 61.760 hours (59,620 plus 2,140).

[301] These estimates are based on filings received in calendar year 1998. The previous Paperwork Reduction Act submission for Form N–3 did not differentiate the hour burden between initial filings

that 10 post-effective amendments to registration statements are filed annually on Form N–3, including approximately 40 portfolios, at a current hour burden of 150 hours per portfolio in a filing, for an annual hour burden of 6,000.[302] Thus, we estimate a current total annual hour burden of 24,000 hours for the preparation and filing of Form N–3.

We estimate that the proposed amendments would increase the hour burden per portfolio per filing of an initial registration statement by 10.5 hours and would increase the hour burden per portfolio per filing of a post-effective amendment to a registration statement by 1.75 hours.[303] Thus, if the proposed amendments to Form N–3 are adopted, the total annual hour burden for all funds for preparation and filing of initial registration statements and post-effective amendments on Form N–3 would be 24,280 hours.[304]

Compliance with the disclosure requirements of Form N–3 is mandatory. Responses to the disclosure requirements will not be kept confidential.

Rule 30e–1 Shareholder Reports[305]

Rule 30e–1, including the proposed amendments to Forms N–1A, N–2, and N–3, contains collection of information requirements.[306] There are approximately 3,490 management investment companies subject to rule 30e–1.[307] We estimate that the current hour burden for preparing and filing semi-annual and annual shareholder reports in compliance with rule 30e–1 is 202 hours.[308] With the proposed amendments, we estimate the hour burden to be 202.5 hours, for a total annual hour burden to the industry of 706,725 hours.[309]

Compliance with the disclosure requirements of rule 30e–1 is mandatory. Responses to the disclosure requirements will not be kept confidential.

Rule 31a–2

Rule 31a–2, including the proposed amendments, contains collection of information requirements. The rule requires funds and certain principal underwriters, broker-dealers, investment advisers and depositors of funds to preserve certain records for at least six years and other records permanently. Its purpose is to ensure that the Commission and the public have access to material business information about funds. The proposed amendments to rule 31a–2 would require funds to preserve for a period of at least six years any record of (i) The initial determination that a director qualifies as an independent director, and (ii) each subsequent determination of whether the director continues to qualify as an independent director. The purpose of this proposal is to enable the Commission to monitor funds' assessments of the independence of their directors.

We estimate that approximately 3,490 management investment companies are likely respondents to rule 31a–2,[310] and that each investment company currently spends about 27.8 hours per year complying with the rule, for a total industry burden of approximately 97,022 hours.[311]

Each of those 3,490 investment companies would be affected by the proposal to amend rule 31a–2 to require funds to preserve records regarding the independence of their directors. We estimate that each of these investment companies would be required to spend an additional 0.2 hours annually to comply with the proposed amendment,[312] for a total additional annual burden for all funds of approximately 698 hours. Thus, we estimate that the total annual burden for all funds of complying with rule 31a–2, as proposed to be amended, would be approximately 97,720 hours.

Compliance with rule 31a–2 is mandatory for every registered fund. The Commission may not keep confidential any records preserved in reliance on the rule.

Rule 32a–4

Proposed rule 32a–4 contains collection of information requirements. The rule provides an exemption from the requirement in section 32(a)(2) of the Act that the selection of a fund's independent public accountant be submitted to shareholders for ratification or rejection, if the fund establishes an audit committee consisting entirely of independent directors to oversee the fund's auditor. To rely on this exemption, among other things, the fund's board of directors must adopt an audit committee charter that sets forth the committee's structure, duties, powers and methods of operation. The fund also must preserve that charter, and any modifications to the charter, permanently in an easily accessible place. The purpose of these conditions is to ensure that the Commission staff will be able to monitor the duties and responsibilities of an independent audit committee formed by a fund relying on this exemption.

We estimate that there are approximately 3,490 investment companies that could rely on the proposed rule. We assume that approximately 15 percent (524) of those funds are likely to rely on the

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and post-effective amendments. the approved hour burden at that time was 518.8 hours per filing based on 53 filings. Based upon experience with Form N–3, we have reevaluated the hour burden for Form N–3 and estimated that exclusive of the proposed amendments, the hour burden for initial filings is 900 hours.

[302] These estimates are based on filings received in calendar year 1998. The previous Paperwork Reduction Act submission for Form N–3 did not differentiate the hour burden between initial filings and post-effective amendments. The approved hour burden at that time was 518.8 hours per filing based on 53 filings. Based upon experience with Form N–3, we have reevaluated the hour burden for Form N–3 and estimated that exclusive of the proposed amendments, the hour burden for post-effective amendments is 150 hours.

[303] *See supra* Section III.F. As stated above, the additional hours are based on the additional time funds would devote the determining what information needs to be disclosed and preparing the disclosure documents.

For post-effective amendments, although funds would only have to update the information about current directors and add information about new directors, we anticipate that funds would incur some burden hours in regularly collecting information from directors, determining what information needs to be disclosed, and preparing the updated disclosure.

The hour burden for the first post-effective amendment to a registration statement filed by an existing fund after the rules take effect generally would be higher than for subsequent post-effective amendments because the fund would need to compile and disclose the required information for the first time.

[304] This total annual hour burden is calculated by adding the hour burden for initial registration statements and the hour burden for post-effective amendments, based on the proposed amendments. the annual hour burden per portfolio for an initial filing would be 910.5 hours (900 plus 10.5), for 20 portfolios, for a total of 18,210 hours. The annual hour burden per portfolio for a post-effective amendment would be 151.75 hours (150 plus 1.75), for 40 portfolios, for a total of 6,070 hours. The total annual hour burden for all funds for preparing and filing of initial registration statements and post-effective amendments on Form N–3 would be 24,280 hours (18,210 plus 6,070).

[305] Because we are proposing to redesignate rule 30d–1 as rule 30e–1, we refer to the newly designated rule 30e–1 in this section.

[306] The proposed amendments are to Forms N–1A, N–2, and N–3. Rule 30e–1 requires funds to include in the shareholder reports the information that is required by the fund's registration statement form.

[307] This estimate is based on statistics compiled by Commission staff from January 1, 1997 through December 31, 1998.

[308] The current approved PRA hour burden for rule 30e–1 is 202 hours per investment company.

[309] *See Supra* section III.F.

[310] The burdens associated with the rule's requirements that investment advisers, underwriters, brokers, dealers, and depositors preserve certain records have been addressed separately in connection with rules adopted under section 204 of the Investment Advisers Act [15 U.S.C. 80b–4] and section 17 of the exchange Act [15 U.S.C. 78q].

[311] The Commission staff surveyed representatives of several funds to determine the current burden hour estimate for rule 31a–2.

[312] *See suprs* note 283 for the basis of this estimate.

exemption. For each of those funds, we estimate that the adoption of the audit committee charter would require, on average, 2 hours of director time and 2 hours of professional time,[313] for a total one-time burden of 2,096 hours. We also estimate that each of the funds relying on the rule would be required to spend approximately 0.2 hours annually to comply with the proposed requirement that they preserve permanently their audit committee charters,[314] for an additional annual hour burden of 105 hours.

Compliance with rule 32a–4 is voluntary. The Commission may not keep confidential the records preserved pursuant to the rule.

Request for Comments

We request your comments on the accuracy of our estimates. Pursuant to 44 U.S.C. 3506(c)(2)(B), the Commission solicits comments to: (i) evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Commission's estimate of the burden of the proposed collection of information; (iii) determine whether there are ways to enhance the quality, utility, and clarity of the information to be collected; and (iv) evaluate whether there are ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

Persons submitting comments on the collection of information requirements should direct the comments to the Office of Management and Budget, Attention: Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Washington, D.C. 20503, and should send a copy to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549, with reference to File No. S7–23–99. The Office of Management and Budget is required to make a decision concerning the collection of information between 30 and 60 days after publication of this release. Consequently, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days after publication of this Release.

[313] *See supra* note 260 for the basis of this estimate.

[314] *See supra* note 262 for the basis of this estimate.

V. Summary of Initial Regulatory Flexibility Analysis

The Commission has prepared an Initial Regulatory Flexibility Analysis (''IRFA'' or ''analysis'') in accordance with 5 U.S.C. 603. The IRFA relates to proposed rules 2a19–3, 10e–1, and 32a–4, and the proposed amendments to rules 0–1, 2a19–1, 10f–3, 12b–1, 15a–4, 17a–7, 17a–8, 17d–1, 17e–1, 17g–1, 18f–3, 23c–3, and 31a–2 (the ''substantive rule proposals''). The IRFA also relates to the proposed amendments to Schedule 14A, Forms N–1A, N–2, and N–3, and rules 30e–1 and 30e–2 (the ''disclosure proposals'').[315] The following summarizes the IRFA.

The analysis explains that the substantive rule proposals contained in this Release include proposed amendments to the Exemptive Rules that are designed to enhance the independence and effectiveness of fund independent directors.[316] The proposals also include new rules and rule amendments that would prevent qualified individuals from being unnecessarily disqualified from serving as independent directors, protect independent directors from the costs of legal disputes with fund management, permit the Commission to monitor the independence of directors by requiring funds to preserve records of their assessments of director independence, and temporarily suspend the independent director minimum percentage requirements if a fund falls below the required percentage due to an independent director's death or resignation. In addition, the Commission is proposing to exempt funds from the requirement that shareholders ratify or reject the directors' selection of an independent public accountant, if the fund establishes an audit committee composed entirely of independent directors.

The analysis also explains that the proposals contained in this Release would require enhanced disclosure about directors that should allow a fund shareholder to evaluate whether his designated representatives can, in fact, act as independent, vigorous, and effective representatives. The analysis explains that the proposed amendments would impose enhanced disclosure requirements on all funds by requiring disclosure of basic information about directors to shareholders in the SAI, proxy solicitations for the election of directors, and annual reports to shareholders. The proposed amendments also would require improved disclosure in the SAI and proxy solicitations for the election of directors about fund shares owned by directors, information about directors that may raise conflict of interest concerns, and information on the board's role in governing the fund.

The analysis discusses the impact of the proposed amendments on small entities. For purposes of the Regulatory Flexibility Act, a fund is a small entity if the fund, together with other funds in the same group of related funds, has net assets of $50 million or less as of the end of its most recent fiscal year.[317]

The analysis notes that as of December 1998, there were approximately 3,560 investment companies that may be affected by one or more of the substantive and disclosure rule proposals, including 320 investment companies that are small entities. The proposed amendments to the Exemptive Rules would affect any of these funds, including those that are small entities, that rely on an Exemptive Rule and do not already meet the proposed new conditions to those rules. The analysis explains that although it appears that funds may incur certain costs in complying with those proposed conditions, the Commission does not have a reasonable basis for estimating those costs. The analysis also explains that the Commission believes that the other substantive rule proposals are not expected to have a significant economic impact on funds, including those that are small entities. The analysis states that the Commission believes that the disclosure changes may have a significant impact on small entities.

The analysis also discusses the reporting, recordkeeping and other compliance requirements associated with the proposals contained in this Release. It notes that the proposed amendments to the Exemptive Rules would require that, for funds relying on those rules: (i) independent directors constitute either a majority or a super-majority (two-thirds) of the fund's board of directors; (ii) independent directors select and nominate other independent directors; and (iii) any legal counsel for

[315] Because we are proposing to redesignate rule 30d–1 as rule 30e–1, and rule 30d–2 as 30e–2, we refer to the newly designated rules 30e–1 and 30e–2 in this section.

[316] These proposals would require that, for funds relying on those exemptive rules, (i) independent directors constitute either a majority or a super-majority (two-thirds) of the fund's board of directors; (ii) independent directors select and nominate other independent directors; and (iii) any legal counsel for the independent directors be an independent legal counsel. In connection with these proposals, we also are proposing to amend rule 0–1 under the Act to add definitions of the terms ''independent legal counsel'' and ''administrator.''

[317] 17 CFR 270.0–10.

the independent directors be an independent legal counsel.

The analysis explains that the proposed amendments to rule 0–1 would add a definition of ''independent legal counsel.'' Under this proposed definition, a person is an independent legal counsel if (i) a fund reasonably believes that the person has not acted as legal counsel to the fund's adviser, principal underwriter, administrator, or any of their control persons during the last two years, or (ii) a majority of the fund's independent directors determines that the person's representation of the fund's adviser, principal underwriter, administrator, or a control person is or was so limited that it would not adversely affect the person's ability to provide impartial, objective, and unbiased legal counsel to the independent directors. The basis of the independent directors' determination must be recorded in the minutes of the fund. The analysis explains that each fund whose independent directors make a determination under the proposed definition would be required to spend approximately 0.75 hours annually to comply with the requirement that the determination be recorded in the minutes of the fund.[318]

Proposed rule 32a–4 would require any fund relying on the exemption provided by the rule to (i) establish an audit committee comprised solely of independent directors, (ii) adopt an audit committee charter, and (iii) preserve that charter, and any modifications to that charter, permanently in an easily accessible place. The analysis explains that the staff estimates that each fund relying on the proposed rule would be required to spend approximately 4 hours to comply with the requirement that it adopt an audit committee charter, and approximately 0.2 hours annually to comply with the requirement that it preserve that charter in an easily accessible place.[319]

In addition, the analysis notes that the proposed amendments to rule 31a–2 would require funds to preserve for a period of at least six years any record of (i) the initial determination that a director qualifies as an independent director, and (ii) each subsequent determination of whether the director continues to qualify as an independent director. The analysis explains the Commission staff estimates that each investment company that must comply with the rule would be required to spend 0.2 hours annually to comply with this new recordkeeping requirement.[320]

The disclosure proposals would require all funds subject to the amendments to provide enhanced disclosure about directors. As explained in the analysis, based upon staff assessment of the proposed amendments in light of the current hour burden and current reporting requirements, the Commission estimates it will take approximately 10 additional hours per proxy statement to include the proposed disclosure about directors; 24 additional hours per portfolio to prepare an initial registration statement on Form N–1A and 4 additional hours per portfolio to prepare post-effective amendments to the registration statement on Form N–1A that include the proposed disclosure about directors; 42 additional hours per registrant to prepare an initial registration statement on Form N–2 and 7 additional hours per registrant to prepare post-effective amendments to the registration statement on Form N–2 that include the proposed disclosure about directors; 10.5 additional hours per portfolio to prepare an initial registration statement on Form N–3 and 1.75 additional hours per portfolio to prepare post-effective amendments to the registration statement on Form N–3 that include the proposed disclosure about directors; and 0.5 additional hours per investment company to include the proposed basic information about directors in the annual report to shareholders.[321]

As stated in the analysis, the Commission considered several alternatives to both the substantive rule proposals and the disclosure proposals, including establishing different compliance or reporting requirements for small entities or exempting them from all or part of the proposed amendments. The Commission believes that establishing different substantive or disclosure requirements applicable specifically to small entities is inconsistent with the protection of investors. The Commission also believes that adjusting the proposals to establish different compliance requirements for small entities could undercut the purpose of the proposals: to enhance the effectiveness of independent directors, and thus better enable those directors to fulfill their role of protecting shareholder interests.

The Commission encourages the submission of comments on matters discussed in the IRFA. Comment specifically is requested on the number of small entities that would be affected by the proposals and the impact of the proposals on small entities. Commenters are asked to describe the nature of any impact and provide empirical data supporting the extent of the impact. These comments will be placed in the same public comment file as comments on the proposals. A copy of the IRFA may be obtained by contacting Jennifer B. McHugh or Heather A. Seidel, Securities and Exchange Commission, 450 5th Street, N.W., Washington, D.C. 20549–0506.

VI. Statutory Authority

The Commission is proposing rules 2a19–3, 10e–1, and 32a–4, and amendments to rules 0–1, 2a19–1, 10f–3, 12b–1, 15a–4, 17a–7, 17a–8, 17d–1, 17e–1, 17g–1, 18f–3, 23c–3, 30d–1, 30d–2, and 31a–2 pursuant to authority set forth in sections 6(c), 10(e), 30(e), 31, and 38(a) of the Investment Company Act [15 U.S.C. 80a–6(c), 80a–10(e), 80a–29(e), 80a–30, 80a–37(a)]. The Commission is proposing amendments to Schedule 14A pursuant to authority set forth in sections 14 and 23(a)(1) of the Exchange Act [15 U.S.C. 78n, 78w(a)(1)] and sections 20(a) and 38 of the Investment Company Act [15 U.S.C. 80a–20(a), 80a–37]. The Commission is proposing amendments to Forms N–1A, N–2, and N–3 pursuant to authority set forth in sections 5, 6, 7, 10, and 19(a) of the Securities Act of 1933 [15 U.S.C. 77e, 77f, 77g, 77j, 77s(a)] and sections 8, 24(a), 30, and 38 of the Investment Company Act [15 U.S.C. 80a–8, 80a–24(a), 80a–29, 80a–37].

List of Subjects

17 CFR Parts 239 and 240

Reporting and recordkeeping requirements, Securities.

17 CFR Parts 270 and 274

Investment companies, Reporting and recordkeeping requirements, Securities.

Text of Proposed Rules and Forms

1. For the reasons set out in the preamble, Title 17, Chapter II of the Code of Federal Regulations is proposed to be amended as follows:

[318] *See supra* note 255 for the basis of this estimate.

[319] *See supra* notes 260 and 262 for the basis of these estimates.

[320] *See supra* note 283 for the basis of this estimate.

[321] The hour burden for the first post-effective amendment to a registration statement filed by an existing fund after the rules take effect generally would be higher than for subsequent post-effective amendments because the fund would need to compile and disclose the required information for the first time.

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

1. The authority citation for part 240 continues to read, in part, as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78f, 78i, 78j, 78j–1, 78k, 78k–1, 78l, 78m, 78n, 78o, 78p, 78q, 78s, 78u–5, 78w, 78x, 78ll(d), 78mm, 79q, 79t, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4 and 80b–11, unless otherwise noted.

* * * * *

2. Section 240.14a–101 is amended by revising paragraphs (d) and (e) of Item 7 to read as follows:

§ 240.14a–101 Schedule 14A. Information required in proxy statement.

* * * * *

Item 7. Directors and executive officers.

* * * * *

(d)(1) State whether or not the registrant has standing audit, nominating and compensation committees of the Board of Directors, or committees performing similar functions. If the registrant has such committees, however designated, identify each committee member, state the number of committee meetings held by each such committee during the last fiscal year and describe briefly the functions performed by such committees.

(2) If the registrant has a nominating or similar committee, state whether the committee will consider nominees recommended by security holders and, if so, describe the procedures to be followed by security holders in submitting such recommendations.

(e) In lieu of paragraphs (a) through (d) of this Item, investment companies registered under the Investment Company Act of 1940 must furnish the information required by Item 22(b) of this Schedule 14A.

* * * * *

3. In § 240.14a–101 amend Item 8(d), before the Instruction, by revising ''Item 22(b)(6)'' to read ''Item 22(b)(12)''.

4. In § 240.14a–101 amend the Instruction following Item 10(a)(2)(ii)(A) by revising ''Item 22(b)(6)'' to read ''Item 22(b)(12)''.

5. In § 240.14a–101 amend the Instruction following Item 10(b)(1)(ii) by revising ''Item 22(b)(6)(ii)'' to read ''Item 22(b)(12)(ii)''.

6. Item 22 of § 240.14a–101 is amended by:

A. Revising paragraph (a)(1)(i);

B. Redesignating paragraphs (a)(1)(vi), (vii), and (viii) as paragraphs (a)(1)(viii), (ix), and (xi);

C. Adding new paragraphs (a)(1)(vi), (vii), and (x); and

D. Revising newly designated paragraph (a)(1) (ix).

The revisions and additions read as follows:

§ 240.14a–101 Schedule 14A. Information required in proxy statement.

* * * * *

Item 22. Information required in investment company proxy statement.

(a) * * *

(1) * * *

(i) *Administrator.* The term ''Administrator'' shall mean any person who provides significant administrative or business affairs management services to a Fund.

* * * * *

(vi) *Immediate family member.* The term ''Immediate Family Member'' shall mean a person's spouse, parent, child, sibling, mother- or father-in-law, son- or daughter-in-law, or brother- or sister-in-law, and includes step and adoptive relationships.

(vii) *Officer.* The term ''Officer'' shall mean the president, vice-president, secretary, treasurer, controller, or any other officer who performs policy-making functions.

* * * * *

(ix) *Registrant.* The term ''Registrant'' shall mean an investment company registered under the Investment Company Act of 1940 or a business development company as defined by section 2(a)(48) of the Investment Company Act of 1940.

(x) *Sponsoring Insurance Company.* The term ''Sponsoring Insurance Company'' of a Fund that is a separate account shall mean the insurance company that establishes and maintains the separate account and that owns the assets of the separate account.

* * * * *

7. Section 240.14a–101 is amended by revising paragraph (b) of Item 22 to read as follows:

§ 240.14a–101 Schedule 14A. Information required in proxy statement.

* * * * *

Item 22. Information required in investment company proxy statement.

* * * * *

(b) *Election of directors.* If action is to be taken with respect to the election of directors of a Fund, furnish the following information in the proxy statement in addition to the information (and in the format) required by paragraphs (f) and (g) of Item 7 of Schedule 14A.

Instructions to introductory text of paragraph (b). 1. Furnish information with respect to a prospective investment adviser to the extent applicable.

2. If the solicitation is made by or on behalf of a person other than the Fund or an investment adviser of the Fund, provide information only as to nominees of the person making the solicitation.

3. When providing information about directors and nominees for election as directors in response to this Item 22(b), furnish information for directors or nominees who are or would be ''interested persons'' within the meaning of section 2(a)(19) of the Investment Company Act of 1940 separately from the information for directors or nominees who are not or would not be ''interested persons.'' For example, when furnishing information in a table, you should provide separate tables (or separate sections of a single table) for directors and nominees who are or would be interested persons and for directors or nominees who are not or would not be interested persons. When furnishing information in narrative form, indicate by heading or otherwise the directors or nominees who are or would be interested persons and the ones who are not or would not be interested persons.

4. No information need be given about any director whose term of office as a director will not continue after the meeting to which the proxy statement relates.

(1) Provide the information required by the following table for each director, nominee for election as director, Officer of the Fund, person chosen to become an Officer of the Fund, and, if the Fund has an advisory board, member of the board. Explain in a footnote to the table any family relationship between the persons listed.

(1)	(2)	(3)	(4)	(5)	(6)
Name, Address, and Age	Position(s) Held with Fund	Term of Office and Length of Time Served	Principal Occupation(s) During Past 5 Years	Number of Portfolios in Fund Complex Overseen by Director or Nominee for Director	Other Directorships Held by Director or Nominee for Director

Instructions to paragraph (b)(1). 1. For purposes of this paragraph, the term ''family relationship'' means any relationship by blood, marriage, or adoption, not more remote than first cousin.

2. No nominee or person chosen to become a director or Officer who has not consented to act as such may be named in response to this Item. In this regard, see Rule 14a–4(d) under the Exchange Act (§ 240.14a–4(d) of this chapter).

3. If fewer nominees are named than the number fixed by or pursuant to the governing instruments, state the reasons for this procedure and that the proxies cannot be voted for a greater number of persons than the number of nominees named.

4. For each director or nominee for election as director who is or would be an ''interested person'' within the meaning of section 2(a)(19) of the Investment Company Act of 1940, describe, in a footnote or otherwise, the relationship, events, or transactions by reason of which the director or nominee is or would be an interested person.

5. State the principal business of any company listed under column (4) unless the principal business is implicit in its name.

6. Include in column (5) the total number of separate portfolios that a nominee for election as director would oversee if he were elected.

7. Indicate in column (6) directorships not included in column (5) that are held by a director or nominee for election as director in any company with a class of securities registered pursuant to section 12 of the Exchange Act or subject to the requirements of section 15(d) of the Exchange Act or any company registered as an investment company under the Investment Company Act of 1940, 15 U.S.C. 80a, as amended, and name the companies in which the directorships are held. Where the other directorships include directorships overseeing two or more portfolios in the same Fund Complex, identify the Fund Complex and provide the number of portfolios overseen as a director in the Fund Complex rather than listing each portfolio separately.

(2) Describe briefly any arrangement or understanding between any director, nominee for election as director, Officer, or person chosen to become an Officer, and any other person(s) (naming the person(s)) pursuant to which he was or is to be selected as a director, nominee, or Officer.

Instruction to paragraph (b)(2). Do not include arrangements or understandings with directors or Officers acting solely in their capacities as such.

(3) Unless disclosed in the table required by paragraph (b)(1) of this Item, describe any positions, including as an officer, employee, director, or general partner, held by a director, nominee for election as director, or Immediate Family Member of the director or nominee, during the past five years, with:

(i) The Fund;

(ii) An investment company, or a person that would be an investment company but for the exclusions provided by sections 3(c)(1) and 3(c)(7) of the Investment Company Act of 1940 (15 U.S.C. 80a–3(c)(1) and (c)(7)), having the same investment adviser, principal underwriter, Administrator, or Sponsoring Insurance Company as the Fund or having an investment adviser, principal underwriter, Administrator, or Sponsoring Insurance Company that directly or indirectly controls, is controlled by, or is under common control with an investment adviser, principal underwriter, Administrator, or Sponsoring Insurance Company of the Fund;

(iii) An investment adviser, principal underwriter, Administrator, Sponsoring Insurance Company, or affiliated person of the Fund; or

(iv) Any person directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, Administrator, or Sponsoring Insurance Company of the Fund.

Instruction to paragraph (b)(3). When an individual holds the same position(s) with two or more portfolios that are part of the same Fund Complex, identify the Fund Complex and provide the number of portfolios for which the position(s) are held rather than listing each portfolio separately.

(4) For each director or nominee for election as director, state the aggregate dollar amount of equity securities of Funds in the same Fund Complex as the Fund owned beneficially or of record by the director or nominee as required by the following table:

(1)	(2)	(3)
Name of Director or Nominee	Identity of Fund Complex	Aggregate Dollar Amount of Equity Securities in Fund Complex

Instructions to paragraph (b)(4). 1. Information should be provided as of the most recent practicable date. Specify the valuation date by footnote or otherwise.

2. Determine ''beneficial ownership'' in accordance with rule 13d–3 under the Exchange (§ 240.13d–3 of this chapter).

(5) For each director or nominee for election as director and his Immediate Family Members, furnish the information required by the following table as to each class of securities owned beneficially or of record in:

(i) An investment adviser, principal underwriter, Administrator, or Sponsoring Insurance Company of the Fund; or

(ii) a person (other than a registered investment company) directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, Administrator, or Sponsoring Insurance Company of the Fund:

(1)	(2)	(3)	(4)	(5)	(6)
Name of Director or Nominee	Name of Owners and Relationships to Director or Nominee	Company	Title of Class	Value of Securities	Percent of Class

Instructions to paragraph (b)(5).

1. Information should be provided as of the most recent practicable date. Specify the valuation date by footnote or otherwise.

2. Determine ''beneficial ownership'' in accordance with rule 13d-3 under the Exchange Act (§ 240.13d-3 of this chapter).

3. Identify the company in which the director, nominee, or Immediate Family Member of the director or nominee owns securities in column (3). When the company is a person directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, Administrator, or Sponsoring Insurance Company, describe the company's relationship with the investment adviser, principal underwriter, Administrator, or Sponsoring Insurance Company.

4. Provide the information required by columns (5) and (6) on an aggregate basis for each director (or nominee) and his Immediate Family Members.

(6) Unless disclosed in response to paragraph (b)(5) of this Item, describe any material interest, direct or indirect, of each director, nominee for election as director, or Immediate Family Member of a director or nominee, during the past five years, in:

(i) An investment adviser, principal underwriter, Administrator, or Sponsoring Insurance Company of the Fund; or

(ii) A person (other than a registered investment company) directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, Administrator, or Sponsoring Insurance Company of the Fund.

Instruction to paragraph (b)(6). A director, nominee, or Immediate Family Member has an interest in a company if he is a party to a contract, arrangement, or understanding with respect to any securities of, or interest in, the company.

(7) Describe briefly any material interest, direct or indirect, of any director, nominee for election as director, or Immediate Family Member of a director or nominee in any material transaction, or material series of similar transactions, since the beginning of the last two completed fiscal years of the Fund, or in any currently proposed material transaction, or material series of similar transactions, to which any of the following persons was or is to be a party:

(i) The Fund;

(ii) An Officer of the Fund;

(iii) An investment company, or a person that would be an investment company but for the exclusions provided by sections 3(c)(1) and 3(c)(7) of the Investment Company Act of 1940 (15 U.S.C. 80a-3(c)(1) and (c)(7)), having the same investment adviser, principal underwriter, Administrator, or Sponsoring Insurance Company as the Fund or having an investment adviser, principal underwriter, Administrator, or Sponsoring Insurance Company that directly or indirectly controls, is controlled by, or is under common control with an investment adviser, principal underwriter, Administrator, or Sponsoring Insurance Company of the Fund;

(iv) An Officer of an investment company, or a person that would be an investment company but for the exclusions provided by sections 3(c)(1) and 3(c)(7) of the Investment Company Act of 1940 (15 U.S.C. 80a-3(c)(1)

and (c)(7)), having the same investment adviser, principal underwriter, Administrator, or Sponsoring Insurance Company as the Fund or having an investment adviser, principal underwriter, Administrator, or Sponsoring Insurance Company that directly or indirectly controls, is controlled by, or is under common control with an investment adviser, principal underwriter, Administrator, or Sponsoring Insurance Company of the Fund;

(v) An investment adviser, principal underwriter, Administrator, or Sponsoring Insurance Company of the Fund;

(vi) An Officer of an investment adviser, principal underwriter, Administrator, or Sponsoring Insurance Company of the Fund;

(vii) A person directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, Administrator, or Sponsoring Insurance Company of the Fund; or

(viii) An Officer of a person directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, Administrator, or Sponsoring Insurance Company of the Fund.

Instructions to paragraph (b)(7).

1. Include the name of each director, nominee, or Immediate Family Member whose interest in any transaction or series of similar transactions is described and the nature of the circumstances by reason of which the interest is required to be described.

2. State the nature of the interest, the approximate dollar amount involved in the transaction, and, where practicable, the approximate dollar amount of the interest.

3. In computing the amount involved in the transaction or series of similar transactions, include all periodic payments in the case of any lease or other agreement providing for periodic payments.

4. Compute the amount of the interest of any director, nominee, or Immediate Family Member of the director or nominee without regard to the amount of profit or loss involved in the transaction(s).

5. As to any transaction involving the purchase or sale of assets, state the cost of the assets to the purchaser and, if acquired by the seller within two years prior to the transaction, the cost to the seller. Describe the method used in determining the purchase or sale price and the name of the person making the determination.

6. If the proxy statement relates to multiple portfolios of a series Fund with different fiscal years, then, in determining the date that is the beginning of the last two completed fiscal years of the Fund, use the earliest date of any series covered by the proxy statement.

7. Disclose indirect, as well as direct, material interests in transactions. A person who has a position or relationship with, or interest in, a company that engages in a transaction with one of the persons listed in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item may have an indirect interest in the transaction by reason of the position, relationship, or interest. The interest in the transaction, however, will not be deemed ''material'' within the meaning of paragraph (b)(7) of this Item where the interest of the director, nominee, or Immediate Family Member arises solely from the holding of an equity interest (including a limited partnership interest, but excluding a general partnership interest) or a creditor interest in a company that is a party to the transaction with one of the persons specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item, and the transaction is not material to the company.

8. No information need be given as to any transaction where the interest of the director, nominee, or Immediate Family Member arises solely from the ownership of securities of a person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item and the director, nominee, or Immediate Family Member receives no extra or special benefit not shared on a pro rata basis by all holders of the class of securities.

9. Transactions include loans, lines of credit, and other indebtedness. For indebtedness, indicate the largest aggregate amount of indebtedness outstanding at any time during the period, the nature of the indebtedness and the transaction in which it was incurred, the amount outstanding as of the latest practicable date, and the rate of interest paid or charged.

10. No information need be given as to any routine, retail transaction. For example, the Fund need not disclose that a director holds a credit card or bank or brokerage account with a person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item unless the director is accorded special treatment.

(8) Describe briefly any material relationship, direct or indirect, of any director, nominee for election as director, or Immediate Family Member of a director or nominee that exists, or has existed at any time since the beginning of the last two completed fiscal years of the Fund, or is currently proposed, with any of the persons specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item. Relationships include:

(i) Payments for property or services to or from any person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item;

(ii) Provision of legal services to any person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item;

(iii) Provision of investment banking services to any person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item, other than as a participating underwriter in a syndicate; and

(iv) Any consulting or other relationship that is substantially similar in nature and scope to the relationships listed in paragraphs (b)(8)(i) through (b)(8)(iii) of this Item.

Instructions to paragraph (b)(8). 1. Include the name of each director, nominee, or Immediate Family Member whose relationship is described and the nature of the circumstances by reason of which the relationship is required to be described.

2. State the nature of the relationship and the amount of business conducted between the director, nominee, or Immediate Family Member and the person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item as a result of the relationship since the beginning of the last two completed fiscal years of the Fund or proposed to be done during the Fund's current fiscal year.

3. In computing the amount involved in a relationship, include all periodic payments in the case of any agreement providing for periodic payments.

4. If the proxy statement relates to multiple portfolios of a series Fund with different fiscal years, then, in determining the date that is the beginning of the last two completed fiscal years of the Fund, use the earliest date of any series covered by the proxy statement.

5. Disclose indirect, as well as direct, material relationships. A person who has a position or relationship with, or interest in, a company that has a relationship with one of the persons listed in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item may have an indirect relationship by reason of the position, relationship, or interest. The relationship, however, will not be deemed ''material'' within the meaning of paragraph (b)(8) of this Item where the relationship of the director, nominee, or Immediate Family Member arises solely from the holding of an equity interest (including a limited partnership interest, but excluding a general partnership interest) or a creditor interest in a company that has a relationship with one of the persons specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item, and the relationship is not material to the company.

6. In the case of an indirect interest, identify the company with which a person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item has a relationship; the name of the director,

nominee, or Immediate Family Member affiliated with the company and the nature of the affiliation; and the amount of business done between the company and the person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item since the beginning of the last two completed fiscal years of the Fund or proposed to be done during the Fund's current fiscal year.

7. In calculating payments for property and services for purposes of paragraph (b)(8)(i) of this Item, the following may be excluded:

A. Payments where the transaction involves the rendering of services as a common contract carrier, or public utility, at rates or charges fixed in conformity with law or governmental authority; or

B. Payments that arise solely from the ownership of securities of a person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item and no extra or special benefit not shared on a pro rata basis by all holders of the class of securities is received.

8. No information need be given as to any routine, retail relationship. For example, the Fund need not disclose that a director holds a credit card or bank or brokerage account with a person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item unless the director is accorded special treatment.

(9) If an Officer of an investment adviser, principal underwriter, Administrator, or Sponsoring Insurance Company of the Fund, or an Officer of a person directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, Administrator, or Sponsoring Insurance Company of the Fund, serves, or has served since the beginning of the last two completed fiscal years of the Fund, on the board of directors of a company where a director of the Fund, nominee for election as director, or Immediate Family Member of a director or nominee is, or was since the beginning of the last two completed fiscal years of the Fund, an Officer, identify:

(i) The company;

(ii) The individual who serves or has served as a director of the company and the period of service as director;

(iii) The investment adviser, principal underwriter, Administrator, or Sponsoring Insurance Company or person controlling, controlled by, or under common control with the investment adviser, principal underwriter, Administrator, or Sponsoring Insurance Company where the individual named in paragraph (b)(9)(ii) of this Item holds or held office and the office held; and

(iv) The director of the Fund, nominee for election as director, or Immediate Family Member who is or was an Officer of the company; the office held; and the period of holding the office.

Instruction to paragraph (b)(9). If the proxy statement relates to multiple portfolios of a series Fund with different fiscal years, then, in determining the date that is the beginning of the last two completed fiscal years of the Fund, use the earliest date of any series covered by the proxy statement.

(10) Provide in tabular form, to the extent practicable, the information required by Items 401(f) and (g), 404(a) and (c), and 405 of Regulation S-K (§§ 229.401(f) and (g), 229.404(a) and (c), and 229.405 of this chapter).

Instruction to paragraph (b)(10). Information provided under paragraph (b)(7) of this Item 22 is deemed to satisfy the requirements of Items 404(a) and (c) of Regulation S-K for information about directors, nominees for election as directors, and Immediate Family Members of directors and nominees, and need not be provided under this paragraph (b)(10).

(11) Describe briefly any material pending legal proceedings, other than ordinary routine litigation incidental to the Fund's business, to which any director or nominee for director or affiliated person of such director or nominee is a party adverse to the Fund or any of its affiliated persons or has a material interest adverse to the Fund or any of its affiliated persons. Include the name of the court where the case is pending, the date instituted, the principal parties, a description of the factual basis alleged to underlie the proceeding, and the relief sought.

(12) For all directors, and for each of the three highest-paid Officers that have aggregate compensation from the Fund for the most recently completed fiscal year in excess of $60,000 (''Compensated Persons''):

(i) Furnish the information required by the following table for the last fiscal year:

COMPENSATION TABLE

(1)	(2)	(3)	(4)	(5)
Name of Person, Position	Aggregate Compensation From Fund	Pension or Retirement Benefits Accrued as Part of Fund Expenses	Estimated Annual Benefits Upon Retirement	Total Compensation From Fund and Fund Complex Paid to Directors

Instructions to paragraph (b)(12)(i). 1. For column (1), indicate, if necessary, the capacity in which the remuneration is received. For Compensated Persons that are directors of the Fund, compensation is amounts received for service as a director.

2. If the Fund has not completed its first full year since its organization, furnish the information for the current fiscal year, estimating future payments that would be made pursuant to an existing agreement or understanding. Disclose in a footnote to the Compensation Table the period for which the information is furnished.

3. Include in column (2) amounts deferred at the election of the Compensated Person, whether pursuant to a plan established under Section 401(k) of the Internal Revenue Code (26 U.S.C. 401(k)) or otherwise, for the fiscal year in which earned. Disclose in a footnote to the Compensation Table the total amount of deferred compensation (including interest) payable to or accrued for any Compensated Person.

4. Include in columns (3) and (4) all pension or retirement benefits proposed to be paid under any existing plan in the event of retirement at normal retirement date, directly or indirectly, by the Fund or any of its Subsidiaries, or by other companies in the Fund Complex. Omit column (4) where retirement benefits are not determinable.

5. For any defined benefit or actuarial plan under which benefits are determined primarily by final compensation (or average final compensation) and years of service, provide the information required in column (4) in a separate table showing estimated annual benefits payable upon retirement (including amounts attributable to any defined benefit supplementary or excess pension award plans) in specified compensation and years of service classifications. Also provide the estimated credited years of service for each Compensated Person.

6. Include in column (5) only aggregate compensation paid to a director for service on the board and other boards of investment companies in a Fund Complex specifying the number of such other investment companies.

(ii) Describe briefly the material provisions of any pension, retirement, or other plan or any arrangement other than fee arrangements disclosed in paragraph (b)(12)(i) of this Item pursuant to which Compensated Persons are or may be compensated for any services provided, including amounts paid, if any, to the Compensated Person under any such arrangements during the most recently completed fiscal year. Specifically include the criteria used to determine amounts payable under any plan, the length of service or vesting period required by the plan, the retirement age or other event that gives rise to payments under the plan, and whether the payment of benefits is secured or funded by the Fund.

(iii) With respect to each Compensated Person, business development companies must include the information required by Items 402(b)(2)(iv) and 402(c) of Regulation S–K (§§ 229.402(b)(2)(iv) and 229.402(c) of this chapter).

(13) Identify the standing committees of the Fund's board of directors, and provide the following information about each committee:

(i) A concise statement of the functions of the committee;

(ii) The members of the committee;

(iii) The number of committee meetings held during the last fiscal year; and

(iv) If the committee is a nominating or similar committee, state whether the committee will consider nominees recommended by security holders and, if so, describe the procedures to be followed by security holders in submitting recommendations.

* * * * *

PART 270—RULES AND REGULATIONS, INVESTMENT COMPANY ACT OF 1940

8. The authority citation for part 270 is amended by adding the following citation to read as follows:

Authority: 15 U.S.C. 80a–1 *et seq.*, 80a–34(d), 80a–37, 80a–39 unless otherwise noted:

* * * * *

Section 270.10e–1 is also issued under 15 U.S.C. 80a–10(e).

* * * * *

9. Section 270.0–1 is amended by adding paragraphs (a)(5) and (a)(6) to read as follows:

§ 270.0–1 Definition of terms used in this part.

* * * * *

(a) * * *

(5) The term *administrator* means any person who provides significant administrative or business affairs management services to an investment company.

(6)(i) A person is an *independent legal counsel* with respect to the directors who are not interested persons of an investment company (''disinterested directors'') if:

(A) The investment company reasonably believes that the person has not acted as legal counsel for the company's investment adviser, principal underwriter, administrator (collectively, ''management organizations''), or any of their control persons at any time since the beginning of the company's last two completed fiscal years; or

(B) A majority of the disinterested directors determine (and record the basis for that determination in the minutes of their meeting) that the person's representation of any of the company's management organizations or any of their control persons is or was so limited that it would not adversely affect the person's ability to provide impartial, objective, and unbiased legal counsel to the disinterested directors.

(ii) For purposes of paragraph (a)(6)(i) of this section:

(A) The term *person* has the same meaning as in section 2(a)(28) of the Act (15 U.S.C. 80a–2(a)(28)) and, in addition, includes a partner, co-member, or employee of any person; and

(B) The term *control person* means any person (other than an investment company) directly or indirectly controlling, controlled by, or under common control with any of the investment company's management organizations.

* * * * *

10. The section heading for § 270.2a19–1 is revised to read as follows:

§ 270.2a19–1 Certain investment company directors not considered interested persons because of broker-dealer affiliation.

* * * * *

11. Section 270.2a19–1 is amended by removing the phrase ''a minority of the directors f'' in paragraph (a)(3) and adding in its place the phrase ''one-half of the directors of''.

12. Section 270.2a19–3 is added to read as follows:

§ 270.2a19–3 Certain investment company directors not considered interested persons because of ownership of index fund securities.

If a director of a registered investment company (''Fund'') owns shares of a registered investment company (including the Fund) with an investment objective to replicate the performance of one or more securities indices (''Index Fund''), ownership of the Index Fund shares will not cause the director to be considered an ''interested person'' of the Fund or of the Fund's investment adviser or principal underwriter (as defined by section 2(a)(19)(A)(iii) and (B)(iii) of the Act (15 U.S.C. 80a–2(a)(19)(A)(iii) and (B)(iii))), if the value of the securities of the Fund's investment adviser or principal underwriter (or a controlling person of the investment adviser or principal underwriter) in any of the securities indices constitutes no more than five percent of the value of that index.

13. Section 270.10e–1 is added to read as follows:

§ 270.10e–1 Death, disqualification, or bona fide resignation of directors.

If a registered investment company, by reason of the death, disqualification, or bona fide resignation of any director, does not meet any requirement of the Act or any rule or regulation regarding the composition of the company's board of directors, the operation of the relevant subsection of the Act, rule, or regulation will be suspended as to the company:

(a) For 60 days if the vacancy may be filled by action of the board of directors; or

(b) For 150 days if a vote of stockholders is required to fill the vacancy.

14. Section 270.10f–3 is amended by redesignating paragraph (b)(11) as paragraph (b)(12) and adding new paragraph (b)(11) to read as follows:

§ 270.10f–3 Exemption for the acquisition of securities during the existence of an underwriting or selling syndicate.

* * * * *

(b) * * *

(11) *Board Composition, Selection, and Representation.* (i) [A majority/At least two-thirds] of the directors of the investment company are not interested persons of the company, and those directors select and nominate any other disinterested directors of the company; and

(ii) Any person who acts as legal counsel for the disinterested directors of the company is an independent legal counsel.

* * * * *

Section 270.12b–1 is amended by revising paragraph (c) to read as follows:

§ 270.12b–1 Distribution of shares by registered open-end management investment company.

* * * * *

(c) A registered open-end management investment company may rely on the provisions of paragraph (b) of this section only if:

(1) [A majority/At least two-thirds] of the directors of the company are not interested persons of the company, and those directors select and nominate any other disinterested directors of the company; and

(2) Any person who acts as legal counsel for the disinterested directors of the company is an independent legal counsel;

* * * * *

16. Section 270.15a–4 is amended by removing the word ''and'' at the end of paragraph (a), removing the period at the end of paragraph (b) and adding in its place ''; and'' and adding paragraph (c) to read as follows:

§ 270.15a–4 Temporary exemption for certain investment advisers.

* * * * *

(c)(1) [A majority/At least two-thirds] of the directors of the investment company are not interested persons of the company, and those directors select and nominate any other disinterested directors of the company; and

(2) Any person who acts as legal counsel for the disinterested directors of the company is an independent legal counsel.

17. Section 270.17

a–7 is amended by:

A. Removing the ''and'' at the end of paragraph (e)(3), IPB. Redesignating paragraph (f) as paragraph (g), and

C. Adding new paragraph (f) to read as follows:

§ 270.17a–7 Exemption of certain purchase or sale transactions between an investment company and certain affiliated persons thereof.

* * * * *

(f)(1) [A majority/At least two-thirds] of the directors of the investment company are not interested persons of the company, and those directors select and nominate any other disinterested directors of the company; and

(2) Any person who acts as legal counsel for the disinterested directors of the company is an independent legal counsel; and

* * * * *

18. Section 270.17a–8 is amended by:

A. Removing the ‘‘, and’’ at the end of paragraph (a)(2) and in its place adding a semi-colon,

B. Removing the period at the end of paragraph (b) and adding in its place ‘‘; and’’, and

C. Adding paragraph (c) to read as follows:

§ 270.17a–8 Mergers of certain affiliated investment companies.

* * * * *

(c)(1) [A majority/At least two-thirds] of the directors of the investment company are not interested persons of the company, and those directors select and nominate any other disinterested directors of the company; and

(2) Any person who acts as legal counsel for the disinterested directors of the company is an independent legal counsel.

19. Section 270.17d–1 is amended by:

A. Removing the word ‘‘and’’ at the end of paragraph (d)(7)(ii),

B. Redesignating paragraph (d)(7)(iii) as paragraph (d)(7)(iv),

C. Removing the period at the end of newly designated paragraph (d)(7)(iv) and adding in is place ‘‘; and’’, and

D. Adding new paragraphs (d)(7)(iii) and (d)(7)(v) to read as follows:

§ 270.17d–1 Applications regarding joint enterprises or arrangements and certain profit-sharing plans.

* * * * *

(d) * * *

(7) * * *

(iii) The joint liability insurance policy does not exclude coverage for bona fide claims made against any director who is not an interested person of the investment company, or against the investment company if it is a co-defendant in the claim with the disinterested director, by another person insured under the joint liability insurance policy;

* * * * *

(v)(A) [A majority/At least two-thirds] of the directors of the investment company are not interested persons of the company, and those directors select and nominate any other disinterested directors of the company; and

(B) Any person who acts as legal counsel for the disinterested directors of the company is an independent legal counsel.

* * * * *

20. Section 270.17e–1 is amended by:

Removing the word ‘‘and’’ at the end of paragraph (b)(3), redesignating paragraph (c) as paragraph (d), and adding new paragraph (c) to read as follows:

§ 270.17e–1 Brokerage transactions on a securities exchange.

* * * * *

(c)(1) [A majority / At least two-thirds] of the directors of the investment company are not interested persons of the company, and those directors select and nominate any other disinterested directors of the company; and

(2) Any person who acts as legal counsel for the disinterested directors of the company is an independent legal counsel; and

* * * * *

21. Section 270.17g–1 is amended by revising paragraph (j) to read as follows:

§ 270.17g–1 Bonding of officers and employees of registered management investment companies.

* * * * *

(j) Any joint insured bond provided and maintained by a registered management investment company and one or more other parties shall be a transaction exempt from the provisions of section 17(d) of the Act (15 U.S.C. 80a–17(d)) and the rules thereunder, if:

(1) The terms and provisions of the bond comply with the provisions of this section;

(2) The terms and provisions of any agreement required by paragraph (f) of this section comply with the provisions of that paragraph; and

(3)(i) [A majority / At least two-thirds] of the directors of the investment company are not interested persons of the company, and those directors select and nominate any other disinterested directors of the company; and

(ii) Any person who acts as legal counsel for the disinterested directors of the company is an independent legal counsel.

* * * * *

22. Section 270.18f–3 is amended by redesigning paragraph (e) as paragraph (f), and adding new paragraph (e) to read as follows:

§ 270.18f–3 Multiple class companies.

* * * * *

(e)(1) [A majority / At least two-thirds] of the directors of the investment company are not interested persons of the company, and those directors select and nominate any other disinterested directors of the company; and

(2) Any person who acts as legal counsel for the disinterested directors of the company is an independent legal counsel.

* * * * *

23. Section 270.23c–3 is amended by revising paragraph (b)(8) to read as follows:

§ 270.23c–3 Repurchase offers by closed-end companies.

* * * * *

(b) * * *

(8)(i) [A majority / At least two-thirds] of the directors of the investment company are not interested persons of the company, and those directors select and nominate any other disinterested directors of the company; and

(ii) Any person who acts as legal counsel for the disinterested directors of the company is an independent legal counsel.

* * * * *

24. Redesignate § 270.30d–1 as § 270.30e–1; in newly designated § 270.30e–1, in paragraph (a), revise ‘‘financial statements’’ to read ‘‘information’’; and revise paragraph (d) to read as follows:

§ 270.30e–1 Reports to stockholders of management companies.

* * * * *

(d) An open-end company may transmit a copy of its current effective prospectus or Statement of Additional Information, or both, under the Securities Act, inplace of any report required to be transmitted to shareholders by this section, provided that the prospectus or Statement of Additional Information, or both, include all the information that would otherwise be required to be contained in the report by this section. Such prospectus or Statement of Additional Information, or both, shall be transmitted within 60 days after the close of the period for which the report is being made.

* * * * *

§ 270.30d–2 [Redesignated as § 270.30e–2]

25. Redesignate § 270.30d–2 as § 270.30e–2 and in newly designated § 270.30e–2 revise ‘‘Rule N–30D–1’’ to read ‘‘§ 270.30e–1 of this chapter’’ in the first and second sentence.

26. Section 270.31a–2 is amended by removing the period at end of paragraph (a)(3) and in its place adding a semi-

colon, and adding paragraphs (a)(4) and (a)(5) to read as follows:

§ 270.31a–2 Records to be preserved by registered investment companies, certain majority-owned subsidiaries thereof, and other persons having transactions with registered investment companies.

(a) * * *

(4) Preserve for a period not less than six years, the first two years in an easily accessible place, any record of the initial determination that a director is not an interested person of the investment company, and each subsequent determination that the director is not an interested person of the investment company. These records must include any questionnaire and any other document used to determine that a director is not an interested person of the company; and

(5) Preserve for a period not less than six years, the first two years in an easily accessible place, any document used by an investment company to establish a reasonable belief that any person who acts as legal counsel to the directors who are not interested persons of the company is an independent legal counsel and any document used by the disinterested directors to determine that any current or prior representation is or was so limited that it will not adversely affect the counsel's ability to provide impartial, objective, and unbiased legal advice.

* * * * *

27. Section 270.32a–4 is added to read as follows:

§ 270.32a–4 Exemption from ratification or rejection requirement of section 32(a)(2) for certain registered investment companies with independent audit committees.

A registered management investment company or a registered face-amount certificate company is exempt from the requirement of section 32(a)(2) of the Act (15 U.S.C. 80a–31(a)(2)) that the selection of the company's independent public accountant be submitted for ratification or rejection at the next succeeding annual meeting of shareholders, if:

(a) The company's board of directors has established a committee that has responsibility for overseeing the fund's accounting and auditing processes (''audit committee'');

(b) The audit committee is composed solely of directors who are not interested persons of the fund;

(c) The company's board of directors has adopted a charter for the audit committee setting forth the committee's structure, duties, powers, and methods of operation; and

(d) The company maintains and preserves permanently in an easily accessible place a copy of the audit committee's charter and any modification to the charter.

PART 239—FORMS PRESCRIBED UNDER THE SECURITIES ACT OF 1933

28. The authority citation for part 239 continues to read, in part, as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 77z–2, 77sss, 78c, 78l, 78m, 78n, 78o(d), 78u–5, 78w(a), 78ll(d), 79e, 79f, 79g, 79j, 79l, 79m, 79n, 79q, 79t, 80a–8, 80a–24, 80a–29, 80a–30 and 80a–37, unless otherwise noted.

* * * * *

PART 274—FORMS PRESCRIBED UNDER THE INVESTMENT COMPANY ACT OF 1940

29. The authority citation for part 274 continues to read as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 78c(b), 78l, 78m, 78n, 78o(d), 80a–8, 80a–24, and 80a–29, unless otherwise noted.

Note: The text of Form N–1A does not and these amendments will not appear in the Code of Federal Regulations.

30. Item 13 of Form N–1A (referenced in §§ 239.15A and 274.11A) is amended by adding Instructions 1 and 2 before paragraph (a); removing paragraphs (a), (b), and (c) and adding paragraphs (a) and (b) in their place; redesignating paragraphs (d) and (e) as paragraphs (c) and (d); and removing ''executive'' from the first sentence of newly redesignated paragraph (c) to read as follows:

Form N–1A

* * * * *

Item 13. Management of the Fund

Instructions

1. For purposes of this Item 13, the terms below have the following meanings:

(a) The term ''fund complex'' means two or more registered investment companies that:

(1) Hold themselves out to investors as related companies for purposes of investment and investor services; or (2) Have a common investment adviser or have an investment adviser that is an affiliated person of the investment adviser of any of the other registered investment companies.

(b) The term ''immediate family member'' means a person's spouse, parent, child, sibling, mother- or father-in-law, son- or daughter-in-law, or brother- or sister-in-law, and includes step and adoptive relationships.

(c) The term ''officer'' means the president, vice-president, secretary, treasurer, controller, or any other officer who performs policy-making functions.

2. When providing information about directors, furnish information for directors who are interested persons separately from the information for directors who are not interested persons. For example, when furnishing information in a table, you should provide separate tables (or separate sections of a single table) for directors who are interested persons and for directors who are not interested persons. When furnishing information in narrative form, indicate by heading or otherwise the directors who are interested persons and the ones who are not interested persons.

(a) *Management Information.* (1) Provide the information required by the following table for each director and officer of the Fund, and, if the Fund has an advisory board, member of the board. Explain in a footnote to the table any family relationship between the persons listed.

(1)	(2)	(3)	(4)	(5)	(6)
Name, Address, and Age	Position(s) Held with Fund	Term of Office and Length of Time Served	Principal Occupation(s) During Past 5 Years	Number of Portfolios in Fund Complex Overseen by Director	Other Directorships Held by Director

Instructions

1. For purposes of this paragraph, the term ''family relationship'' means any relationship by blood, marriage, or adoption, not more remote than first cousin.

2. For each director who is an interested person, describe, in a footnote or otherwise, the relationship, events, or transactions by reason of which the director is an interested person.

3. State the principal business of any company listed under column (4) unless

the principal business is implicit in its name.

4. Indicate in column (6) directorships not included in column (5) that are held by a director in any company with a class of securities registered pursuant to section 12 of the Securities Exchange Act (15 U.S.C. 78*l*) or subject to the requirements of section 15(d) of the Securities Exchange Act (15 U.S.C. 78o(d)) or any company registered as an investment company under the Investment Company Act, and name the companies in which the directorships are held. Where the other directorships include directorships overseeing two or more portfolios in the same fund complex, identify the fund complex and provide the number of portfolios overseen as a director in the fund complex rather than listing each portfolio separately.

(2) For each individual listed in column (1) of the table required by paragraph (a)(1) of this Item 13 who is not a director, describe any positions, including as an officer, employee, director, or general partner, held with affiliated persons or principal underwriters of the Fund.

Instruction. When an individual holds the same position(s) with two or more registered investment companies that are part of the same fund complex, identify the fund complex and provide the number of registered investment companies for which the position(s) are held rather than listing each registered investment company separately.

(3) Describe briefly any arrangement or understanding between any director or officer and any other person(s) (naming the person(s)) pursuant to which he was selected as a director or officer.

Instruction. Do not include arrangements or understandings with directors or officers acting solely in their capacities as such.

(b) *Board of Directors.*

(1) Briefly describe the responsibilities of the board of directors with respect to the Fund's management.

Instruction. A Fund may respond to this paragraph by providing a general statement as to the responsibilities of the board of directors with respect to the Fund's management under the applicable laws of the state or other jurisdiction in which the Fund is organized.

(2) Identify the standing committees of the Fund's board of directors, and provide the following information about each committee:

(i) A concise statement of the functions of the committee;

(ii) The members of the committee;

(iii) The number of committee meetings held during the last fiscal year; and

(iv) If the committee is a nominating or similar committee, state whether the committee will consider nominees recommended by security holders and, if so, describe the procedures to be followed by security holders in submitting recommendations.

(3) Unless disclosed in the table required by paragraph (a)(1) of this Item 13, describe any positions, including as an officer, employee, director, or general partner, held by a director or immediate family member of the director during the past five years with:

(i) The Fund;

(ii) An investment company, or a person that would be an investment company but for the exclusions provided by sections 3(c)(1) and 3(c)(7) (15 U.S.C. 80a–3(c)(1) and (c)(7)), having the same investment adviser, principal underwriter, or administrator as the Fund or having an investment adviser, principal underwriter, or administrator that directly or indirectly controls, is controlled by, or is under common control with an investment adviser, principal underwriter, or administrator of the Fund;

(iii) An investment adviser, principal underwriter, administrator, or affiliated person of the Fund; or

(iv) Any person directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, or administrator of the Fund.

Instruction. When an individual holds the same position(s) with two or more portfolios that are part of the same fund complex, identify the fund complex and provide the number of portfolios for which the position(s) are held rather than listing each portfolio separately.

(4) For each director, state the aggregate dollar amount of equity securities of registered investment companies in the same fund complex as the Fund owned beneficially or of record by the director as required by the following table:

(1)	(2)	(3)
Name of Director	Identity of Fund Complex	Aggregate Dollar Amount of Equity Securities in Fund Complex

Instructions

1. Information should be provided as of the most recent practicable date. Specify the valuation date by footnote or otherwise.

2. Determine ''beneficial ownership'' in accordance with rule 13d–3 under the Exchange Act (§ 240.13d–3 of this chapter).

(5) For each director and his immediate family members, furnish the information required by the following table as to each class of securities owned beneficially or of record in:

(i) An investment adviser, principal underwriter, or administrator of the Fund; or

(ii) A person (other than a registered investment company) directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, or administrator of the Fund:

(1)	(2)	(3)	(4)	(5)	(6)
Name of Director	Name of Owners and Relationships to Director	Company	Title of Class	Value of Securities	Percent of Class

Instructions

1. Information should be provided as of the most recent practicable date. Specify the valuation date by footnote or otherwise.

2. Determine ''beneficial ownership'' in accordance with rule 13d–3 under the Exchange Act (§ 240.13d–3 of this chapter).

3. Identify the company in which the director or immediate family member of the director owns securities in column (3). When the company is a person directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, or administrator, describe the company's relationship with the investment adviser, principal underwriter, or administrator.

4. Provide the information required by columns (5) and (6) on an aggregate

basis for each director and his immediate family members.

(6) Unless disclosed in response to paragraph (b)(5) of this Item 13, describe any material interest, direct or indirect, of each director or immediate family member of a director, during the past five years, in:

(i) An investment adviser, principal underwriter, or administrator of the Fund; or

(ii) A person (other than a registered investment company) directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, or administrator of the Fund.

Instruction. A director or immediate family member has an interest in a company if he is a party to a contract, arrangement, or understanding with respect to any securities of, or interest in, the company.

(7) Describe briefly any material interest, direct or indirect, of any director or immediate family member of a director in any material transaction, or material series of similar transactions, since the beginning of the last two completed fiscal years of the Fund, or in any currently proposed material transaction, or material series of similar transactions, to which any of the following persons was or is to be a party:

(i) The Fund;

(ii) An officer of the Fund;

(iii) An investment company, or a person that would be an investment company but for the exclusions provided by sections 3(c)(1) and 3(c)(7) (15 U.S.C. 80a–3(c)(1) and (c)(7)), having the same investment adviser, principal underwriter, or administrator as the Fund or having an investment adviser, principal underwriter, or administrator that directly or indirectly controls, is controlled by, or is under common control with an investment adviser, principal underwriter, or administrator of the Fund;

(iv) An officer of an investment company, or a person that would be an investment company but for the exclusions provided by sections 3(c)(1) and 3(c)(7) (15 U.S.C. 80a–3(c)(1) and (7)), having the same investment adviser, principal underwriter, or administrator as the Fund or having an investment adviser, principal underwriter, or administrator that directly or indirectly controls, is controlled by, or is under common control with an investment adviser, principal underwriter, or administrator of the Fund;

(v) An investment adviser, principal underwriter, or administrator of the Fund;

(vi) An officer of an investment adviser, principal underwriter, or administrator of the Fund;

(vii) A person directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, or administrator of the Fund; or

(viii) An officer of a person directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, or administrator of the Fund.

Instructions

1. Include the name of each director or immediate family member whose interest in any transaction or series of similar transactions is described and the nature of the circumstances by reason of which the interest is required to be described.

2. State the nature of the interest, the approximate dollar amount involved in the transaction, and, where practicable, the approximate dollar amount of the interest.

3. In computing the amount involved in the transaction or series of similar transactions, include all periodic payments in the case of any lease or other agreement providing for periodic payments.

4. Compute the amount of the interest of any director or immediate family member of the director without regard to the amount of profit or loss involved in the transaction(s).

5. As to any transaction involving the purchase or sale of assets, state the cost of the assets to the purchaser and, if acquired by the seller within two years prior to the transaction, the cost to the seller. Describe the method used in determining the purchase or sale price and the name of the person making the determination.

6. If the Registrant is a Series company whose Series have different fiscal years, then, in determining the date that is the beginning of the last two completed fiscal years of the Registrant, use the earliest date of any Series.

7. Disclose indirect, as well as direct, material interests in transactions. A person who has a position or relationship with, or interest in, a company that engages in a transaction with one of the persons listed in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13 may have an indirect interest in the transaction by reason of the position, relationship, or interest. The interest in the transaction, however, will not be deemed ''material'' within the meaning of paragraph (b)(7) of this Item 13 where the interest of the director or immediate family member arises solely from the holding of an equity interest (including a limited partnership interest, but excluding a general partnership interest) or a creditor interest in a company that is a party to the transaction with one of the persons specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13, and the transaction is not material to the company.

8. No information need be given as to any transaction where the interest of the director or immediate family member arises solely from the ownership of securities of a person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13 and the director or immediate family member receives no extra or special benefit not shared on a pro rata basis by all holders of the class of securities.

9. Transactions include loans, lines of credit, and other indebtedness. For indebtedness, indicate the largest aggregate amount of indebtedness outstanding at any time during the period, the nature of the indebtedness and the transaction in which it was incurred, the amount outstanding as of the latest practicable date, and the rate of interest paid or charged.

10. No information need be given as to any routine, retail transaction. For example, the Fund need not disclose that a director holds a credit card or bank or brokerage account with a person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13 unless the director is accorded special treatment.

(8) Describe briefly any material relationship, direct or indirect, of any director or immediate family member of a director that exists, or has existed at any time since the beginning of the last two completed fiscal years of the Fund, or is currently proposed, with any of the persons specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13. Relationships include:

(i) Payments for property or services to or from any person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13;

(ii) Provision of legal services to any person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13;

(iii) Provision of investment banking services to any person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13, other than as a participating underwriter in a syndicate; and

(iv) Any consulting or other relationship that is substantially similar in nature and scope to the relationships

listed in paragraphs (b)(8)(i) through (b)(8)(iii) of this Item 13.

Instructions

1. Include the name of each director or immediate family member whose relationship is described and the nature of the circumstances by reason of which the relationship is required to be described.

2. State the nature of the relationship and the amount of business conducted between the director or immediate family member and the person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13 as a result of the relationship since the beginning of the last two completed fiscal years of the Fund or proposed to be done during the Fund's current fiscal year.

3. In computing the amount involved in a relationship, include all periodic payments in the case of any agreement providing for periodic payments.

4. If the Registrant is a Series company whose Series have different fiscal years, then, in determining the date that is the beginning of the last two completed fiscal years of the Registrant, use the earliest date of any Series.

5. Disclose indirect, as well as direct, material relationships. A person who has a position or relationship with, or interest in, a company that has a relationship with one of the persons listed in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13 may have an indirect relationship by reason of the position, relationship, or interest. The relationship, however, will not be deemed ''material'' within the meaning of paragraph (b)(8) of this Item 13 where the relationship of the director or immediate family member arises solely from the holding of an equity interest (including a limited partnership interest, but excluding a general partnership interest) or a creditor interest in a company that has a relationship with one of the persons specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13, and the relationship is not material to the company.

6. In the case of an indirect interest, identify the company with which a person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13 has a relationship; the name of the director or immediate family member affiliated with the company and the nature of the affiliation; and the amount of business done between the company and the person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13 since the beginning of the last two completed fiscal years of the Fund or proposed to be done during the Fund's current fiscal year.

7. In calculating payments for property and services for purposes of paragraph (b)(8)(i) of this Item 13, the following may be excluded:

A. Payments where the transaction involves the rendering of services as a common contract carrier, or public utility, at rates or charges fixed in conformity with law or governmental authority; or

B. Payments that arise solely from the ownership of securities of a person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13 and no extra or special benefit not shared on a pro rata basis by all holders of the class of securities is received.

8. No information need be given as to any routine, retail relationship. For example, the Fund need not disclose that a director holds a credit card or bank or brokerage account with a person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13 unless the director is accorded special treatment.

(9) If an officer of an investment adviser, principal underwriter, or administrator of the Fund, or an officer of a person directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, or administrator of the Fund, serves, or has served since the beginning of the last two completed fiscal years of the Fund, on the board of directors of a company where a director of the Fund or immediate family member of a director is, or was since the beginning of the last two completed fiscal years of the Fund, an officer, identify:

(i) The company;

(ii) The individual who serves or has served as a director of the company and the period of service as director;

(iii) The investment adviser, principal underwriter, or administrator or person controlling, controlled by, or under common control with the investment adviser, principal underwriter, or administrator where the individual named in paragraph (b)(9)(ii) of this Item 13 holds or held office and the office held; and

(iv) The director of the Fund or immediate family member who is or was an officer of the company; the office held; and the period of holding the office.

Instruction. If the Registrant is a Series company whose Series have different fiscal years, then, in determining the date that is the beginning of the last two completed fiscal years of the Registrant, use the earliest date of any Series.

(10) Discuss in reasonable detail the material factors and the conclusions with respect thereto that formed the basis for the board of directors approving the existing investment advisory contract. If applicable, include a discussion of any benefits derived or to be derived by the investment adviser from the relationship with the Fund such as soft dollar arrangements by which brokers provide research to the Fund or its investment adviser in return for allocating fund brokerage.

Instruction. Conclusory statements or a list of factors will not be considered sufficient disclosure. The discussion should relate the factors to the specific circumstances of the Fund and the investment advisory contract.

* * * * *

31. Item 22 of Form N–1A (referenced in §§ 239.15A and 274.11A) is amended by adding paragraphs (b)(5) and (b)(6) to read as follows:

Form N–1A

* * * * *

Item 22. Financial Statements

* * * * *

(b) * * *

(5) The management information required by Item 13(a)(1).

(6) A statement that the SAI includes additional information about Fund directors and is available, without charge, upon request, and a toll-free (or collect) telephone number for shareholders to call to request the SAI.

* * * * *

Note: The text of Form N–2 does not and these amendments will not appear in the Code of Federal Regulations

32. Item 18 of Form N–2 (referenced in §§ 239.14 and 274.11a–1) is amended by adding Instructions 1 and 2 before paragraph 1; revising paragraphs 1 and 2; redesignating paragraphs 3 and 4 as paragraphs 4 and 14; adding new paragraphs 3 and 5 through 13; and removing ''executive'' from the first sentence of newly designated paragraph 14 to read as follows:

Form N–2

* * * * *

Item 18. Management

Instructions

1. For purposes of this Item 18, the terms below have the following meanings:

a. The term ''fund complex'' means two or more registered investment companies that:

(i) Hold themselves out to investors as related companies for purposes of investment and investor services; or

(ii) Have a common investment adviser or have an investment adviser

that is an affiliated person of the investment adviser of any of the other registered investment companies.

b. The term ''immediate family member'' means a person's spouse, parent, child, sibling, mother- or father-in-law, son- or daughter-in-law, or brother- or sister-in-law, and includes step and adoptive relationships.

c. The term ''officer'' means the president, vice-president, secretary, treasurer, controller, or any other officer who performs policy-making functions.

2. When providing information about directors, furnish information for directors who are interested persons as defined in Section 2(a)(19) of the 1940 Act (15 U.S.C. 80a–2(a)(19)) and the rules thereunder separately from the information for directors who are not interested persons. For example, when furnishing information in a table, you should provide separate tables (or separate sections of a single table) for directors who are interested persons and for directors who are not interested persons. When furnishing information in narrative form, indicate by heading or otherwise the directors who are interested persons and the ones who are not interested persons.

1. Provide the information required by the following table for each director and officer of the Registrant, and, if the Registrant has an advisory board, member of the board. Explain in a footnote to the table any family relationship between the persons listed.

(1)	(2)	(3)	(4)	(5)	(6)
Name, Address, and Age	Position(s) Held with Registrant	Term of Office and Length of Time Served	Principal Occupation(s) During Past 5 Years	Number of Portfolios in Fund Complex Overseen by Director	Other Directorships Held by Director

Instructions

1. For purposes of this paragraph, the term ''family relationship'' means any relationship by blood, marriage, or adoption, not more remote than first cousin.

2. For each director who is an interested person as defined in Section 2(a)(19) of the 1940 Act (15 U.S.C. 80a–2(a)(19)) and the rules thereunder, describe, in a footnote or otherwise, the relationship, events, or transactions by reason of which the director is an interested person.

3. State the principal business of any company listed under column (4) unless the principal business is implicit in its name.

4. Indicate in column (6) directorships not included in column (5) that are held by a director in any company with a class of securities registered pursuant to section 12 of the Exchange Act (15 U.S.C. 78*l*) or subject to the requirements of section 15(d) of the Exchange Act (15 U.S.C. 78o(d)) or any company registered as an investment company under the 1940 Act, and name the companies in which the directorships are held. Where the other directorships include directorships overseeing two or more portfolios in the same fund complex, identify the fund complex and provide the number of portfolios overseen as a director in the fund complex rather than listing each portfolio separately.

2. For each individual listed in column (1) of the table required by paragraph 1 who is not a director, describe any positions, including as an officer, employee, director, or general partner, held with affiliated persons or principal underwriters of the Registrant.

Instruction: When an individual holds the same position(s) with two or more registered investment companies that are part of the same fund complex, identify the fund complex and provide the number of registered investment companies for which the position(s) are held rather than listing each registered investment company separately.

3. Describe briefly any arrangement or understanding between any director or officer and any other person(s) (naming the person(s)) pursuant to which he was selected as a director or officer.

Instruction: Do not include arrangements or understandings with directors or officers acting solely in their capacities as such.

4. For each non-resident director or officer of the Registrant listed in column (1) of the table required by paragraph 1, disclose whether he has authorized an agent in the United States to receive notice and, if so, disclose the name and address of the agent.

5. Identify the standing committees of the Registrant's board of directors, and provide the following information about each committee:

(a) A concise statement of the functions of the committee;

(b) The members of the committee;

(c) The number of committee meetings held during the last fiscal year; and

(d) If the committee is a nominating or similar committee, state whether the committee will consider nominees recommended by security holders and, if so, describe the procedures to be followed by security holders in submitting recommendations.

6. Unless disclosed in the table required by paragraph 1 of this Item 18, describe any positions, including as an officer, employee, director, or general partner, held by a director or immediate family member of the director during the past five years with:

(a) The Registrant;

(b) An investment company, or a person that would be an investment company but for the exclusions provided by sections 3(c)(1) and 3(c)(7) of the 1940 Act (15 U.S.C. 80a–3(c)(1) and (c)(7)), having the same investment adviser, principal underwriter, or administrator as the Registrant or having an investment adviser, principal underwriter, or administrator that directly or indirectly controls, is controlled by, or is under common control with an investment adviser, principal underwriter, or administrator of the Registrant;

(c) An investment adviser, principal underwriter, administrator, or affiliated person of the Registrant; or

(d) Any person directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, or administrator of the Registrant.

Instruction: When an individual holds the same position(s) with two or more portfolios that are part of the same fund complex, identify the fund complex and provide the number of portfolios for which the position(s) are held rather than listing each portfolio separately.

7. For each director, state the aggregate dollar amount of equity securities of registered investment companies in the same fund complex as the Registrant owned beneficially or of record by the director as required by the following table:

(1)	(2)	(3)
Name of Director	Identity of Fund Complex	Aggregate Dollar Amount of Equity Securities in Fund Complex

Instructions

1. Information should be provided as of the most recent practicable date. Specify the valuation date by footnote or otherwise.

2. Determine ''beneficial ownership'' in accordance with rule 13d–3 under the Exchange Act (§ 240.13d–3 of this chapter).

8. For each director and his immediate family members, furnish the information required by the following table as to each class of securities owned beneficially or of record in:

(a) An investment adviser, principal underwriter, or administrator of the Registrant; or

(b) A person (other than a registered investment company) directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, or administrator of the Registrant:

(1)	(2)	(3)	(4)	(5)	(6)
Name of Director	Name of Owners and Relationships to Director	Company	Title of Class	Value of Securities	Percent of Class

Instructions

1. Information should be provided as of the most recent practicable date. Specify the valuation date by footnote or otherwise.

2. Determine ''beneficial ownership'' in accordance with rule 13d–3 under the Exchange Act (§ 240.13d–3 of this chapter).

3. Identify the company in which the director or immediate family member of the director owns securities in column (3). When the company is a person directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, or administrator, describe the company's relationship with the investment adviser, principal underwriter, or administrator.

4. Provide the information required by columns (5) and (6) on an aggregate basis for each director and his immediate family members.

9. Unless disclosed in response to paragraph 8 of this Item 18, describe any material interest, direct or indirect, of each director or immediate family member of a director, during the past five years, in:

(a) An investment adviser, principal underwriter, or administrator of the Registrant; or

(b) A person (other than a registered investment company) directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, or administrator of the Registrant.

Instruction: A director or immediate family member has an interest in a company if he is a party to a contract, arrangement, or understanding with respect to any securities of, or interest in, the company.

10. Describe briefly any material interest, direct or indirect, of any director or immediate family member of a director in any material transaction, or material series of similar transactions, since the beginning of the last two completed fiscal years of the Registrant, or in any currently proposed material transaction, or material series of similar transactions, to which any of the following persons was or is to be a party:

(a) The Registrant;

(b) An officer of the Registrant;

(c) An investment company, or a person that would be an investment company but for the exclusions provided by sections 3(c)(1) and 3(c)(7) of the 1940 Act (15 U.S.C. 80a–3(c)(1) and (c)(7)), having the same investment adviser, principal underwriter, or administrator as the Registrant or having an investment adviser, principal underwriter, or administrator that directly or indirectly controls, is controlled by, or is under common control with an investment adviser, principal underwriter, or administrator of the Registrant;

(d) An officer of an investment company, or a person that would be an investment company but for the exclusions provided by sections 3(c)(1) and 3(c)(7) of the 1940 Act (15 U.S.C. 80a–3(c)(1) and (c)(7)), having the same investment adviser, principal underwriter, or administrator as the Registrant or having an investment adviser, principal underwriter, or administrator that directly or indirectly controls, is controlled by, or is under common control with an investment adviser, principal underwriter, or administrator of the Registrant;

(e) An investment adviser, principal underwriter, or administrator of the Registrant;

(f) An officer of an investment adviser, principal underwriter, or administrator of the Registrant;

(g) A person directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, or administrator of the Registrant; or

(h) An officer of a person directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, or administrator of the Registrant.

Instructions

1. Include the name of each director or immediate family member whose interest in any transaction or series of similar transactions is described and the nature of the circumstances by reason of which the interest is required to be described.

2. State the nature of the interest, the approximate dollar amount involved in the transaction, and, where practicable, the approximate dollar amount of the interest.

3. In computing the amount involved in the transaction or series of similar transactions, include all periodic payments in the case of any lease or other agreement providing for periodic payments.

4. Compute the amount of the interest of any director or immediate family member of the director without regard to the amount of profit or loss involved in the transaction(s).

5. As to any transaction involving the purchase or sale of assets, state the cost of the assets to the purchaser and, if acquired by the seller within two years prior to the transaction, the cost to the seller. Describe the method used in determining the purchase or sale price and the name of the person making the determination.

6. Disclose indirect, as well as direct, material interests in transactions. A person who has a position or relationship with, or interest in, a company that engages in a transaction with one of the persons listed in paragraphs 10(a) through (h) of this Item 18 may have an indirect interest in the transaction by reason of the position, relationship, or interest. The interest in the transaction, however, will not be deemed ''material'' within the meaning of paragraph 10 of this Item 18 where the interest of the director or immediate

family member arises solely from the holding of an equity interest (including a limited partnership interest, but excluding a general partnership interest) or a creditor interest in a company that is a party to the transaction with one of the persons specified in paragraphs 10(a) through (h) of this Item 18, and the transaction is not material to the company.

7. No information need be given as to any transaction where the interest of the director or immediate family member arises solely from the ownership of securities of a person specified in paragraphs 10(a) through (h) of this Item 18 and the director or immediate family member receives no extra or special benefit not shared on a pro rata basis by all holders of the class of securities.

8. Transactions include loans, lines of credit, and other indebtedness. For indebtedness, indicate the largest aggregate amount of indebtedness outstanding at any time during the period, the nature of the indebtedness and the transaction in which it was incurred, the amount outstanding as of the latest practicable date, and the rate of interest paid or charged.

9. No information need be given as to any routine, retail transaction. For example, the Registrant need not disclose that a director holds a credit card or bank or brokerage account with a person specified in paragraphs 10(a) through (h) of this Item 18 unless the director is accorded special treatment.

11. Describe briefly any material relationship, direct or indirect, of any director or immediate family member of a director that exists, or has existed at any time since the beginning of the last two completed fiscal years of the Registrant, or is currently proposed, with any of the persons specified in paragraphs 10(a) through (h) of this Item 18. Relationships include:

(a) Payments for property or services to or from any person specified in paragraphs 10(a) through (h) of this Item 18;

(b) Provision of legal services to any person specified in paragraphs 10(a) through (h) of this Item 18;

(c) Provision of investment banking services to any person specified in paragraphs 10(a) through (h) of this Item 18, other than as a participating underwriter in a syndicate; and

(d) Any consulting or other relationship that is substantially similar in nature and scope to the relationships listed in paragraphs 11(a) through (c) of this Item 18.

Instructions

1. Include the name of each director or immediate family member whose relationship is described and the nature of the circumstances by reason of which the relationship is required to be described.

2. State the nature of the relationship and the amount of business conducted between the director or immediate family member and the person specified in paragraphs 10(a) through (h) of this Item 18 as a result of the relationship since the beginning of the last two completed fiscal years of the Registrant or proposed to be done during the Registrant's current fiscal year.

3. In computing the amount involved in a relationship, include all periodic payments in the case of any agreement providing for periodic payments.

4. Disclose indirect, as well as direct, material relationships. A person who has a position or relationship with, or interest in, a company that has a relationship with one of the persons listed in paragraphs 10(a) through (h) of this Item 18 may have an indirect relationship by reason of the position, relationship, or interest. The relationship, however, will not be deemed ''material'' within the meaning of paragraph 11 of this Item 18 where the relationship of the director or immediate family member arises solely from the holding of an equity interest (including a limited partnership interest, but excluding a general partnership interest) or a creditor interest in a company that has a relationship with one of the persons specified in paragraphs 10(a) through (h) of this Item 18, and the relationship is not material to the company.

5. In the case of an indirect interest, identify the company with which a person specified in paragraphs 10(a) through (h) of this Item 18 has a relationship; the name of the director or immediate family member affiliated with the company and the nature of the affiliation; and the amount of business done between the company and the person specified in paragraphs 10(a) through (h) of this Item 18 since the beginning of the last two completed fiscal years of the Registrant or proposed to be done during the Registrant's current fiscal year.

6. In calculating payments for property and services for purposes of paragraph 11(a) of this Item 18, the following may be excluded:

a. Payments where the transaction involves the rendering of services as a common contract carrier, or public utility, at rates or charges fixed in conformity with law or governmental authority; or

b. Payments that arise solely from the ownership of securities of a person specified in paragraphs 10(a) through (h) of this Item 18 and no extra or special benefit not shared on a pro rata basis by all holders of the class of securities is received.

7. No information need be given as to any routine, retail relationship. For example, the Registrant need not disclose that a director holds a credit card or bank or brokerage account with a person specified in paragraphs 10(a) through (h) of this Item 18 unless the director is accorded special treatment.

* * * * *

12. If an officer of an investment adviser, principal underwriter, or administrator of the Registrant, or an officer of a person directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, or administrator of the Registrant, serves, or has served since the beginning of the last two completed fiscal years of the Registrant, on the board of directors of a company where a director of the Registrant or immediate family member of a director is, or was since the beginning of the last two completed fiscal years of the Registrant, an officer, identify:

(a) The company;

(b) The individual who serves or has served as a director of the company and the period of service as director;

(c) The investment adviser, principal underwriter, or administrator or person controlling, controlled by, or under common control with the investment adviser, principal underwriter, or administrator where the individual named in paragraph 12(b) of this Item 18 holds or held office and the office held; and

(d) The director of the Registrant or immediate family member who is or was an officer of the company; the office held; and the period of holding the office.

13. Discuss in reasonable detail the material factors and the conclusions with respect thereto that formed the basis for the board of directors approving the existing investment advisory contract. If applicable, include a discussion of any benefits derived or to be derived by the investment adviser from the relationship with the Registrant such as soft dollar arrangements by which brokers provide research to the Registrant or its investment adviser in return for allocating fund brokerage.

Instruction: Conclusory statements or a list of factors will not be considered sufficient disclosure. The discussion should relate the factors to the specific circumstances of the Registrant and the investment advisory contract.

* * * * *

33. Instruction 4 to Item 23 of Form N–2 (referenced in §§ 239.14 and 274.11a–1) is amended by removing ''and'' from the end of paragraph c., removing the period at the end of paragraph d. and in its place adding a semi-colon, and adding paragraphs e. and f. to read as follows:

Form N–2

* * * * *

Item 23. Financial Statements

* * * * *

Instructions

* * * * *

4. * * *

e. the management information required by paragraph 1 of Item 18; and

f. a statement that the SAI includes additional information about directors of the Registrant and is available, without charge, upon request, and a toll-free (or collect) telephone number for shareholders to call to request the SAI.

* * * * *

Note: The text of Form N–3 does not and these amendments will not appear in the *Code of Federal Regulations.*

34. Item 20 of Form N–3 (referenced in §§ 239.17a and 274.11b) is amended by adding instructions 1 and 2 before paragraph (a); revising paragraphs (a) and (b); redesignating paragraph (c) as paragraph (m); adding paragraphs (c) through (l); and removing ''executive'' from the first sentence of newly designated paragraph (m) to read as follows:

Form N–3

* * * * *

Item 20. Management

Instructions

1. For purposes of this Item 20, the terms below have the following meanings:

a. The term ''fund complex'' means two or more registered investment companies that:

(i) Hold themselves out to investors as related companies for purposes of investment and investor services; or

(ii) Have a common investment adviser or have an investment adviser that is an affiliated person of the investment adviser of any of the other registered investment companies.

b. The term ''immediate family member'' means a person's spouse, parent, child, sibling, mother- or father-in-law, son- or daughter-in-law, or brother or sister-in-law, and includes step and adoptive relationships.

c. The term ''officer'' means the president, vice-president, secretary, treasurer, controller, or any other officer who performs policy-making functions.

2. When providing information about directors, furnish information for directors who are interested persons as defined in Section 2(a)(19) of the 1940 Act (15 U.S.C. 80a–2(a)(19)) and the rules thereunder separately from the information for directors who are not interested persons. For example, when furnishing information in a table, you should provide separate tables (or separate sections of a single table) for directors who are interested persons and for directors who are not interested persons. When furnishing information in narrative form, indicate by heading or otherwise the directors who are interested persons and the ones who are not interested persons.

(a) Provide the information required by the following table for each member of the board of managers (''director'') and officer of the Registrant, and, if the Registrant has an advisory board, member of the board. Explain in a footnote to the table any family relationship between the persons listed.

(1)	(2)	(3)	(4)	(5)	(6)
Name, Address, and Age	Position(s) Held with Registrant	Term of Office and Length of Time Served	Principal Occupation(s) During Past 5 Years	Number of Portfolios in Fund Complex Overseen by Director	Other Directorships Held by Director

Instructions

1. For purposes of this paragraph, the term ''family relationship'' means any relationship by blood, marriage, or adoption, not more remote than first cousin.

2. For each director who is an interested person as defined in Section 2(a)(19) of the 1940 Act (15 U.S.C. 80a–2(a)(19)) and the rules thereunder, describe, in a footnote or otherwise, the relationship, events, or transactions by reason of which the director is an interested person.

3. State the principal business of any company listed under column (4) unless the principal business is implicit in its name.

4. Indicate in column (6) directorships not included in column (5) that are held by a director in any company with a class of securities registered pursuant to section 12 of the Exchange Act (15 U.S.C. 78*l*) or subject to the requirements of section 15(d) of the Exchange Act (15 U.S.C. 78o(d)) or any company registered as an investment company under the 1940 Act, and name the companies in which the directorships are held. Where the other directorships include directorships overseeing two or more portfolios in the same fund complex, identify the fund complex and provide the number of portfolios overseen as a director in the fund complex rather than listing each portfolio separately.

(b) For each individual listed in column (1) of the table required by paragraph (a) of this Item 20 who is not a director, describe any positions, including as an officer, employee, director, or general partner, held with affiliated persons or principal underwriters of the Registrant.

Instruction: When an individual holds the same position(s) with two or more registered investment companies that are part of the same fund complex, identify the fund complex and provide the number of registered investment companies for which the position(s) are held rather than listing each registered investment company separately.

(c) Describe briefly any arrangement or understanding between any director or officer and any other person(s) (naming the person(s)) pursuant to which he was selected as a director or officer.

Instruction: Do not include arrangements or understandings with directors or officers acting solely in their capacities as such.

(d) Identify the standing committees of the Registrant's board of managers, and provide the following information about each committee:

(i) A concise statement of the functions of the committee;

(ii) The members of the committee;

(iii) The number of committee meetings held during the last fiscal year; and

(iv) If the committee is a nominating or similar committee, state whether the committee will consider nominees recommended by security holders and, if so, describe the procedures to be followed by security holders in submitting recommendations.

(e) Unless disclosed in the table required by paragraph (a) of this Item 20, describe any positions, including as an officer, employee, director, or general partner, held by a director or immediate family member of the director during the past five years with:

(i) The Registrant;

(ii) An investment company, or a person that would be an investment company but for the exclusions provided by sections 3(c)(1) and 3(c)(7) of the 1940 Act (15 U.S.C. 80a–3(c)(1) and (c)(7)), having the same Insurance Company, investment adviser, principal underwriter, or administrator as the Registrant or having an Insurance Company, investment adviser, principal underwriter, or administrator that directly or indirectly controls, is controlled by, or is under common control with the Insurance Company or an investment adviser, principal underwriter, or administrator of the Registrant;

(iii) The Insurance Company or an investment adviser, principal underwriter, administrator, or affiliated person of the Registrant; or

(iv) Any person directly or indirectly controlling, controlled by, or under common control with the Insurance Company or an investment adviser, principal underwriter, or administrator of the Registrant.

Instruction:

When an individual holds the same position(s) with two or more portfolios that are part of the same fund complex, identify the fund complex and provide the number of portfolios for which the position(s) are held rather than listing each portfolio separately.

(f) For each director, state the aggregate dollar amount of equity securities of registered investment companies in the same fund complex as the Registrant owned beneficially or of record by the director as required by the following table:

(1)	(2)	(3)
Name of Director	Identity of fund Complex	Aggregate Dollar Amount of Equity Securities in Fund Complex

Instructions:

1. Information should be provided as of the most recent practicable date. Specify the valuation date by footnote or otherwise.

2. Determine ''beneficial ownership'' in accordance with rule 13d–3 under the Exchange Act (§ 240.13d–3 of this chapter).

(g) For each director and his immediate family members, furnish the information required by the following table as to each class of securities owned beneficially or of record in:

(i) The Insurance Company or an investment adviser, principal underwriter, or administrator of the Registrant; or

(ii) A person (other than a registered investment company) directly or indirectly controlling, controlled by, or under common control with the Insurance Company or an investment adviser, principal underwriter, or administrator of the Registrant:

(1)	(2)	(3)	(4)	(5)	(6)
Name of Director	Name of Owners and Relationships to Director	Company	Title of Class	Value of Securities	Percent of Class

Instructions

1. Information should be provided as of the most recent practicable date. Specify the valuation date by footnote or otherwise.

2. Determine ''beneficial ownership'' in accordance with rule 13d–3 under the Exchange Act (§ 240.13d–3 of this chapter).

3. Identify the company in which the director or immediate family member of the director owns securities in column (3). When the company is a person directly or indirectly controlling, controlled by, or under common control with the Insurance Company or an investment adviser, principal underwriter, or administrator, describe the company's relationship with the Insurance Company, investment adviser, principal underwriter, or administrator.

4. Provide the information required by columns (5) and (6) on an aggregate basis for each director and his immediate family members.

(h) Unless disclosed in response to paragraph (g) of this Item 20, describe any material interest, direct or indirect, of each director or immediate family member of a director, during the past five years, in:

(i) The Insurance Company or an investment adviser, principal underwriter, or administrator of the Registrant; or

(ii) A person (other than a registered investment company) directly or indirectly controlling, controlled by, or under common control with the Insurance Company or an investment adviser, principal underwriter, or administrator of the Registrant.

Instruction

A director or immediate family member has an interest in a company if he is a party to a contract, arrangement, or understanding with respect to any securities of, or interest in, the company.

(i) Describe briefly any material interest, direct or indirect, of any director or immediate family member of a director in any material transaction, or material series of similar transactions, since the beginning of the last two completed fiscal years of the Registrant, or in any currently proposed material transaction, or material series of similar transactions, to which any of the following persons was or is to be a party:

(i) The Registrant;

(ii) An officer of the Registrant;

(iii) An investment company, or a person that would be an investment company but for the exclusions provided by sections 3(c)(1) and 3(c)(7) of the 1940 Act (15 U.S.C. 80a–3(c)(1) and (c)(7)), having the same Insurance Company, investment adviser, principal underwriter, or administrator as the Registrant or having an Insurance Company, investment adviser, principal underwriter, or administrator that directly or indirectly controls, is controlled by, or is under common control with the Insurance Company or an investment adviser, principal underwriter, or administrator of the Registrant;

(iv) An officer of an investment company, or a person that would be an investment company but for the exclusions provided by sections 3(c)(1) and 3(c)(7) of the 1940 Act (15 U.S.C. 80a–3(c)(1) and (c)(7)), having the same Insurance Company, investment adviser, principal underwriter, or administrator as the Registrant or having an Insurance Company, investment adviser, principal underwriter, or administrator that directly or indirectly controls, is controlled by, or is under common control with the Insurance Company or an investment adviser, principal underwriter, or administrator of the Registrant;

(v) The Insurance Company or an investment adviser, principal underwriter, or administrator of the Registrant;

(vi) An officer of the Insurance Company or an investment adviser, principal underwriter, or administrator of the Registrant;

(vii) A person directly or indirectly controlling, controlled by, or under common control with the Insurance Company or an investment adviser, principal underwriter, or administrator of the Registrant; or

(viii) An officer of a person directly or indirectly controlling, controlled by, or under common control with the Insurance Company or an investment adviser, principal underwriter, or administrator of the Registrant.

Instructions

1. Include the name of each director or immediate family member whose interest in any transaction or series of similar transactions is described and the nature of the circumstances by reason of which the interest is required to be described.

2. State the nature of the interest, the approximate dollar amount involved in the transaction, and, where practicable, the approximate dollar amount of the interest.

3. In computing the amount involved in the transaction or series of similar transactions, include all periodic payments in the case of any lease or other agreement providing for periodic payments.

4. Compute the amount of the interest of any director or immediate family member of the director without regard to the amount of profit or loss involved in the transaction(s).

5. As to any transaction involving the purchase or sale of assets, state the cost of the assets to the purchaser and, if acquired by the seller within two years prior to the transaction, the cost to the seller. Describe the method used in determining the purchase or sale price and the name of the person making the determination.

6. Disclose indirect, as well as direct, material interests in transactions. A person who has a position or relationship with, or interest in, a company that engages in a transaction with one of the persons listed in paragraphs (i) through (viii) of paragraph (i) of this Item 20 may have an indirect interest in the transaction by reason of the position, relationship, or interest. The interest in the transaction, however, will not be deemed ''material'' within the meaning of paragraph (i) of this Item 20 where the interest of the director or immediate family member arises solely from the holding of an equity interest (including a limited partnership interest, but excluding a general partnership interest) or a creditor interest in a company that is a party to the transaction with one of the persons specified in paragraphs (i) through (viii) of paragraph (i) of this Item 20, and the transaction is not material to the company.

7. No information need be given as to any transaction where the interest of the director or immediate family member arises solely from the ownership of securities of a person specified in paragraphs (i) through (viii) of paragraph (i) of this Item 20 and the director or immediate family member receives no extra or special benefit not shared on a pro rata basis by all holders of the class of securities.

8. Transactions include loans, lines of credit, and other indebtedness. For indebtedness, indicate the largest aggregate amount of indebtedness outstanding at any time during the period, the nature of the indebtedness and the transaction in which it was incurred, the amount outstanding as of the latest practicable date, and the rate of interest paid or charged.

9. No information need be given as to any routine, retail transaction. For example, the Registrant need not disclose that a director holds a credit card or bank or brokerage account with a person specified in paragraphs (i) through (viii) of paragraph (i) of this Item 20 unless the director is accorded special treatment.

(j) Describe briefly any material relationship, direct or indirect, of any director or immediate family member of a director that exists, or has existed at any time since the beginning of the last two completed fiscal years of the Registrant, or is currently proposed, with any of the persons specified in paragraphs (i) through (viii) of paragraph (i) of this Item 20. Relationships include:

(i) Payments for property or services to or from any person specified in paragraphs (i) through (viii) of paragraph (i) of this Item 20;

(ii) Provision of legal services to any person specified in paragraphs (i) through (viii) of paragraph (i) of this Item 20;

(iii) Provision of investment banking services to any person specified in paragraphs (i) through (viii) of paragraph (i) of this Item 20, other than as a participating underwriter in a syndicate; and

(iv) Any consulting or other relationship that is substantially similar in nature and scope to the relationships listed in paragraphs (j)(i) through (j)(iii) of this Item 20.

Instructions

1. Include the name of each director or immediate family member whose relationship is described and the nature of the circumstances by reason of which the relationship is required to be described.

2. State the nature of the relationship and the amount of business conducted between the director or immediate family member and the person specified in paragraphs (i) through (viii) of paragraph (i) of this Item 20 as a result of the relationship since the beginning of the last two completed fiscal years of the Registrant or proposed to be done during the Registrant's current fiscal year.

3. In computing the amount involved in a relationship, include all periodic payments in the case of any agreement providing for periodic payments.

4. Disclose indirect, as well as direct, material relationships. A person who has a position or relationship with, or interest in, a company that has a relationship with one of the persons listed in paragraphs (i) through (viii) of paragraph (i) of this Item 20 may have an indirect relationship by reason of the position, relationship, or interest. The relationship, however, will not be deemed ''material'' within the meaning of paragraph (j) of this Item 20 where the relationship of the director or immediate family member arises solely from the holding of an equity interest (including a limited partnership interest, but excluding a general partnership interest) or a creditor interest in a company that has a relationship with one of the persons specified in paragraphs (i) through (viii) of paragraph (i) of this Item 20, and the relationship is not material to the company.

5. In the case of an indirect interest, identify the company with which a person specified in paragraphs (i)

through (viii) of paragraph (i) of this Item 20 has a relationship; the name of the director or immediate family member affiliated with the company and the nature of the affiliation; and the amount of business done between the company and the person specified in paragraphs (i) through (viii) of paragraph (i) of this Item 20 since the beginning of the last two completed fiscal years of the Registrant or proposed to be done during the Registrant's current fiscal year.

6. In calculating payments for property and services for purposes of paragraph (j)(i) of this Item 20, the following may be excluded:

a. Payments where the transaction involves the rendering of services as a common contract carrier, or public utility, at rates or charges fixed in conformity with law or governmental authority; or

b. Payments that arise solely from the ownership of securities of a person specified in paragraphs (i) through (viii) of paragraph (i) of this Item 20 and no extra or special benefit not shared on a pro rata basis by all holders of the class of securities is received.

7. No information need be given as to any routine, retail relationship. For example, the Registrant need not disclose that a director holds a credit card or bank or brokerage account with a person specified in paragraphs (i) through (viii) of paragraph (i) of this Item 20 unless the director is accorded special treatment.

(k) If an officer of the Insurance Company or an investment adviser, principal underwriter, or administrator of the Registrant, or an officer of a person directly or indirectly controlling, controlled by, or under common control with the Insurance Company or an investment adviser, principal underwriter, or administrator of the Registrant, serves, or has served since the beginning of the last two completed fiscal years of the Registrant, on the board of directors of a company where a director of the Registrant or immediate family member of a director is, or was since the beginning of the last two completed fiscal years of the Registrant, an officer, identify:

(i) The company;

(ii) The individual who serves or has served as a director of the company and the period of service as director;

(iii) The Insurance Company, investment adviser, principal underwriter, or administrator or person controlling, controlled by, or under common control with the Insurance Company, investment adviser, principal underwriter, or administrator where the individual named in paragraph (k)(ii) of this Item 20 holds or held office and the office held; and

(iv) The director of the Registrant or immediate family member who is or was an officer of the company; the office held; and the period of holding the office.

(l) Discuss in reasonable detail the material factors and the conclusions with respect thereto that formed the basis for the board of managers approving the existing investment advisory contract. If applicable, include a discussion of any benefits derived or to be derived by the investment adviser from the relationship with the Registrant such as soft dollar arrangements by which brokers provide research to the Registrant or its investment adviser in return for allocating fund brokerage.

Instruction: Conclusory statements or a list of factors will not be considered sufficient disclosure. The discussion should relate the factors to the specific circumstances of the Registrant and the investment advisory contract.

* * * * *

35. Instruction 4 to Item 27 of Form N–3 (referenced in §§ 239.17a and 274.11b) is amended by removing ''and'' from the end of paragraph (iii), removing the period at the end of paragraph (iv) and in its place adding a semi-colon, and adding paragraphs (v) and (vi) to read as follows:

Item 27. Financial Statements

* * * * *

Instructions

* * * * *

4. * * *

(v) The management information required by paragraph (a) of Item 20; and

(vi) A statement that the SAI includes additional information about members of the board of managers of the Registrant and is available, without charge, upon request, and a toll-free (or collect) telephone number for contract owners to call to request the SAI.

* * * * *

Dated: October 14, 1999.

By the Commission.

Jonathan G. Katz,

Secretary.

Note: Appendix A to the preamble will not appear in the Code of Federal Regulations.

APPENDIX A.—ANALYSIS OF PROPOSED AMENDMENTS TO SCHEDULE 14A UNDER THE EXCHANGE ACT AND FORM N–1A UNDER THE INVESTMENT COMPANY ACT

Proposed item 22 of Schedule 14A	Proposed items 13 and 22 of Form N–1A	Source of proposed items in current rules and forms
Item 22. Information Required in Investment Company Proxy Statement	Item 13. Management Information.	
	Instr. 1.a. to Item 13 (Defn. of fund complex)	Item 22(a)(v) of Schedule 14A.
22(a)(1)(i) (Defn. of Administrator)	.....	Item 15(h)(1) of Form N–1A.
22(a)(1)(vi) (Defn. of Immediate Family Member)	Instr. 1.b. to Item 13	Instruction 2 to 404(a) of Reg. S–K.
22(a)(1)(vii) (Defn. of Officer)	Instr. 1.c. to Item 13	Instruction 1 to Item 13(b) of Form N–1A.
22(a)(1)(ix) (Defn. of Registrant)	.....	Item 22(a)(1)(vii) of Schedule 14A.
22(a)(1)(x) (Defn. of Sponsoring Insurance Company.	.....	Instruction D. of General Instructions to Form N–3.
22(b) (Applies when there is an election of directors):		
Instr. 1	.....	Instruction 1 to Item 22(b) of Schedule 14A.
Instr. 2	.....	Instruction 2 to Item 22(b) of Schedule 14A.
Instr. 3	Instr. 2 to Item 13	New.
Instr. 4	.....	Instruction 3 to Item 401(a) of Reg. S–K.

APPENDIX A.—ANALYSIS OF PROPOSED AMENDMENTS TO SCHEDULE 14A UNDER THE EXCHANGE ACT AND FORM N–1A UNDER THE INVESTMENT COMPANY ACT—Continued

Proposed item 22 of Schedule 14A	Proposed items 13 and 22 of Form N–1A	Source of proposed items in current rules and forms
22(b)(1) (Table of core information about each director, nominee, officer, and advisory board member)	Item 13(a)(1)	Items 401(a), (b), (d), and (e) of Reg. S–K and Item 13 of Form N–1A.
Instr. 1	Instr. 1 to Item 13(a)(1)	Instruction to 401(d) of Reg. S–K and Instruction 1 to Item 13(b) of Form N–1A.
Instr. 2		Instruction 2 to Item 401(a) and Instruction 2 to Item 401(b) to Reg. S–K.
Instr. 3		Instruction 4 to Item 401(a) of Reg. S–K.
Instr. 4	Instr. 2 to Item 13(a)(1)	Instruction 1 to Item 22(b)(4) of Schedule 14A.
Instr. 5	Instr. 3 to Item 13(a)(1)	Instruction 2 to Item 13(b) of Form N–1A.
Instr. 6		New.
Instr. 7	Instr. 4 to Item 13(a)(1)	Item 401(e)(2) and Instruction to Item 401(e)(2) of Reg. S–K.
	Item 13(a)(2) (Positions held by officers):	Item 13(c) of Form N–1A.
	Instr. to Item 13(a)(2)	Instruction to Item 13(c) of Form N–1A.
22(b)(2) (Any agreement regarding selection as director, nominee, or officer).	Item 13(a)(3)	Items 401(a) and 401(b) of Reg. S–K.
Instr.	Instr. to Item 13(a)(3)	Instruction 1 to Item 401(a) and Instruction 1 to Item 401(b) of Reg. S–K.
	Item 13(b)(1) (Description of board responsibilities).	Item 13(a) of Form N–1A.
	Instr. to Item 13(b)(1)	Instruction to Item 13(a) of Form N–1A.

APPENDIX A—ANALYSIS OF PROPOSED AMENDMENTS TO SCHEDULE 14A UNDER THE EXCHANGE ACT AND FORM N–1A UNDER THE INVESTMENT COMPANY ACT

Proposed item 22 of Schedule 14A	Proposed items 13 and 22 of Form N–1A	Source of proposed items in current rules and forms
22(b)(3) (Positions held by director, nominee, or immediate family members at fund and related persons (*i.e.,* other funds in fund complex, investment adviser, principal underwriter, administrator, or control-affiliates of adviser, underwriter, or administrator).	Item 13(b)(3)	Item 22(b)(1) of Schedule 14A and Item 13(c) of Form N–1A.
Instr	Instr. to Item 13(b)(3)	Instruction to Item 13(c) of Form N–1A.
22(b)(4) (Ownership of funds in fund complex)	Item 13(b)(4)	New.
Instr. 1	Instr. 1 to Item 13(b)(4)	Item 403(b) of Reg. S–K.
Instr. 2	Instr. 2 to Item 13(b)(4)	Instruction 2 to Item 403 of Reg. S–K.
22(b)(5) (Ownership of securities of investment adviser, principal underwriter, administrator, and control-affiliates of adviser, underwriter, and administrator).	Item 13(b)(5)	Item 22(b)(1) of Schedule 14A.
Instr. 1	Instr. 1 to Item 13(b)(5)	Item 403(b) of Reg. S–K.
Instr. 2	Instr. 2 to Item 13(b)(5)	Instruction 2 to Item 403 of Reg. S–K.
Instr. 3	Instr. 3 to Item 13(b)(5)	New.
Instr. 4	Instr. 4 to Item 13(b)(5)	New.
22(b)(6) (Material interests in fund and related persons).	Item 13(b)(6)	Items 22(b)(1) and (2) of Schedule 14A.
Instr	Instr. to Item 13(b)(6)	Item 5(b)(1)(viii) of Schedule 14A.

APPENDIX A—ANALYSIS OF PROPOSED AMENDMENTS TO SCHEDULE 14A UNDER THE EXCHANGE ACT AND FORM N–1A UNDER THE INVESTMENT COMPANY ACT

Proposed item 22 of Schedule 14A	Proposed items 13 and 22 of Form N–1A	Source of proposed items in current rules and forms
22(b)(7) (Material interests in material transactions involving fund and related persons).	Item 13(b)(7)	Item 22(b)(3) of Schedule 14A and Item 404(a) of Reg. S–K.
Instr. 1	Instr. 1 to Item 13(b)(7)	Instruction 1 to Item 22(b)(3) of Schedule 14A.
Instr. 2	Instr. 2 to Item 13(b)(7)	Item 404(a) of Reg. S–K.
Instr. 3	Instr. 3 to Item 13(b)(7)	Instruction 3 of Item 404(a) of Reg. S–K.

APPENDIX A—ANALYSIS OF PROPOSED AMENDMENTS TO SCHEDULE 14A UNDER THE EXCHANGE ACT AND FORM N–1A UNDER THE INVESTMENT COMPANY ACT—Continued

Proposed item 22 of Schedule 14A	Proposed items 13 and 22 of Form N–1A	Source of proposed items in current rules and forms
Instr. 4	Instr. 4 to Item 13(b)(7)	Instruction 4 to Item 404(a) of Reg. S–K.
Instr. 5	Instr. 5 to Item 13(b)(7)	Instruction 2 to Item 22(b)(3) of Schedule 14A and Instruction 5 to Item 404(a) of Reg. S–K.
Instr. 6	Instr. 6 to Item 13(b)(7)	New.
Instr. 7	Instr. 7 to Item 13(b)(7)	Instruction 8 to Item 404(a) of Reg. S–K.
Instr. 8	Instr. 8 to Item 13(b)(7)	Instruction 7.C to Item 404(a) of Reg. S–K.
Instr. 9	Instr. 9 to Item 13(b)(7)	New.
22(b)(8) (Material relationships with fund and related persons).	Item 13(b)(8)	New. Derived from Item 404(b) of Reg. S–K.
Instr. 1	Instr. 1 to Item 13(b)(8)	New. Derived from Instruction 1 to Item 22(b)(3) of Schedule 14A.
Instr. 2	Instr. 2 to Item 13(b)(8)	New. Derived from Item 404(b) of Reg. S–K.
Instr. 3	Instr. 3 to Item 13(b)(8)	New. Derived from Instruction 3 of Item 404(a) of Reg. S–K.
Instr. 4	Instr. 4 to Item 13(b)(8)	New.
Instr. 5	Instr. 5 to Item 13(b)(8)	New. Derived from Instruction 8 of Item 404(a) of Reg. S–K.
Instr. 6	Instr. 6 to Item 13(b)(8)	New. Derived from Item 404(b) of Reg. S–K.
Instr. 7	Instr. 7 to Item 13(b)(8)	New. Derived from Instructions 2.A and B to 404(b) of Reg. S–K.
22(b)(9) (Cross-directorships)	Item 13(b)(9)	New.
Instr.	Instr. to Item 13(b)(9)	New.
22(b)(10) (Incorporates parts of Reg. S–K into Item 22).		Item 22(b)(4) of Schedule 14A.
Instr.		New.
22(b)(11) (Material pending legal proceedings)		Item 22(b)(5) of Schedule 14A.
22(b)(12) (Compensation table)	Item 13(c)	Item 22(b)(6) of Schedule 14A and Item 13(d) of Form N–1A.
22(b)(13) (Board committees)	Item 13(b)(2)	Item 7(e) (1) and (2) of Schedule 14A and Instruction 3 of Item 13(b) of Form N–1A.
	Item 13(b)(10) (Basis for approving advisory contract).	Item 22(c)(11) of Schedule 14A.
	Item 22. Financial Statements.	
	Item 22(b)(5) (Management information required by Item 13(a)(1).	New.
	Item 22(b)(6) (Reference to SAI)	New.

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SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 271

[Release No. IC–24083]

Interpretive Matters Concerning Independent Directors of Investment Companies

AGENCY: Securities and Exchange Commission.

ACTION: Statement of Staff Position.

SUMMARY: The Securities and Exchange Commission is publishing the views of the Commission and its staff concerning certain issues under the Investment Company Act of 1940 that are related to the independent directors of registered investment companies.

EFFECTIVE DATE: October 14, 1999.

FOR FURTHER INFORMATION CONTACT: Mercer E. Bullard, Assistant Chief Counsel, or Alison M. Fuller, Assistant Chief Counsel, at 202–942–0659, in the Office of Chief Counsel, Division of Investment Management, or by writing to the Office of Chief Counsel, Division of Investment Management, Securities and Exchange Commission, 450 5th St., NW., Washington, DC 20549–0506.

SUPPLEMENTARY INFORMATION:

Executive Summary

Management investment companies are governed by a board of directors, at least 40% of whom must not be ''interested persons'' of the company under section 2(a)(19) of the Investment Company Act of 1940 (the ''Act'') (*i.e.*, ''independent directors'').[1] Independent directors of registered investment companies (''investment companies'' or ''funds'') play a critical role in overseeing the funds operations and protecting the interests of their shareholders. Today, in a companion release,[2] the Commission is proposing to amend a number of rules and forms as part of a broad initiative to enhance the effectiveness of independent directors. Simultaneously, the Commission is publishing this release, which contains the views of its staff concerning a number of interpretive issues under the Act that relate to independent directors, and briefly describes the role of the Commission in connection with certain disputes between independent fund directors and fund management.

Following some general background on the role and duties of fund directors, this release addresses the following interpretive topics:

- Section 2(a)(19) of the Act authorizes the Commission to issue an order finding that a person is an ''interested person'' due to a material business or professional relationship with a fund or certain persons or entities. This release provides guidance from the staff about the types of business and professional relationships that may be material for purposes of section 2(a)(19).
- Some have argued that, if fund directors take an action on behalf of the fund that benefits themselves, the action may constitute a ''joint transaction'' under section 17(d) of the Act and rule 17d–1 thereunder, thereby requiring prior Commission approval. This release explains the view of the staff that actions taken by fund directors within the scope of their duties generally would not be ''joint transactions.''
- Some have questioned when a fund may pay an advance of legal fees to its directors consistent with section 17(h) of the Act, which limits a fund's ability to indemnify its directors. This release provides guidance from the staff regarding when funds may pay such advances.
- Section 22(g) of the Act prohibits open-end funds from compensating their directors with shares of the fund. This release provides guidance from the staff concerning the circumstances under which open-end funds may compensate fund directors with fund shares consistent with section 22(g).

The Commission believes that publishing the staff's views on these issues will enhance the effectiveness of independent directors by: encouraging funds to nominate directors who will effectively protect the interests of shareholders; relieving independent directors of concerns regarding their ability to act in shareholders' best interests without undue fear of personal liability; helping funds attract the most qualified persons to serve on their boards; and facilitating the implementation of fund policies that encourage or require that fund directors be compensated with fund shares, thereby aligning more closely the interests of independent directors and fund shareholders.

We also discuss the Commission's views regarding its role and response in disputes between independent directors and investment advisers when there are allegations of violations of the federal securities laws. The Commission and the staff hope thereby to dispel any confusion that may exist regarding the Commission's role in connection with disputes between independent fund directors and fund management.

I. Background

A. The Role and Independence of Independent Directors

The critical role of independent directors of investment companies is necessitated, in part, by the unique structure of investment companies. Unlike a typical corporation, a fund generally has no employees of its own. Its officers are usually employed and compensated by the fund's investment adviser, which is a separately owned and operated entity. The fund relies on its investment adviser and other affiliates—who are usually the very companies that sponsored the fund's organization—for basic services, including investment advice, administration, and distribution.

Due to this unique structure, conflicts of interest can arise between a fund and the fund's investment adviser because the interests of the fund do not always parallel the interests of the adviser. An investment adviser's interest in maximizing its own profits for the benefit of its owners may conflict with its paramount duty to act solely in the best interests of the fund and its shareholders.

In an effort to control conflicts of interest between funds and their investment advisers, Congress required that at least 40% of a fund's board be composed of independent directors.[3] Congress intended to place independent directors in the role of ''independent watchdogs,'' who would furnish an independent check upon the management of funds and provide a means for the representation of shareholder interests in fund affairs.[4]

Independent directors play a critical role in policing the potential conflicts of interest between a fund and its investment adviser. The Act requires that a majority of a fund's independent directors: approve the fund's contracts with its investment adviser and

[1] 15 U.S.C. § 80a–10(a).

[2] Role of Independent Directors of Investment Companies, Investment Company Act Release No. 24082 (Oct. 14, 1999) (''Companion Release'').

[3] Section 2(a)(19) [15 U.S.C. § 80a–2(a)(19)] (defining the term ''interested person'') and Section 19(a) [15 U.S.C. § 80a–10(a)]. In addition, Congress required that at least a majority of the directors not be: (1) ''interested persons'' of the fund's principal underwriter, Section 10(v) [15 U.S.C. § 80a–10(b)]; (2) investment bankers, or affiliated persons of investment bankers, Section 10(b)(3) [15 U.S.C. § 80a–10(b)(3)]; or (3) officers, directors or employees of any one bank. Section 10(c) [15 U.S.C. § 80a–10(c)].

[4] *See Burks* v. *Lasker*, 44 U.S. 471, 484 (1979) (quoting *Tannenbaum* v. *Zeller*, 552 F. 2d 402, 406 (2d Cir. 1979) and *Investment Trusts and Investment Companies: Hearings on H.R. 10065 Before the House Subcomm. on Interstate and Foreign Commerce*, 76th Cong., 3d Sess. 109 (1940) (statement of David Schenker, Chief Counsel, Investment Trust Study, SEC) (''House Hearings'')).

principal underwriter;[5] select the independent public accountant of the fund;[6] and select and nominate individuals to fill independent director vacancies resulting from the assignment of an advisory contract.[7] In addition, rules promulgated under the Act require independent directors to: approve distribution fees paid under rule 12b–1 under the Act;[8] approve and oversee affiliated securities transactions;[9] set the amount of the fund's fidelity bond;[10] and determine if participation in joint insurance contracts is in the best interest of the fund.[11] Each of these duties and responsibilities is vital to the proper functioning of fund operations and, ultimately, the protection of fund shareholders.[12]

In addition to the requirements of federal law, directors must abide by standards of care prescribed by state statutory and common law. Specifically, directors are subject to state law duties of care and loyalty.[13] The duty of care generally requires that directors act in good faith and with that degree of diligence, care and skill that a person of ordinary prudence would exercise under similar circumstances in a like position.[14] The duty of loyalty generally requires that directors exercise their powers in the interests of the fund and not in the directors' own interests or in the interests of another person or organization.[15]

B. Improving Fund Governance

The role of independent fund directors, and proposals to enhance their independence and effectiveness, have been the subject of a number of initiatives since the Act was enacted in 1940. For example, the Wharton School, at the request of the Commission, began a detailed study of the fund industry in the late 1950s. At that time, any person who was not an officer, employee or investment adviser of a fund, or an affiliated person of the investment adviser, could serve as an independent director of the fund. Under this standard, the Wharton study questioned the ''extent to which reliance can be placed on the independent directors to safeguard adequately the rights of shareholders in negotiations between the [fund] and the investment adviser.'' [16] The Commission followed the Wharton study with its own study, which agreed that the then-current standard for director independence was inadequate.[17] Subsequently, Congress enacted an amendment to the Act in 1970 which required that independent directors not be ''interested persons'' of a fund under new section 2(a)(19) of the Act.[18] The amendment substantially limited the categories of persons who could serve as independent directors for funds.[19]

The Commission staff revisited the issue of the effectiveness of fund directors in the early 1990s, which culminated in a published report in 1992.[20] The staff concluded that the governance model embodied in the Act was sound, but suggested a number of changes designed to improve the effectiveness of fund directors. One of these recommendations was to increase the minimum percentage of independent directors on fund boards from 40% to greater than 50%. In addition, the staff suggested that a fund's independent directors be allowed to choose the persons who would fill independent director vacancies and that the independent directors be given the express authority to terminate advisory contracts.

Fund governance has recently returned to the forefront. The press has questioned the effectiveness of independent directors [21] and, in a number of instances, independent directors have come under fire by fund management and been replaced with directors who were nominated by management.[22] Private litigants have challenged independent directors' independence,[23] and the Commission has instituted enforcement actions against independent directors for failing to fulfill their legal obligations.[24] The prominence of these developments has been magnified by the extraordinary growth of the fund industry.[25]

In recognition of the increasingly important role that funds play in Americans' finances, and that independent directors play in protecting fund investors, the Commission launched an initiative to explore the state of fund governance and to determine what improvements could be made. Last February, the Commission hosted a Roundtable on the Role of Independent Investment Company Directors to discuss the role of

[5] Sections 15(a) and (b) [15 U.S.C. §§ 80a–15(a), (b)].

[6] Section 32(a) [15 U.S.C. § 80a–31(a)].

[7] Sections 16(b) and 15(f)(1)(A) [15 U.S.C. §§ 80a–16(b), 15(f)(1)(A)].

[8] Rule 12b–1 [17 CFR 270.12b–1]

[9] Rules 10f–3, 17a–7, 17a–8, and 17e–1 [17 CFR 270.10f–3, 270.17a–7, 270.17a–8, and 270.17e–1]

[10] Rule 17g–1 [17 CFR 270.17g–1]

[11] Rule 17d–1(d)(7) [17 CFR 270.17d–1(d)(7)].

[12] The full board of directors also has certain other responsibilities, including, but not limited to: (1) Approving the fund's valuation procedures, custody agreements, and brokerage allocation policies; (2) monitoring the fund's investments and investment performance and any allocation of expenses between the company and its affiliates; (3) authorizing the mergers of two or more affiliated funds and the issuance and sale of shares of the fund; and (3) declaring dividends in accordance with the fund's investment policies and objectives.

[13] The business judgment rule generally protects fund directors from liability for their decisions so long as the directors acted in good faith, were reasonably informed, and rationally believed that the action taken was in the best interests of the fund. *See Solomon* v. *Armstrong,* 1999 Del. Ch. LEXIS 62, 23 (Del. Ch. Mar. 25, 1999). *See generally* James Solheim, J.D. and Kenneth Elkins, J.D., 3A Flechter Cyc Corp § 1036 (perm. ed.).

[14] *See Hanson Trust PLC* v. *ML SCM Acquisition Inc.,* 781 F.2d 264, 273 (2d Cir. 1986) and *Norlin Corp.* v. *Rooney, Pace Inc.,* 744 F.2d 255, 264 (2d Cir. 1984). *See generally* Solheim and Elkins, *supra* note 13 at § 1029.

[15] *See Norlin Corp.* 744 F.2d at 264 (*citing Pepper* v. *Litton,* 308 U.S. 295, 306–07 (1939)). *See generally* Beth A. Buday and Gail A. O'Gradney, 3 Fletcher Cyc Corp § 913 (Perm Ed).

[16] Wharton School of Finance and Commerce, A Study of Mutual Funds, H.R. Rep. No. 2274, 87th Cong., 2d Sess. 8 (1962).

[17] SEC, Public Policy Implications of Investment Company Growth, H.R. Rep. No. 2337, 89th Cong., 2d Sess. 333 (1966).

[18] *See* S. Rep. No. 184, 91st Cong., 1st Sess. 32–33 (1969).

[19] The Commission, however, has provided some flexibility by promulgating rules that broaden the categories of persons who can serve as independent directors of a fund. For example, registered broker-dealers and their affiliated persons are considered ''interested persons'' of a fund, and its investment adviser or principal underwriter. *See* Sections 2(a)(19)(A) and (B)(v) [15 U.S.C. §§ 80a–2(a)(19)(A)(v), (B)(v)]. Under rule 2a19–1, however, a fund director who is an affiliated person of a registered broker or dealer will not be deemed to be an ''interested person'' of the fund, or its investment adviser or principal underwriter, provided that, among other things, the broker or dealer does not sell fund shares or effect portfolio transactions for the fund. Rule 2a19–1 [17 CFR 270.2a19–1].

[20] Division of Investment Management, SEC, Protecting Investors: A Half Century of Investment Company Regulation, Ch. 7 (1992).

[21] *See, e.g.,* Russ Wiles, *Third Quarter Review: Your Money, Investments and Personal Finance; Study Raises Questions About the Vigilance of the Family Watchdog,* L.A. Times, Oct. 6, 1996, at D5; Charles Jaffe, *Don't Count on Directors to Guard Your Interests,* Kansas City Star, Mar. 9, 1999, at D19; and Edward Wyatt, *Empty Suits in the Board Room; Under Fire, Mutual Fund Directors Seem Increasingly Hamstrung,* N.Y. Times, June 7, 1998, at C1.

[22] *See, e.g., Defeating Dissidents,* Institutional Investor, Feb. z1999, at 112; and Edward Wyatt, *Investing: Funds Watch; SEC Explores Directors' Roles,* N.Y. Times, Jan. 31, 1999, at C9.

[23] *See, e.g., Strougo* v. *Scudder, Stevens & Clark, Inc.,* 964 F.Supp. 783 (S.D.N.Y. 1997); *Strougo* v. *Bassini, et al.,* 97 Civ. 3579 (S.D.N.Y. 1998); *Strougo* v. *BEA Associates.,* 98 Civ. 3725 (S.D.N.Y. 1999); and *Verkouteren* v. *Blackrock Financial Management, Inc.,* 98 Civ. 4673 (S.D.N.Y. 1999).

[24] *See, e.g., In the Matter of Parnassus Investments, et al.,* Initial Decision Release No. 131 (Sept. 3, 1998); *In the Matter of the Rockies Fund, Inc., et al.,* Investment Company Act Release No. 23229 (June 1, 1998) (pending); and *In the Matter of Monetta Financial Services, Inc., et al.,* Investment Company Act Release No. 23048 (May 8, 1998) (pending).

[25] *See* Investment Company Institute, Mutual Fund Fact Book 3 (1999). Total assets of open-end funds were $5.525 trillion at the end of 1998, compared with $809.4 billion in 1988. In 1998, an estimated 44 percent of U.S. households owned open-end funds, up from 5.7 percent in 1980 and 24.4 percent in 1988. *Id.* at 45.

independent directors and the steps that could be taken to improve their effectiveness. There was broad agreement among Roundtable participants that fund governance could be improved to enable independent directors to better serve fund shareholders.[26]

Following the Roundtable, the Commission undertook a rulemaking initiative to implement some of the suggestions made at the Roundtable on how to improve fund governance.[27] In the Companion Release, the Commission is proposing amendments to a number of exemptive rules under the Act, and is proposing to amend a number of forms to provide fund shareholders with improved information with which to judge the independence of their funds' directors. This release provides staff interpretive guidance regarding certain issues relating to the independence and role of independent fund directors, and briefly describes the role of the Commission in connection with disputes between independent fund directors and fund management.

II. Interpretive Guidance

A. Commission Orders Under Section 2(a)(19) of the Act

Sections 2(a)(19)(A)(vi) and (B)(vi) of the Act authorize the Commission to issue an order finding that a person is ''interested'' by reason of a material business or professional relationship with certain persons and entities.[28] The Commission and the staff have not publicly provided guidance concerning these sections for a significant period of time.[29] The staff believes that it would be useful to provide additional guidance about the types of professional and business relationships that may be considered to be material for purposes of sections 2(a)(19)(A)(vi) and (B)(vi).[30] This guidance should be particularly useful because the staff understands that many fund groups will not nominate an individual as an independent director if they identify a material business or professional relationship that the individual has with a Specified Entity (as defined below) due to concerns that the Commission may commence proceedings under section 2(a)(19).[31]

The Commission has the authority to issue an order under section 2(a)(19) of the Act when it finds that a person has or had a ''material business or professional relationship'' with certain specified persons and entities, including some fund affiliates (''Specified Entities'').[32] Section 2(a)(19) does not define a ''material business or professional relationship.'' The legislative history, however, indicates that a business or professional relationship would be material if it ''might tend to impair the independence of [a] director.''[33] The legislative history also states that ''[o]rdinarily, a business or professional relationship would not be deemed to impair independence where the benefits flow from the director of an investment company to the other party to the relationship. In such instances the relationship is not likely to make the director beholden to that party.''[34]

The staff believes that issues arising under sections 2(a)(19)(A)(vi) and (B)(vi) must be analyzed based on the particular facts of each case to determine whether a director's interests and relationships might tend to impair his or her independence.[35] The staff also believes, however, that it would be useful to provide guidance about the types of professional and business relationships between a director and a Specified Entity that may be considered to be material. In particular, this section of the release describes how the staff will analyze whether a person should be treated as ''interested'' by virtue of (1) holding or having held certain positions with a Specified Entity, and (2) engaging or having engaged in certain material transactions with a Specified Entity.[36]

Positions as Material Business or Professional Relationships

The staff believes that a fund director may be treated as ''interested'' if he or she currently holds or held, at any time since the beginning of the last two completed fiscal years of the fund (the ''two-year period''), certain positions with a Specified Entity. The staff would consider a position that a director holds with a Specified Entity as a ''material business or professional relationship'' if it would tend to impair a director's independence by providing incentives for the director to place his or her own interests over the interests of fund shareholders. The key factors in evaluating whether a director's position with a Specified Entity would tend to impair his or her independence include the level of the director's responsibility in the position and the level of compensation or other benefits that the director receives or received from the position.

For instance, the staff would consider an individual who served as the fund's portfolio manager during the two-year

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[26] *See* SEC, Roundtable on the Role of Independent Investment Company Directors, Feb. 23–24, 1999 (''Roundtable Transcript''). The Roundtable Transcripts are available to the public in the Commission's public reference room, the Commission's Louis Loss Library, and on the Commission's Web site at www.sec.gov/offices/invmgmt/roundtab.htm. *See also* Companion Release, *supra* note 2, nn. 41, 63 and 76 (citing statements of Roundtable participants).

[27] At the Roundtable, Commission Chairman Arthur Levitt also asked the fund industry to assume an active role in establishing and promoting best fund governance practices. In June 1999, the Investment Company Institute issued a Report of the Advisory Group on Best Practices for Fund Directors (''ICI Advisory Group Report'').

[28] Section 2(a)(19)(A)(vi) of the Act defines ''interested person,'' when used with respect to an investment company, in part, as: ''any natural person whom the Commission by order shall have determined to be an interested person by reason of having had, at any time since the beginning of the last two completed fiscal years of such company, a material business or professional relationship with such company or with the principal executive officer of such company or with any other investment company having the same investment adviser or principal underwriter or with the principal executive officer of such other investment company.'' 15 U.S.C. § 80a–2(a)(19)(A)(vi).

Section 2(a)(19)(B)(vi) of the Act defines ''interested person,'' when used with respect to an investment adviser of or principal underwriter for, any investment company, in part, as: ''any natural person whom the Commission by order shall have determined to be an interested person by reason of having had at any time since the beginning of the last two completed fiscal years of such investment company a material business or professional relationship with such investment adviser or principal underwriter or with the principal executive officer or any controlling person of such investment adviser or principal underwriter.''

15 U.S.C. § 80a–2(a)(19)(B)(vi).

[29] For a number of years, the staff provided some informal guidance by issuing no-action letters, but has not done so since 1984 as a matter of policy. *See* Daniel Calabria, SEC No-Action Letter (Sept. 12, 1984); Capital Supervisors Helios Fund, Inc., SEC No-Action Letter (June 13, 1984).

[30] In the Companion Release, the Commission has proposed rules that would require additional disclosure about fund directors to, among other things, assist the Commission and its staff in evaluating directors' independence. Companion Release, *supra* note 2.

[31] *See* ICI Advisory Group Report, *supra* note 27, at 6; Roundtable Transcript of Feb. 24, 1999, at 253 (statement by Thomas R. Smith, Jr.). The staff believes that the guidance provided in this portion of the release may assist funds in the independent director nominating process.

[32] Those entities include the fund, its principal executive officer, the investment adviser and principal underwriter of the fund, the principal executive officer of the investment adviser or principal underwriter, or any controlling person of the investment adviser or principal underwriter, any other fund with the same investment adviser or principal underwriter, and the principal executive officer of such other fund. *See* Sections 2(a)(19)(A)(iv) and (B)(vi) [15 U.S.C. §§ 80a–2(a)(19)(A)(vi), (B)(vi)].

[32] H.R. Rep. No. 1382, 91st Cong., 2d Sess. 14 (1970); S. Rep. No. 184, 91st Cong., 1st Sess. 33 (1969).

[34] *Id.*

[35] The legislative history indicates that Congress intended for the Commission to determine whether a material business and professional relationship exists on a case-by-case basis. H.R. Rep. No. 1382, 91st Cong. 2d Sess. 15 (1970); S. Rep. No. 184, 91st Cong., 1st Sess. 33 (1969).

[36] The examples discussed in this release are not exhaustive and are provided for illustrative purposes only. There may be other relationships that would be viewed by the staff as material under section 2(a)(19).

period to have had a material business or professional relationship with the fund and its investment adviser. The staff previously has informally advised certain funds of this position on several occasions. The staff believes that a fund's former portfolio manager must be viewed as having had a material business or professional relationship with the fund and its adviser because he or she would have had significant responsibilities with the fund and the adviser, and likely would have received substantial compensation and other benefits from the adviser and/or the fund.[37] Indeed, the staff would view the former portfolio manager's position as material due to the manager's responsibility in the position even if the manager had not received substantial compensation from adviser or the fund. Similarly, the staff believes that former directors, officers, and employees of the fund's investment adviser or principal underwriter could be viewed as having had a material business or professional relationship with a Specified Entity, depending on the facts and circumstances.[38]

In addition, a fund director who at any time during the two-year period also was a director, officer or employee of a current or former holding company of the fund's investment adviser may be treated as interested by reason of a material business or professional relationship with the controlling person of the fund's adviser (a Specified Entity).[39] As described above, the staff's analysis of the materiality of the relationship would focus on, among other things, the level of the director's responsibility with the holding company and the level of compensation or other benefits that the director received from the position.

The staff believes that not every position that a director holds or held with a Specified Entity would be deemed to impair his or her independence. For example, a director of a fund who also is a director of another fund managed by the same adviser generally would not be viewed as an interested person of the fund under section 2(a)(19) solely as a result of this relationship.[40]

Material Transactions as Material Business or Professional Relationships

The staff believes that a fund director may be treated as ''interested'' if he or she has, at any time during the two-year period, directly or indirectly engaged (or proposed to engage) in any material transactions (or proposed material transactions) with a Specified Entity. Such a relationship could result from a single transaction or from multiple transactions. These transactions may be structured as service arrangements, including legal, investment banking, and consulting services, or other business transactions, such as business and personal loans, and real estate purchases.[41] In addition, a material business or professional relationship with a Specified Entity may result from a fund director's position with, or ownership interest in, an entity that engages in material transactions with a Specified Entity.

For example, the staff believes that a fund director may be treated as ''interested'' if the fund's investment adviser manages or managed for the director, at any time during the two-year period, an advisory or brokerage account, and the adviser favors, or creates the expectation that it will favor, the account over the other accounts that it manages.[42] In the staff's view, a director would receive favored treatment, for instance, if the adviser charged the director no fees or fees that were lower than the fees that it charged for similar types of accounts, or accorded the director's account special treatment regarding portfolio management decisions or securities allocations. By favoring the director's account over other accounts that it manages, the adviser may create an incentive for the director to act in a manner that will preserve or increase the favorable treatment.[43] In this instance, significant economic benefits from the relationship between the director and the adviser would flow to the director, or the director may have the expectation that significant economic benefits would flow in the future to the director.[44]

The staff believes that a fund director who serves as a chief executive officer of any company for which the chief executive officer of the fund's adviser serves as a director also may be treated as ''interested.'' The relationship between the fund director and the adviser's chief executive officer may tend to impair the director's independence because the adviser's chief executive officer has the power to vote on matters that affect the director's compensation and status as chief executive officer of the company. In this instance, the fund director may act with respect to fund matters in a manner to preserve his or her relationship with the company and with the adviser's chief executive officer, rather than in the interest of the fund's shareholders.[45]

A fund director may be deemed to have indirectly engaged in a material transaction with a Specified Entity through his or her interest in a company that conducted business with the Specified Entity.[46] In determining

[37] Similarly, the ICI Advisory Group recommends that former employees of a fund's investment adviser who had significant responsibilities in their positions with the adviser not serve as independent directors of the fund. *See* ICI Advisory Group Report, *supra* note 27, at 13.

[38] In addition, the staff notes that many former officers and employees of a fund's investment adviser or principal underwriter may own securities issued by the adviser or underwriter. Such persons are interested persons of the fund by virtue of sections 2(a)(19)(A)(iii) and (B)(iii) [15 U.S.C. §§ 80a–2(a)(19)(A)(iii), (B)(iii)].

[39] *See also* Western Separate Account A, SEC No-Action Letter (Mar. 8, 1976) (directors who are employees or executives of a fund adviser, principal underwriter or controlling person may not be disinterested); NEA Mutual Fund, SEC No-Action Letter (June 3, 1971) (directors who are employees or executives of an entity that controls the fund's adviser or principal underwriter may not be disinterested).

[40] *See* H.R. Rep. No. 1382, 91st Cong., 2d Sess. 15 (1970); S. Rep. No. 184, 91st Cong., 1st Sess. 34 (1969) (stating that ''a director of one investment company would not ordinarily be deemed an interested person of that company by reason of being a director of another investment company with the same adviser'').

[41] *See, e.g.,* Alpha Investors Fund, SEC No-Action Letter (Jan. 9, 1972) (director who is a partner at a law firm that provides legal services to an entity that controls the fund's adviser may be interested under section 2(a)(19)(B)(vi) because the director has a material business or professional relationship with that entity).

[42] *Cf.* H.R. Rep. No. 1382, 91st Cong., 2d Sess. 15 (1970); S. Rep. No. 184, 91st Cong., 1st Sess. 34 (1969) (stating that ''a director ordinarily would not be considered to have a material business relationship with the investment adviser simply because he is a brokerage customer who is not accorded special treatment'').

[43] Such favoritism would raise additional issues under the federal securities laws. See, *e.g.,* In the Matter of Monetta Financial Services, Inc., *supra* note 24.

[44] For an example of a relationship in which the staff believed that significant economic benefits did not flow to the director, *see* Securities Groups, SEC No-Action Letter (Apr. 20, 1981) (staff stated that a nominated director's participation in a symposium sponsored by the parent of the fund's adviser did not constitute a material relationship because ''the $2,000 paid to him for taking part in that seminar is not so significant as to tend to impair his independence were he to serve as a disinterested director of the fund'').

[45] *See* Southwestern Investors, Inc., SEC No-Action Letter (June 13, 1971) (fund director who is an officer and director of company A may not be disinterested if the president of a company that indirectly controls the fund's investment adviser and principal underwriter also serves as a director of company A). *Cf.* H.R. Rep. No. 1382, 91st Cong., 2d Sess. 15 (1970); S. Rep. No. 184, 91st Cong., 1st Sess. 34 (1969) (fund director that serves with the chief executive officer of the fund's adviser on the board of another company generally would not be deemed to have a material business or professional relationship with the chief executive officer). Unlike the facts in Southwestern Investors, Inc., the fund director described in the House and Senate Reports was not an officer or employee of the other company, such that the chief executive officer of the fund's adviser did not appear to have the power to vote on matters affecting the fund director's status with the other company.

[46] *See also* The MONY Fund, Inc., SEC No-Action Letter (Jan. 29, 1972) (director who is a senior

whether the director would have a material business or professional relationship with a Specified Entity due to his or her interest in the company and the company's transaction with the Specified Entity, the staff would look to the nature and significance of the director's interest in the company and the company's interest in the transaction. In particular, the staff would focus on the significance of any economic or other benefit that would flow to the director. For example, a fund director who had a controlling interest in a company that conducted material business with a fund would likely receive significant economic benefits, either directly or indirectly, as a result.[47] Such a director may be treated as interested because the director may have a material business or professional relationship with the fund as a result of having indirectly engaged in a material transaction with the fund.

A material relationship resulting from a *proposed* material transaction with a Specified Entity might include the negotiation of a service contract between a company controlled by the director and the Specified Entity. During the negotiation of such a contract (and even if such contract is never finalized), the director may be concerned about interests other than those of the fund and its shareholders. As a result, the process of negotiating a material transaction may tend to impair the director's independence, and thus may itself create a material business or professional relationship with a Specified Entity for purposes of section 2(a)(19).

Other Related Matters

In the Companion Release, the Commission is proposing amendments to various disclosure requirements. The purpose of the proposed disclosure amendments is, in part, to assist the Commission and the staff in determining whether it would be appropriate to make further inquiry into a particular director's independence. If the proposed rules are adopted, the staff will review and monitor the new disclosure. Based on its review of the disclosure, the staff will consider whether to issue additional guidance regarding other types of relationships that may be considered to be material under section 2(a)(19).

B. Independent Directors and Section 17(d) and Rule 17d–1

In the course of their duties, fund directors often take actions on behalf of a fund that may also benefit themselves in some way. Some have questioned whether these actions may run afoul of certain provisions of the Act that prohibit affiliated transactions. As discussed in greater detail below, the staff generally believes that they do not, and believes that it would be beneficial to fund directors for the staff to clarify its views on these matters.

As discussed previously, a fund's board of directors is charged with the responsibility of protecting the interests of fund shareholders by overseeing the operations of the fund and policing conflicts of interests. Fund directors must fulfill this responsibility, regardless of whether they may personally benefit from their actions, or whether their actions are contrary to the wishes of fund management. Some have argued that actions taken by directors on behalf of a fund that also provide some benefit to the directors could constitute a joint transaction for purposes of section 17(d)[48] of the Act and rule 17d–1[49] thereunder.[50]

Section 17(d) and rule 17d–1 generally prohibit an affiliated person of an investment company (which includes a fund director) or an affiliated person of such person (''affiliate''), acting as principal, from participating in or effecting any transaction in connection with any joint enterprise or other joint arrangement or profit-sharing plan in which the investment company is also a participant, unless an application regarding the joint arrangement has been filed with and an order authorizing the transaction has been granted by the Commission. A joint enterprise or other joint arrangement or profit-sharing plan (''joint arrangement'') is broadly defined in rule 17d–1(c) to include any written or oral plan, contract, authorization or arrangement, or any practice or understanding concerning an enterprise or undertaking whereby the investment company and the affiliate have a joint or a joint and several participation, or share in the profits of such enterprise or undertaking.

Fund directors commonly authorize the use of fund assets to make payments from which the directors may personally benefit, such as director salaries, board meeting expenses, proxy expenses, and legal fees of counsel to the independent directors. As a practical matter, the staff believes that interpreting rule 17d–1 as encompassing such actions could impede, or in some cases prevent, fund directors from taking actions that would be in the best interests of shareholders. Such a broad reading also could be used to prevent fund directors from fulfilling their responsibilities, such as opposing a proxy solicitation that they believe is not in the best interests of fund shareholders, or otherwise acting to protect shareholder interests.[51] Furthermore, the staff believes that requiring a fund to obtain a Commission order for every action that results in some benefit to directors would be unduly burdensome and could impede the efficient operation of funds.

The staff believes that it would be helpful to fund directors to clarify the meaning of ''joint arrangement'' in the context of actions taken in their capacities as directors. As a general matter, the staff believes that the actions of fund directors taken in their capacities as directors would not constitute joint arrangements for purposes of rule 17d–1. Joint arrangements require ''some element of combination'' between the fund and its affiliate.[52] The staff believes that, when a fund's directors are acting on behalf of the fund in their capacities as fund directors, the requisite element of ''combination'' is not present. Indeed, in order for the requisite element of ''combination'' to be present, the staff generally believes that the joint arrangement must involve activities that

officer of a company that contracted with company A, which wholly owns the fund's investment adviser, to find a vice president for company A, may have a material relationship with a controlling person of the fund's adviser).

[47] *Cf.* Travelers Equities Fund, Inc., SEC No-Action Letter (Jan. 11, 1982) (director who is a limited partner of a partnership that obtained a loan from the principal underwriter of the fund is not an interested person of the underwriter).

[48] Section 17(d) [15 U.S.C. § 80a–17(d)].

[49] Rule 17d–1 [17 CFR 270.17d–1].

[50] *See* Verified Complaint, *In the Matter of Yacktman* v. *Carlson,* No. 98278117 (Cir. Ct. Md. 1998).

[51] This prospect was raised in connection with recent litigation arising out of a dispute between the independent directors of a fund and its investment adviser. In the course of the dispute, the president of the fund, who also was the president of the investment adviser, called a special shareholders meeting and initiated a proxy contest to replace the independent directors. In addition, the investment adviser filed a lawsuit seeking to enjoin the fund's independent directors from using the fund's assets to pay for the fund's proxy expenses on the theory that such payment would be a joint arrangement among the fund and the independent directors in violation of section 17(d) and rule 17d–1. In response, the staff issued a letter to the parties indicating that it seriously questioned whether payment of the proxy expenses out of fund assets required a prior order under section 17(d) and rule 17d–1. *See* Letter from Jacob H. Stillman and Douglas Scheidt to Richard Teigen, Esq., *et. al,* October 16, 1998. This letter is included in the public comment file for the Companion Release. *See supra* note 2, at S7–23–99.

[52] *SEC* v. *Tally Industries, Inc.,* 399 F.2d 396, 403 (2d Cir. 1968), *cert. denied,* 393 U.S. 1015 (1969); and Deferred Compensation Plans for Investment Company Directors, SEC No-Action Letter (May 14, 1998).

are beyond the scope of the directors' duties to the fund.[53]

In the staff's view, the fact that fund expenditures may benefit the directors in some way is not sufficient to render them ''joint arrangements'' among the fund and the directors for purposes of rule 17d–1. Whether there is ''some element of combination'' does not depend on whether the directors' actions were motivated by self-interest. If, in fact, the directors were motivated solely by self-interest, they may have breached their duties of care or loyalty under state law or breached their fiduciary duties under section 36(a) of the Act.[54] But whether rule 17d–1 applies turns on the nature of the transaction, not on its propriety or the affiliate's motives, provided that the directors are acting within the scope of their duties. The staff believes that fund directors must be able to fulfill their duties without fear that their actions, even those from which they may personally benefit, may result in a joint transaction for purposes of rule 17d–1.

C. Advances of Legal Expenses to Independent Directors

As a consequence of their ''watchdog'' role in policing potential conflicts of interests, fund directors have heightened exposure to personal liability for actions that they take which they believe to be in the best interests of the fund and its shareholders.[55] The risk of personal liability could, however, deter some independent directors from making controversial decisions that may benefit the fund and discourage qualified individuals from serving as independent directors. The staff has sought to address these concerns by interpreting the Act to permit funds to advance legal fees to their directors under certain circumstances. Nonetheless, participants at the Commission's Roundtable on the Role of Independent Investment Company Directors (and others) have advised the staff that additional guidance may be necessary to clarify some uncertainties that may exist about certain aspects of the staff's positions. These uncertainties could make it unnecessarily difficult for some independent directors to receive advances of legal fees, particularly during disputes with the fund's investment adviser. The staff therefore is providing the following guidance regarding when funds may advance legal fees to their independent directors.

The defense of a lawsuit against a fund director can severely deplete the director's personal assets. If a director is found liable, even for mere negligence, the potential financial burdens may far exceed the director's ability to pay, and be greatly disproportionate to the financial and other benefits of serving as a director. Even if the lawsuit is without legal merit, the costs of defending it can be high. Without some protection against the risks of incurring these costs, directors may avoid making controversial decisions, even if those decisions would have been in the best interests of the fund and its shareholders. Indeed, the potential liability attendant upon service as a director of a fund can have the effect of discouraging qualified individuals from serving in that capacity.

One commonly used approach to address this problem is for funds to agree to indemnify directors for personal financial liability arising out of actions taken in their capacities as directors.[56] Any indemnification provisions, however, are subject to section 17(h) of the Act. Section 17(h) generally prohibits a fund from including in its organizational documents any provision that protects a director or officer of a fund against any liability to the fund or its shareholders by reason of willful misfeasance, bad faith, gross negligence or reckless disregard of his or her duties as director or officer (collectively, ''disabling conduct'').[57] Section 17(h) is intended to balance the need to ensure that funds have the ability to indemnify directors for liability arising out of actions that they took in good faith with the need for funds and their shareholders to be able to hold fund directors personally accountable for their actions as directors.[58]

The staff has taken the position that the prohibitions of section 17(h) apply to advances for legal fees, as well as to payments for settlements and judgments.[59] The staff believes that

[53] For example, the staff believes that a joint transaction would not exist if fund directors authorized the use of fund assets to pay for proxy expenses incurred in connection with the directors' uncontested re-election, notwithstanding that they could benefit personally from such expenditures. Similarly, the staff believes that, if a third party such as the fund's investment adviser initiated a proxy contest to unseat the fund's independent directors, the directors' use of fund assets to solicit proxies in favor of their re-election would not constitute a joint transaction. *Accord* Order Granting Defendants' Emergency Motion to Modify Temporary Restraining Order, *Yacktman* v. *Carlson*, Case No. AMD 98–3496 (D. Md. 1998) (vacating temporary restraining order enjoining directors from using fund assets to pay proxy expenses).

[54] Section 36(a) [15 U.S.C. 80a–35(a)]. Section 36(a) authorizes the Commission to institute a lawsuit alleging, among other things, that an officer or director of a fund, including an independent director, has engaged in an ''act or practice constituting a breach of fiduciary duty involving personal misconduct in respect of any [fund] for which such person so serves or acts.'' The Commission has used its authority under section 36(a) in a number of cases, including cases in which the Commission called into question the conduct of a fund's independent directors. *See, e.g., SEC* v. *Treasury First, Inc.*, Litigation Release No. 13094 (Nov. 19, 1991); *SEC* v. *Forty Four Management, Ltd.*, Litigation Release No. 11717 (Apr. 28, 1988); and *SEC* v. *American Birthright Trust Management Company, Inc.*, Litigation Release No. 9266 (Dec. 30, 1980).

In addition, section 37 of the Act prohibits persons from unlawfully and willfully converting to their own use or the use of another person any funds or assets of a registered investment company. *See, e.g., SEC* v. *Donna Tumminia*, Litigation Release No. 14217 (Sept. 1, 1994); and SEC v. Lazzell, Litigation Release No. 12585 (Aug. 17, 1990).

[55] The Act places substantial responsibilities on the independent directors of investment companies to protect the interests of fund shareholders by policing potential conflicts of interest. These responsibilities are in addition to the general duties of loyalty and care imposed on directors under state law. The Act and state law also provide fund shareholders with private rights of action against directors who fail to exercise reasonable care in the fulfillment of their duties. *See, e.g., Strougo* v. *Scudder, Stevens & Clark, Inc., supra* note 23, at 796–798 (holding that fund shareholder has a private right of action under section 36(a) against, among others, the independent directors of the fund). *See also* Pui-Wing Tam, ''Jury Gives Boost to Independent Directors,'' Wall St. J. at C19 (July 26, 1999) (trial of action by certain shareholders of a fund and the fund's investment adviser against former independent fund directors for breach of fiduciary duty resulted in jury verdict for defendants); Richard A. Oppel Jr., *A Potentially Costly Lawsuit*, N.Y. Times at sec. 3, at 7 (Aug. 1, 1999) (former independent fund directors sued by investment adviser and fund shareholders, *see supra*, may seek recovery of millions of dollars in legal fees from fund that has assets of only $37.5 million).

[56] American Bar Association, Section of Business Law, Fund Director's Guidebook 70 (1996). Funds also commonly obtain ''errors and omissions'' insurance policies to cover expenses incurred by directors and officers in the event of litigation. These policies often are joint policies that cover numerous funds within a fund family as well as the funds' investment adviser and principal underwriter, and have generally excluded claims in which one party covered by the policy sues another. Although section 17(d) of the Act and rule 17d–1 thereunder generally prohibit such jointly arrangements, *see supra* text accompanying notes 48–51, rule 17d–1(d)(7) permits the purchase of joint errors and omission policies. The Commission is proposing to amend rule 17d–1(d)(7) [17 CFR 270.17d–1(d)(7)] to make the rule available only for joint insurance policies that do not exclude coverage for litigation between a fund's independent directors and investment adviser. *See* Companion Release, *supra* note 2, at Section II.B.

[57] *See* Section 17(h) [15 U.S.C. § 80a–17(h)]. State laws similarly limit the ability of investment companies to indemnify their directors and officers. At least one commenter has suggested that such state law provisions that are more restrictive than section 17(h) probably are not susceptible to challenge on the grounds of federal preemption. *See* Newman, O'Dell and Kenyon, *Indemnification and Insurance*, ALI–ABA Course of Study: Investment Company Regulation and Compliance 217,220 (June 11, 1998).

[58] *See Chabot* v. *Empire Trust Co.*, 301 F.2d 458,460 (2d Cir. 1962) (''The purpose of [section] 17(h) is to ensure that liability for violation of the duties and standards provided by the Act will not be defeated by the inclusion of protective contractual clauses'').

[59] ''Indemnification by Investment Companies,'' Investment Company Act Release No. 11330 (Sept.

section 17(h) is intended to ensure that directors can be held personally accountable for any costs that may result from their disabling conduct, including those costs, such as legal fees, that are indirect results of litigation or the threat thereof.

The staff also has taken the position that, before advancing legal fees to a director, a fund's board must either (1) obtain assurances, such as by obtaining insurance or receiving collateral provided by the director, that the advance will be repaid if the director is found to have engaged in disabling conduct, or (2) have a reasonable belief that the director has not engaged in disabling conduct and ultimately will be entitled to indemnification.[60] The staff has stated that a reasonable belief may be formed either by a majority of a quorum of the independent, non-party directors of the investment company, or based on a written opinion [61] provided by independent legal counsel that in turn is based on counsel's review of the readily available facts (as opposed to a full trial-type inquiry).[62] These positions are intended to permit a fund to protect its directors against the legal costs attendant upon defending and resolving lawsuits, while preventing or minimizing the risk that a fund's assets will be used to indemnify directors for legal fees that are incurred as a result of the directors' disabling conduct.

The staff has been advised that these positions may make it unnecessarily difficult for funds to advance legal fees to their directors. This could inhibit the willingness of independent directors to take appropriate but controversial actions and discourage qualified individuals from serving as independent directors. This problem may be particularly acute when there is a dispute between the fund's investment adviser and the fund's independent directors, as the investment adviser in some circumstances would be able to influence any determination about the whether the directors had engaged in disabling conduct. For example, persons who had been ousted as independent directors in a proxy battle with management might question the ability or willingness of the fund's new independent directors to objectively determine whether there was reason to believe that the ousted directors had engaged in disabling conduct because the directors may have been nominated by the fund's investment adviser.

The staff has recently addressed the issue of whether independent directors should be afforded a presumption that they have not engaged in disabling conduct within the meaning of section 17(h). Independent directors are presumed by the nature of their qualifications to be free of many of the kinds of conflicts that may color their judgment and affect their actions as directors.[63] On this basis, the staff reasoned that it would be consistent with section 17(h) and prior staff positions if legal counsel—in providing an opinion as to whether a fund should advance legal fees either to its independent directors or to any directors who are interested persons solely by reason of serving as officers of the fund—afforded the directors a rebuttable presumption that they had not engaged in disabling conduct.[64] The staff stated that this position was limited to actions taken by directors while acting in their capacities as directors. The staff believes that the rebuttable presumption also should apply in situations when the independent, non-party directors of the investment company, rather than independent legal counsel, make the reasonable belief determination.

Another related issue is the degree of due diligence that would be necessary for independent, non-party directors or independent legal counsel to make a reasonable belief determination. As noted above, the staff has stated that the directors or counsel could rely on a review of the readily available facts, and that a full trial-type inquiry was unnecessary. Thus, we would not expect the directors or counsel to engage in fact-finding to the same degree as one might undertake to prepare for a trial, which might include taking depositions, issuing interrogatories, or interviewing every witness involved in the dispute. Furthermore, while the level of review that would be required to be undertaken by the directors or counsel would depend on the particular facts and circumstances of each situation, the review need only be sufficient to form the basis of a reasonable, but not necessarily conclusive, belief.

The staff believes, however, that the directors and counsel should give certain information significant weight when making a reasonable belief determination. For example, the staff believes that the directors and counsel would be precluded, in most cases, from making a reasonable belief determination once a court or other body before which the relevant proceeding was brought found that a director had engaged in disabling conduct, notwithstanding the possibility that the director might prevail on appeal.[65] When directors and counsel cannot make a reasonable belief determination, the staff believes that section 17(h) would prohibit the fund from advancing legal fees to the director unless the fund obtained assurances that the advance will be repaid if the director ultimately is found to have engaged in disabling conduct. Conversely, the dismissal of a court action or an administrative proceeding against a director for insufficiency of evidence of any disabling conduct would likely provide the basis for a reasonable belief that the director had not engaged in such conduct.[66]

4, 1980) (''Release 11330'') [20 SEC Docket 1342]. As noted in Release 11330, improper advances or payments for settlements or judgments could form the basis of an action under sections 36(a) and 37 of the Act. *See supra* note 54.

[60] Before Release 11330 was issued, the staff has taken the position that a fund could not advance legal fees unless it had obtained insurance or received sufficient collateral. It response to complaints that this requirement was unduly burdensome and expensive, the staff revised its position to permit a fund also to advance legal fees on the basis of a reasonable belief that the director had not engaged in disabling conduct and ultimately would be entitled to indemnification. *See id.*

[61] The opinion must set forth the facts and legal analysis that formed the basis for counsel's conclusion. *See* Steadman Security Corp., SEC No-Action Letter (Apr. 18, 1983) (concluding, among other things, that neither the board's resolutions, nor the legal opinion submitted to the board, contained any facts or legal analysis supporting indemnification). Similarly, any finding made by the disinterested, non-party directors should be memorialized in a written document that also contains the information upon which the directors relied to reach their decision. *Id.*

[62] The staff also believes that non-party independent directors or independent legal counsel must make a reasonable belief determination prior to each advance of legal fees to fund directors. *See infra* note 65. Such a determination should include the consideration of any new information that is readily available.

[63] For example, affiliated persons of the fund's investment adviser cannot serve as a independent directors. *See* Section 2(a)(19) [15 U.S.C. 080a–2(a)(19)].

[64] The Yacktman Funds, Inc., SEC No-Action Letter (Dec. 18, 1998).

[65] The staff also has previously stated that directors should consider whether advances of legal expenses may involve a breach of fiduciary duty involving personal misconduct under section 36(a) of the Act or misuse of fund assets in violation of section 37 of the Act. Sections 36(a) and 37 [15 U.S.C. §§ 80a–35(a), 80a–36]. *Id.* and *supra* note 54. When authorizing the fund to make an advance of legal expenses, fund directors should consider whether the amount of the advance is reasonable at that point in the litigation. For example, it generally may be inappropriate for the fund directors to authorize the fund to advance—at the earliest stages of litigation when little information regarding the dispute may be readily available—an amount that would cover the expenses of an entire trial. If a director-defendant requests additional advances from the fund, and a reasonable belief determination no longer can be made, the fund's board should decline to authorize the advance, unless the fund obtained assurances that the advance will be repaid if the director ultimately is found to have engaged in disabling conduct.

[66] *See* Release 11330, *supra* note 59.

D. Compensating Fund Directors With Fund Shares

The Commission staff believes that effective fund governance can be enhanced when funds align the interests of their directors with the interests of their shareholders. Fund directors who own shares in the funds that they oversee have a clear economic incentive to protect the interests of fund shareholders. In addition, as fund shareholders, these directors are in a better position to evaluate the services that the funds provide to their shareholders.

Certain funds have instituted policies that encourage or require their independent directors to invest the compensation that they receive from the funds in shares of the funds.[67] The Commission staff believes that the implementation of such policies gives the independent directors a direct and tangible stake in the financial performance of the funds that they oversee, and can help more closely align the interests of independent directors and fund shareholders. Recently, an advisory group organized by the Investment Company Institute recommended this practice.[68]

The staff believes that some fund groups have not instituted these policies because of concerns that they may be prohibited by section 22(g) of the Investment Company Act.[69] The staff believes that such concerns may be misplaced, and would like to clarify the circumstances in which open-end funds may (1) encourage or require fund directors to purchase fund shares with the compensation that they receive from a fund and (2) compensate directors directly with fund shares, consistent with section 22(g).

Prior to the enactment of section 22(g) in 1940, some open-end funds issued their shares to fund insiders for providing management, promotion, distribution and other services to the funds.[70] In some instances, this practice apparently resulted in the dilution of shareholder interests. For example, some funds agreed to pay insiders a definite number of shares of the fund at a future date for their services (rather than assign a fixed dollar value to the services). If the value of the fund's shares appreciated by the time that the shares were payable by the fund, the compensation paid to the insiders exceeded the value of the services provided. As a result, the fund treated the insiders on a basis more favorable than other shareholders by allowing them to acquire fund shares at less than the net asset value of the shares. The insiders received a ''windfall'' that diluted the value of the shares of other shareholders.

Consequently, Congress enacted section 22(g) to prohibit open-end funds from issuing shares to any person or entity that performs services for the fund. Section 22(g) generally provides that no open-end fund shall issue any of its securities (1) for services or (2) for property other than cash or securities.[71] Both the Commission and the representatives of investment companies agreed in 1940 that ''[n]o security issued by an investment company shall be sold to insiders or to anyone other than an underwriter or dealer, except on the same terms as are offered to other investors.'' [72]

As previously mentioned, some open-end funds have instituted policies that encourage or require their independent directors to invest their compensation in the shares of the funds that they oversee. Under these policies, a fixed dollar value is assigned to the services provided by the directors prior to the time that the directors perform any services or purchase the funds' shares. The directors' fees, therefore, cannot be inflated by allowing directors to receive fund shares with an aggregate net asset value that exceeds the dollar value that was previously assigned to the directors' services. The staff believes that, under these circumstances, funds may institute policies that encourage or require their directors to purchase fund shares with the compensation that the directors receive from the funds, consistent with section 22(g).[73]

In addition, the staff would not recommend enforcement action to the Commission under section 22(g) if funds directly compensate their directors with fund shares, rather than compensating the directors in cash and requiring them subsequently to purchase fund shares, provided that a fixed dollar value is assigned to the directors' services prior to the time that the compensation is payable.[74] The staff similarly believes that this method of compensation, which is functionally equivalent to paying the directors in cash, does not present the dangers of dilution and the overvaluation of services that section 22(g) was designed to prevent.

In implementing these policies, funds should ensure that their directors purchase their shares from the funds on the same basis as other shareholders, and not on preferential terms.[75] Funds also should disclose the directors' compensation structure and the dollar amount or value of their compensation to current and prospective fund shareholders in registration statements, shareholder reports and proxy statements, as required by the federal securities laws.

III. The Role of the Commission in Disputes Between Independent Fund Directors and Fund Management

Over the past few years, the Commission has been criticized for not taking certain actions in connection with disputes between independent fund directors and fund management.[76] Specifically, some persons have suggested that the Commission should have taken action against certain investment advisers based on allegations made by funds' independent directors that the advisers had violated the federal securities laws. We believe that these suggestions may reflect confusion regarding the significance that should be attached to the Commission's public silence, or

[67] Some funds have implemented deferred compensation plans for directors allowing directors to defer receipt of director fees to obtain tax and other benefits. Under these plans, directors can be credited with amounts tied to the performance of the funds. *See* Deferred Compensation Plans for Investment Company Directors, *supra* note 52.

[68] *See* ICI Advisory Group Report, *supra* note 27, at 17.

[69] *Id.* at n.31.

[70] *See House Hearings, supra* note 4, at 124.

[71] Section 22(g) [15 U.S.C. §§ 80a–22(g)].

[72] *See House Hearings, supra* note 4, at 99 (memorandum of agreement in principle between the Commission and representatives of open-end and closed-end investment companies dated May 13, 1940).

[73] Closed-end funds also may wish to institute policies that encourage or require their directors to use the compensation that they receive from the funds to purchase fund shares in the secondary market on the same basis as other fund shareholders. The staff believes that these policies would be consistent with section 23(a) of the Investment Company Act. Section 23(a) [15 U.S.C. § 80a–23(a)]. Like section 22(g), section 23(a) prohibits a closed-end fund from issuing any of its securities (1) for services or (2) for property other than cash or securities.

[74] Similarly, the staff would not recommend enforcement action to the Commission under section 23(a) if closed-end funds directly compensate their directors with fund shares, provided that the directors' services are assigned a fixed dollar value prior to the time that the compensation is payable. Closed-end funds, however, are generally prohibited by section 23(b) of the Investment Company Act from selling their shares at a price below their current net asset value. Section 23(b) [15 U.S.C. § 80a–23(b)]. As a result, any closed-end fund that compensates its directors by issuing fund shares would generally be required to issue those shares at net asset value, even if the shares are trading at a discount to their net asset value.

[75] A fund may sell its shares to its directors at prices that reflect scheduled variations in, or the elimination of, any sales load pursuant to rule 22d–1 under the Act [17 CFR 270.22d–1].

[76] *See, e.g.,* Charles Jaffe, An oversight on oversight; SEC wants directors to stand by shareholders, but won't help them, Boston Globe, Feb. 28, 1999, at D6; and Edward Wyatt, SEC Explores Directors' Roles, N.Y. Times, Jan. 31, 1999, at S3.

determination not to institute an enforcement action, in the face of allegations of violations of the federal securities laws. Indeed, as discussed below, no one should presume that the Commission has not carefully considered such allegations or that the Commission has failed to take appropriate action merely because the Commission has not instituted an enforcement action or taken other public actions.

Two principles are important to understanding the Commission's response to disputes between independent fund directors and fund management. First, the Commission's staff may conduct an examination or investigation, but the public generally will be unaware of such action. As a matter of policy, the Commission and its staff generally will not comment on the existence or non-existence of a particular examination or investigation, or disclose publicly any actions taken in connection with an examination or investigation, unless the Commission institutes an enforcement action.[77] This policy is necessary to protect both the integrity of an examination or investigation against premature disclosure, and the personal privacy of individuals against whom others may make unfounded charges. Second, the Commission and its staff may decide that enforcement action is not warranted based on all available information, including information to which commentators and others are not privy, even though publicly available information may suggest that a federal securities law violation has occurred. Thus, a decision by the Commission not to institute an enforcement action may be based on nonpublic, exculpatory information, and the Commission's policies preclude it from disclosing this information or explaining its decision to the public. It therefore is wrong to presume, merely because the Commission has not made any public statement or taken any public action in connection with an internal fund dispute, that the Commission has not investigated any allegations made by the parties or failed to take appropriate action in view of all available facts.[78]

We also believe that it would be helpful to clarify the Commission's role and procedures in connection with disputes between independent fund directors and fund management. The Commission's role, as a general matter, is to interpret, administer and enforce the federal securities laws for the protection of investors. Accordingly, the Commission's role in connection with internal fund disputes generally is to provide guidance regarding the requirements of the federal securities laws, investigate possible violations of these laws, and institute enforcement actions in appropriate circumstances when the Commission believes that these laws have been violated. While there may be instances in which the Commission, in fulfilling this role, may indirectly assist one party in a dispute, the Commission generally will not mediate private disputes, side with one party over another, or seek to effect a particular outcome. Rather, the Commission will assist the parties to understand the requirements of the federal securities laws, evaluate all allegations of violations of those laws, and take appropriate action for the protection of investors.

As a general matter, the procedures followed by the Commission and the staff in connection with internal fund disputes are similar to the procedures that it follows in connection with any private dispute that involves the application of, and compliance with, the federal securities laws. As a matter of practice, the Commission affords substantial consideration to all such allegations of violations and promptly assigns staff to carefully evaluate them. During this initial, informal evaluation, the staff typically will review public documents, such as registration statements and other Commission filings, and may invoke the Commission's examination authority to review fund records, including board minutes, or the records of the fund's investment adviser.[79] The staff also may ask interested parties, including independent and interested directors, fund officers, and investment advisory personnel, to cooperate voluntarily by agreeing to provide additional information and documents to the staff. If more information is needed, the staff may conduct an investigation and, if necessary, the Commission may issue a formal order of investigation. Under a formal order, the Commission authorizes the staff to conduct an investigation, pursuant to which the staff may subpoena witnesses and compel the production of documents.[80] This information gathering is critical to the Commission's determination of the appropriate course of action, for it often uncovers exculpatory or inculpatory nonpublic information that bears upon the validity of the allegations.

The Commission may take more serious steps if the public interest so requires. For example, if the Commission finds evidence of serious violations of the federal securities laws, it may institute administrative proceedings or initiate an action in federal district court.[81] In some circumstances, the staff may refer the matter to the Department of Justice to consider whether criminal charges are warranted.

The Commission's role in disputes between independent fund directors and fund management will not necessarily involve an examination or investigation. If, for example, the parties disagree as to the correct interpretation of some provision of the federal securities laws and regulations, or the parties need further clarification of particular legal issues, the staff may provide its interpretation of the provision or its views regarding the issue in question, either in writing or orally. The Commission also may file a friend-of-the-court brief in ongoing litigation, or otherwise seek to intervene in private litigation when it believes that its views on certain matters may be

[77] The Commission's rules require that both informal and formal investigations be non-public. 17 CFR 202.5 and 203.5. Section 210(b) of the Investment Advisers Act of 1940 (''Advisers Act'') [15 U.S.C. § 80b–10(b)] generally prohibits the Commission and its staff from disclosing the existence of, and information obtained as a result of, an examination of an investment adviser under the Act. Further, records or information that are obtained in the course of an investigation or examination generally are exempt from disclosure under the Freedom of Information Act. Exemptions 7 and 8 of the Freedom of Information Act [5 U.S.C. §§ 552(b)(7), (8)].

[78] *See* Roundtable Transcript of Feb. 23, 1999, at 25 (statement of Arthur Levitt, Chairman, SEC) (the Commission ''will aggressively and vigorously pursue reports by directors of violations of federal law and not sit idly by''); Roundtable Transcript of Feb. 24, 1999, at 207–208 (statement of Paul Roye, Director, Division of Investment Management, SEC) (allegations of violations of federal securities laws will be resolutely pursued).

[79] *See* Section 31(b) of the Act [15 U.S.C. § 80a–30(b); Section of the Advisers Act [15 U.S.C. § 80b04].

[80] *See* Section 42(b) of the Act [15 U.S.C. § 80a–41(b)]; Section 209(b) of the Advisers Act [15 U.S.C. § 80b–9(b)].

[81] Section 36(a) of the Act [15 U.S.C. (80a–35(a)] authorizes the Commission to institute an action in federal district court against certain individuals for breaches of fiduciary duties involving personal misconduct regarding a registered investment company. Section 36(b) [15 U.S.C. (80a–35(b)] authorizes the Commission to institute an action in federal district court against an investment adviser for breach of fiduciary duty in connection with its receipt of compensation from a registered investment company. The Commission also may institute other actions in federal district court pursuant to Section 42(d) of the Act [15 U.S.C. (80a–41(d)] and Section 209(d) of the Advisers Act [15 U.S.C. (80b–9(d)]. Administrative proceedings may be instituted under Section 9 of the Act [15 U.S.C. (80a–9] and Section 203 of the Advisers Act [15 U.S.C. (80b–3].

helpful to the court or necessary for the protection of investors.[82]

As described above, the Commission and the staff are committed to carefully reviewing all allegations of violations of the federal securities laws, and taking appropriate action when a violation has occurred. The Commission's and the staff's actions, and any decisions not to act, will be based on all facts that are available to us, and will not necessarily be explained to the public. These positions are necessary to ensure the fairness and integrity of the examination and investigative process. The Commission and the staff also are dedicated to enhancing the fairness and integrity of the fund governance process, and will consider instituting enforcement proceedings or taking other public positions if they will further this goal.

[82] *See, e.g.,* discussion of Letter from Jacob H. Stillman and Douglas Scheidt to Richard Teigen, Esq., *et. al,* October 16, 1998, supra note 51 and accompanying text; and discussion of The Yacktman Funds, Inc., SEC No-Action Letter (Dec. 18, 1998), *supra* note 64 and accompanying text. *See also* Section 44 of the Act [15 U.S.C. § 80a–43] (authorizing the Commission to intervene in private litigation brought under Section 36(b) of the Act) [15 U.S.C. § 80a–35(b)]). *See also* statements of Commission Chairman Arthur Levitt: regarding the need for the fund industry to assume an active role in establishing and promoting best fund governance practices, *supra* note 27, and expressing concerns about standard ''insured versus insured'' exclusions in joint insurance policies. *See* Companion Release, *supra* note 2, n.111; and *supra* note 56.

List of Subjects in 17 CFR Part 271

Investment companies.

Amendment of the Code of Federal Regulations

For the reasons set out in the preamble, title 17 chapter II of the Code of Federal Regulations is amended as set forth below:

PART 271—INTERPRETATIVE RELEASES RELATING TO THE INVESTMENT COMPANY ACT OF 1940 AND GENERAL RULES AND REGULATIONS THEREUNDER

1. Part 271 is amended by adding Release No. IC–24083 and the release date of October 14, 1999, to the list of interpretive releases.

Dated: October 14, 1999.

By the Commission.

Jonathan G. Katz,

Secretary.

[FR Doc. 99–27443 Filed 11–2–99; 8:45 am]

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federal register

Wednesday
November 3, 1999

Part III

Federal Trade Commission

16 CFR Part 312

Children's Online Privacy Protection Rule; Final Rule

FEDERAL TRADE COMMISSION

16 CFR Part 312

RIN 3084–AA84

Children's Online Privacy Protection Rule

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: The Federal Trade Commission issues its final Rule pursuant to the Children's Online Privacy Protection Act of 1998 (''COPPA'' or ''the Act''). Section 6502 of the Act requires the Commission to enact rules governing the online collection of personal information from children under 13 within one year of the date of the enactment of the COPPA, October 21, 1998.

DATES: The rule will become effective on April 21, 2000.

ADDRESSES: Requests for copies of the Rule and the Statement of Basis and Purpose should be sent to Public Reference Branch, Room 130, Federal Trade Commission, 6th Street and Pennsylvania Avenue, N.W., Washington, D.C. 20580. Copies of these documents are also available at the Commission's website, <*www.ftc.gov*>.

FOR FURTHER INFORMATION CONTACT: Division of Advertising Practices: Toby Milgrom Levin (202) 326–3156, Loren G. Thompson (202) 326–2049, or Abbe Goldstein (202) 326–3423, Federal Trade Commission, 6th Street and Pennsylvania Avenue, N.W., Washington, D.C. 20580.

SUPPLEMENTARY INFORMATION: The Rule implements the requirements of the COPPA by requiring operators of websites or online services directed to children and operators of websites or online services who have actual knowledge that the person from whom they seek information is a child (1) to post prominent links on their websites to a notice of how they collect, use, and/or disclose personal information from children; (2) with certain exceptions, to notify parents that they wish to collect information from their children and obtain parental consent prior to collecting, using, and/or disclosing such information; (3) not to condition a child's participation in online activities on the provision of more personal information than is reasonably necessary to participate in the activity; (4) to allow parents the opportunity to review and/or have their children's information deleted from the operator's database and to prohibit further collection from the child; and (5) to establish procedures to protect the confidentiality, security, and integrity of personal information they collect from children. As directed by the COPPA, the Rule also provides a safe harbor for operators following Commission-approved self-regulatory guidelines.

Statement of Basis and Purpose

I. Introduction

Congress enacted the COPPA to prohibit unfair or deceptive acts or practices in connection with the collection, use, or disclosure of personally identifiable information from and about children on the Internet.[1]

Section 6502(b)(1) of the Act sets forth a series of general privacy protections to prevent unfair or deceptive online information collection from or about children, and directs the Commission to adopt regulations to implement those protections. The Act requires operators of websites directed to children and operators who knowingly collect personal information from children to: (1) Provide parents notice of their information practices; (2) obtain prior verifiable parental consent for the collection, use, and/or disclosure of personal information from children (with certain limited exceptions for the collection of ''online contact information,'' *e.g.*, an e-mail address); (3) provide a parent, upon request, with the means to review the personal information collected from his/her child; (4) provide a parent with the opportunity to prevent the further use of personal information that has already been collected, or the future collection of personal information from that child; (5) limit collection of personal information for a child's online participation in a game, prize offer, or other activity to information that is reasonably necessary for the activity; and (6) establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of the personal information collected.[2]

The COPPA authorizes the Commission to bring enforcement actions for violations of the Rule in the same manner as for other rules defining unfair or deceptive acts or practices under section 5 of the Federal Trade Commission Act.[3] In addition, section 6504 of the COPPA authorizes state attorneys general to enforce compliance with the final Rule by filing actions in federal court after serving prior written notice upon the Commission when feasible.[4]

The Commission published a Notice of Proposed Rulemaking and Request for Public Comment (''NPR'') in the **Federal Register** on April 27, 1999,[5] and the 45-day comment period closed on June 11, 1999. The Commission received 132 comments from a wide array of interested parties, all of which were extremely informative and which the Commission has considered in crafting the final Rule. The commenters included private individuals; companies operating Internet sites or businesses; public interest organizations; marketing and advertising trade groups; library, school, and other educational organizations; Federal government entities; State Attorneys General; publishers and publishing trade groups; Internet service providers; and organizations sponsoring Internet privacy seal programs.

Because of particular interest among commenters in the issue of how to obtain verifiable parental consent under the Rule, Commission staff conducted a public workshop on that issue on July 20, 1999, to obtain additional information and learn more about the views expressed.[6] The 32 panelists at the workshop included representatives from industry (including website operators and technology companies), as well as privacy advocates, consumer groups, and representatives of other government agencies. Approximately 100 other parties also attended the workshop. Panelists discussed methods of obtaining verifiable parental consent that are currently in use; whether and how e-mail could be used to obtain verifiable parental consent; and technologies or methods that are under development that could be used in the future to obtain verifiable parental consent. Workshop attendees were invited to comment during question and answer sessions. The proceeding was transcribed, and the transcript was placed on the public record.[7] In addition, the Commission accepted further public comment on issues raised at the workshop. The workshop

[1] 15 U.S.C. 6501–6505.

[2] 15 U.S.C. 6502(b)(1).

[3] Section 6502(c) of the Act provides that the Rule shall be treated as a rule issued under § 18(a)(1)(B) of the FTC Act (15 U.S.C. 57a (a)(1)(B)).

[4] 15 U.S.C. 6504.

[5] 64 FR 22750 (Apr. 27, 1999) (to be codified at 16 CFR pt. 312).

[6] 64 FR 34595 (June 28, 1999) (announcement of the public workshop).

[7] The transcript and all of the comments received in the course of this proceeding appear on the FTC's website at <*www.ftc.gov*>. References to the workshop transcript are cited as ''Speaker/affiliation (Workshop Tr. at ____)'' followed by the appropriate page designation. Initial references to the comments are cited as ''Name of commenter (Comment or Workshop comment number) at (page number).''

comment period, which ended on July 30, 1999, yielded 14 comments.[8]

In drafting this final Rule, the Commission has taken very seriously the concerns expressed about maintaining children's access to the Internet, preserving the interactivity of the medium, and minimizing the potential burdens of compliance on companies, parents, and children. The Commission believes that the final Rule strikes the appropriate balance between these concerns and the Act's goals of protecting children's information in the online environment. It looks forward to continuing to work with industry, consumer groups, and parents to ensure widespread compliance in as efficient a manner as possible, to educate the public about online privacy protections, and to assess the Rule's effectiveness on a periodic basis.[9]

II. The Rule

As noted above, the Commission published the proposed Rule and accompanying analysis in the **Federal Register** in April 1999. Unless specifically modified herein, all of the analysis accompanying the proposed Rule in the NPR is adopted and incorporated into this Statement of Basis and Purpose for the final Rule.

A. Section 312.2: Definitions

Section 312.2 of the proposed Rule included definitions of a number of key terms.[10] The Commission sought comment as to whether these definitions were clear, comprehensive, flexible, and appropriate.[11] In the Rule, the Commission has modified the definitions of four of these terms: ''collects or collection,'' ''disclosure,'' ''personal information,'' and ''third party.'' All other definitions have been adopted without change.

1. Definition of ''Child''

In the proposed Rule, the Commission adopted the statutory definition of ''child'' as ''an individual under the age of 13.''[12] The Commission received only one comment on this issue, which supported the definition.[13] Thus, the final Rule retains the statutory definition.

2. Definition of ''Collects or Collection''

The proposed Rule defined ''collects or collection'' to include ''the direct or passive gathering of any personal information from a child by any means, including but not limited to: (a) [a]ny online request for personal information by the operator regardless of how that personal information is transmitted to the operator; (b) [c]ollection using a chat room, message board, or other public posting of such information on a website or online service; or (c) [p]assive tracking or use of any identifying code linked to an individual, such as a cookie.''[14] The term was meant to encompass the many ways that website operators could gather information from children.

Responsive comments contended that subparagraph (a) swept within the proposed Rule information requested online but submitted offline that was clearly meant to be excluded under the COPPA.[15] These comments also noted that it would be burdensome to require a business that solicits the same information from children in a number of ways, including through the Internet, to determine the source of the request in order to provide the required parental notice and seek consent for information submitted online.

The Commission is persuaded that the Congress intended the COPPA to apply only to information collected online by an operator. Therefore, based on the written comments, subparagraph (a) of the definition of collects or collection has been modified to cover any request by the operator that children submit information online.[16]

Other commenters were concerned that including public postings in the definition of ''collects or collection'' would confer liability on operators of general audience (*i.e.*, non-child-directed) chat sites for unsolicited postings by children.[17] The Commission believes that these concerns are legitimate, and therefore the Rule now provides that such sites would only be liable if they (1) have actual knowledge that postings are being made by a child under 13, and (2) when they have such knowledge, fail to delete any personal information before it is made public, and also to delete it from their records.

For general audience sites, the Act explicitly covers operators who have *actual knowledge* that they are collecting personal information from children.[18] Therefore, the operator of a general audience chat site who has actual knowledge that a child is posting personal information on the site must provide notice and obtain verifiable parental consent if the child is to continue to post such information in that site's chat room.[19] In most cases, if the operator does not monitor the chat room, the operator likely will not have the requisite knowledge under the Act. However, where the operator does monitor the chat room, the Commission has amended the Rule so that, if the operator strips any posting of individually identifiable information before it is made public (and deletes it from the operator's records), that operator will not be deemed to have collected the child's personal information.[20]

One group of commenters stated that requiring operators to get parental consent in order for a child to participate in a chat room would violate the child's First Amendment right to free speech.[21] These commenters also

[8] On July 27, 1999, the Commission also issued an Initial Regulatory Flexibility Analysis (''IRFA'') under the Regulatory Flexibility Act, 64 FR 40525. The IRFA focused on the impact of the proposed Rule on small businesses and sought additional public comment on that issue. This final comment period closed on August 6, 1999. Five comments were received. These comments are cited as ''Name of commenter (IRFA comment number) at (page number).''

[9] Shortly after issuing this final Rule, the Commission plans to develop and distribute educational materials to assist businesses in complying with the Rule and to inform parents of the protections provided by the COPPA.

[10] 64 FR at 22751–53, 22763–64.

[11] 64 FR at 22761.

[12] COPPA, 15 U.S.C. 6501(1). *See* 64 FR at 22751, 22763.

[13] American Psychological Association (''APA'') (Comment 106) at 1.

[14] 64 FR at 22751, 22763.

[15] *See generally*, Direct Marketing Ass'n (''DMA'') (Comment 89) at 31–32; Kraft Foods, Inc. (''Kraft'') (Comment 67) at 2–3; Council of Better Business Bureaus, Inc. (''CBBB'') (Comment 91) at 4; Viacom, Inc. (''Viacom'') (Comment 79) at 4–5; Time Warner, Inc. (''Time Warner'') (Comment 78) at 6–7; Magazine Publishers of America (''MPA'') (Comment 113) at 2. These comments pointed out that the COPPA covers the collection of personal information, which is defined in the statute as ''individually identifiable information about an individual collected online. * * *'' 15 U.S.C. 6501(8). Commenters also noted that the Floor Statement accompanying the Act states ''[t]his is an online children's privacy bill, and its reach is limited to information collected online from a child.'' 144 Cong. Rec. S11657 (daily ed. Oct. 7, 1998) (Statement of Sen. Bryan).

[16] If, however, an operator combines in one database information collected offline with information collected online such that the operator cannot determine the source of the information, the operator will be required to disclose all of that data in response to a parent's request under section 312.6 of the Rule. *See* Section II.E, *infra*.

[17] ZapMe! Corp. (''ZapMe!'') (Comment 76) at 7; Talk City, Inc. (''Talk City'') (Comment 110) at 2. *See also* Promotion Marketing Ass'n. (''PMA'') (Comment 107) at 3.

[18] 15 U.S.C. 6502(a)(1). *See also* Rule section 312.3.

[19] Operators of sites directed to children that provide chat rooms and bulletin boards and who do not delete personally identifiable information from postings before they are made public must always provide notice and obtain parental consent as provided by the Rule.

[20] This amendment applies both to operators of websites directed to children and to websites with actual knowledge that information is being collected from a child. Because an operator who deletes such information will not be deemed to have ''collected'' it, that operator also will not have ''disclosed'' that information under the Rule.

[21] Center for Democracy and Technology, American Civil Liberties Union, American Library

Continued

asserted that the Commission's proposal went beyond what Congress intended with this legislation.[22] Congress, however, specifically included such postings in the COPPA on the grounds that children could be placed at risk in such fora, noting that one of the Act's goals was ''to enhance parental involvement to help protect the safety of children in online fora such as chatrooms, home pages, and pen-pal services in which children may make public postings of identifying information.'' [23] As noted in the Commission's June 1998 report to Congress, children's use of chat rooms and bulletin boards that are accessible to all online users present the most serious safety risks, because it enables them to communicate freely with strangers.[24] Indeed, an investigation conducted by the FBI and the Justice Department revealed that these services are quickly becoming the most common resources used by predators for identifying and contacting children.[25] Commenters also generally acknowledged that these are among the most sensitive online activities.[26]

Several commenters expressed concerns that the proposed Rule would similarly require operators to give notice and obtain parental consent in order to give a child an e-mail account.[27] The Commission notes that, to the extent that operators who provide e-mail accounts keep records of the e-mail addresses they have assigned, along with any associated information, those operators can be considered to have ''collected'' those e-mail addresses under the Act. Operators of sites directed to children are therefore required to comply with the Act when giving children e-mail accounts. For operators of general audience sites, the Rule requires *actual knowledge* that information is being collected from a child. Such operators would only be required to provide notice and obtain parental consent if registration or other information reveals that the person seeking the e-mail account is a child.

A number of commenters noted that operators might be responsible for complying with all of the requirements of the Rule after receiving an unsolicited e-mail from a child.[28] If an operator of a site directed to children receives such an e-mail, that contact is covered under the Act's (and the Rule's) one-time e-mail exception.[29] Under that exception, an operator may collect a child's name and online contact information for the purpose of responding one time in response to a direct request from a child. This exception would allow an operator to receive an e-mail from a child and provide a response without providing parental notice and obtaining consent, as long as the name and online contact information collected from the child are deleted and not used for any other purpose.[30] And again, in the case of a general audience site, these requirements apply only if the site receiving the e-mail has actual knowledge that it was sent by a child.

One commenter noted that a site could collect non-personally identifiable information about a child without parental notice or consent as long as that information was only tied to a screen name.[31] An operator who has solicited such information could obtain the child's name through a subsequent solicitation, and would thus have evaded the Act's requirement of prior parental consent.[32] This is a valid concern, but the Commission believes that the Rule does in fact address the issue. Indeed, under the Rule, once such information is linked to an identifier (the name), it becomes ''personal information'' and the Rule requires the operator to provide notice and obtain consent for the collection, use, and/or disclosure of all of the information.[33]

3. Definition of ''Disclosure''

The definition of ''disclosure'' in the proposed Rule covered: (1) The release of personal information collected from a child in identifiable form by an operator for any purpose, except where the operator provides the information to a person who provides support for the internal operations of the website and who does not use that information for any other purpose; [34] and (2) making personal information collected from a child publicly available in identifiable form, including through public postings, posting of personal home pages, messages boards, and chat rooms, or any other means that would enable a child to reveal personal information to others online.[35]

In the NPR, the Commission sought to clarify that entities that provide fulfillment services or technical support would be considered ''support for the internal operations of the website or online service,'' and thus disclosures to such entities need not be disclosed in the site's notices.[36] The Commission also noted that such services as merely providing the server for the website, or providing chat or e-mail service would also be considered ''support for the internal operations of the website.'' [37] The Commission cautioned, however, that because operators are also required by the Act to establish reasonable procedures to maintain the confidentiality, security, and integrity of personal information collected from children,[38] they should take appropriate measures to safeguard such information in the possession of those who provide support for the internal operations of their websites.[39]

Association (''CDT, et al.'') (Workshop comment 11) at 2–4.

[22] *Id.*

[23] 144 Cong. Rec. S11657 (Statement of Sen. Bryan).

[24] *Privacy Online: A Report to Congress* at 5 (June 1998).

[25] *Id.* The concern may be heightened where such services are directed to children because potential predators know that the majority of the participants are likely to be underage.

[26] Center for Media Education, Consumer Federation of America, Am. Academy of Child and Adolescent Psychiatry, Am. Academy of Pediatrics, Junkbusters Corp., Nat'l Alliance for Non-Violent Programming, Nat'l Ass'n of Elementary School Principals, Nat'l Consumers League, Nat'l Education Ass'n, Privacy Times and Public Advocacy for Kids (''CME/CFA et al.'') (Comment 80) at 30; Viacom (Comment 79) at 13–14; DMA (Workshop comment 02) at 1–2; Bagwell/MTV Networks Online (Workshop Tr. 32–33); Kraft (Comment 67) at 4–5; Children's Advertising Review Unit of the Council of Better Business Bureaus (''CARU'') (Workshop comment 08) at 2; Cartoon Network, et al. (Comment 77) at 18; Nikolai.com, Inc. (Comment 129) at 2; and Consumers Union (Comment 116) at 3.

[27] *See, e.g.,* Commercial Internet eXchange Ass'n and PSINet Inc. (''CIX et al.'') (Comment 83) at 8; Zeeks.com (Comment 98) at 1; CDT et al. (Workshop comment 11) at 3 (noting same First Amendment concerns as for chat rooms). Similar concerns were expressed in connection with the proposed Rule's definition of ''disclosure,'' which included ''any other means that would enable a child to reveal personal information to others online.'' *See* Section II.A.3, *infra.*

[28] *See, e.g.,* ZapMe! (Comment 76) at 7–8. *See also* Highlights for Children, Inc. (''Highlights'') (Comment 124) at 2.

[29] 15 U.S.C. 6502(b)(2)(A); section 312.5(c)(2) of the Rule. *See* Section II.D.3, *infra.*

[30] Moreover, this exception would accommodate sites that automate their responses to incoming e-mails, as long as the child's name and online contact information are deleted and not used for any other purpose. MLG Internet (Comment 119) at 2 (asking about automated e-mail responses).

[31] CDT (Comment 81) at 18.

[32] *Id.*

[33] *See* Section II.A.8, *infra.* Moreover, under section 312.6 of the Rule, the operator must disclose that information to the parent upon request and the parent may request that the operator delete that information. *See* Section II.E, *infra.*

[34] The ''release of personal information'' is defined in the Rule to mean the ''sharing, selling, renting, or any other means of providing personal information to any third party.'' *See* section 312.2 of the Rule. For additional guidance as to whether an entity is a ''third party'' under the Rule, see discussion, *infra,* regarding definitions of ''operator'' and ''third party.''

[35] 64 FR 22752, 22764.

[36] 64 FR at 22752.

[37] *Id.*

[38] 15 U.S.C. 6502(b)(1)(D).

[39] 64 FR at 22752. Some commenters objected to the notion of holding operators liable for the action of contractors because operators have no way of ensuring that contractors will follow the Rule. *See, e.g.,* DMA (Comment 89) at 35. The Act and the Rule require operators to establish and maintain reasonable procedures to protect the confidentiality,

Two commenters expressed a concern that the last clause of the proposed definition, which covered ''any other means that would enable a child to reveal personal information to others online,'' would include an Internet Service Provider (''ISP'') or cable company that simply provides Internet access without offering any content or actively collecting any information from children.[40] Although the Commission notes that this language was not meant to reach such entities,[41] it has decided to eliminate this language as confusing and unnecessary.[42]

4. Definition of ''Internet''

The proposed Rule's definition of ''Internet'' made clear that it applied to the Internet in its current form and to any conceivable successor.[43] Given that the technology used to provide access to the Internet will evolve over time, it is imperative that the Rule not limit itself to current access mechanisms. The Commission received three comments regarding this definition.[44] One commenter suggested that the Commission clarify that the definition ''clearly includes networks parallel to or supplementary to the Internet such as those maintained by the broadband providers * * * [and] intranets maintained by online services which are either accessible via the Internet or have gateways to the Internet.'' [45] The Commission believes that the proposed definition of ''Internet'' was sufficiently broad to encompass such services and adopts that definition in the final Rule.

5. Definition of ''Online Contact Information''

The Commission received several comments [46] regarding the definition of ''online contact information.'' [47] One commenter suggested that the Commission include in the definition such identifiers as instant messaging user identifiers, which are increasingly being used for communicating online.[48] The Commission believes that these identifiers already fall within the proposed definition, which includes ''any other substantially similar identifier that permits direct contact with a person online.'' [49] After reviewing the comments, the Commission has determined that no changes to this definition are necessary.

6. Definition of ''Operator''

The definition of ''operator'' is of central importance because it determines who is covered by the Act and the Rule. Consistent with the Act, the proposed Rule defined operator (with some limitations) as ''any person who operates a website located on the Internet or an online service and who collects or maintains personal information from or about the users or visitors * * * or on whose behalf such information is collected or maintained * * *'' [50] In the NPR, the Commission clarified the scope of the definition by listing a number of factors to consider, including who owns and/or controls the information, who pays for its collection and maintenance, the pre-existing contractual relationships regarding collection and maintenance of the information, and the role of the website or online service in collecting and/or maintaining the information (*i.e.*, whether the site participates in collection or is merely a conduit through which the information flows to another entity).[51] The Commission also clarified that entities that merely provide access to the Internet, without providing content or collecting information from children, would not be considered operators.[52] In the NPR, the Commission asked about the impact of the proposed definition, and whether it was sufficiently clear to provide notice as to who is covered by the Rule.[53] After carefully reviewing the comments received, the Commission has determined that no changes to the proposed definition are necessary.

A number of commenters proposed various tests to determine how corporate affiliates should be treated under the Rule.[54] The Commission believes that an entity's status as an operator or third party under the Rule should be determined not by its characterization as a corporate affiliate, but by its relationship to the information collected under the factors described in the NPR. Not all affiliates play a role in collecting or maintaining the information from children, and making an entity an operator subject to the Act simply because one of its affiliates collects or maintains information from children online would not serve the goals of the COPPA. If, however, the entity has an interest in the data collected under the factors listed in the NPR, then it, too, will be covered by the Rule.[55]

One commenter sought clarification of the status of network advertising companies, or companies that provide banner ads on websites or online

security, and integrity of personal information collected from children. 15 U.S.C. 6502(b)(1)(D); section 312.8 of the Rule. As long as the operator follows reasonable procedures to ensure that such contractors protect the information (for example, contractual provisions that limit the contractors' ability to use the information), operators should not be liable for the actions of contractors.

[40] *See* CIX, *et al.* (Comment 83) at 8–9; National Cable Television Association (''NCTA'') (Comment 71) at 6–8.

[41] *See* 64 FR at 22752. To the extent that ISPs do not operate websites or online services that are directed to children, or knowingly collect information from children, they are not subject to the COPPA.

[42] One commenter also asked whether the term ''disclosure'' covered the inclusion of a child's name on a list of contest winners, which is often required under state laws. *See* PMA (Comment 107) at 4. If the operator collects only name and online contact information, then the exception under section 312.5(c)(5)(iv) would apply. However, if the operator collects additional information online, then the release of that information would be considered a disclosure under the Rule.

[43] 64 FR at 22752, 22764.

[44] CME/CFA et al. (Comment 80) at 18; E.A. Bonnett (Comment 126) at 1; CDT (Comment 81) at 10–11. Two of the comments praised the proposed definition as comprehensive. E.A. Bonnett (Comment 126) at 1; CDT (Comment 81) at 10–11.

[45] CME/CFA et al. (Comment 80) at 18.

[46] CyberAngels (Comment 120) at 1; CME/CFA et al. (Comment 80) at 6–7; Aftab & Savitt (Comment 118) at 3–4; CDT (Comment 81) at 16–18.

[47] The definition in the proposed Rule was identical to the one contained in the Act. *See* 15 U.S.C. 6501(12); 64 FR at 22752, 22764.

[48] CyberAngels (Comment 120) at 1.

[49] Another example of ''online contact information'' could be a screen name that also serves as an e-mail address. *See* Section II.A.8, *infra*.

[50] 15 U.S.C. 6501(2); 64 FR at 22752, 22764.

[51] 64 FR at 22752.

[52] Thus, ISPs and cable operators that merely offer Internet access would not be considered operators under the Rule.

[53] 64 FR at 22761.

[54] *See, e.g.*, Council of Better Business Bureaus, Inc. (''CBBB'') (Comment 91) at 6–7; Attorneys General of the States of New York, Alabama, California, Florida, Georgia, Hawaii, Illinois, Indiana, Maryland, Nevada, Ohio, Oklahoma, Tennessee, Vermont, and Washington (''Attorneys General'') (Comment 114) at 6; PMA (Comment 107) at 4–5; Am. Ass'n of Advertising Agencies (''AAAA'') (Comment 134) at 3; Ass'n of Nat'l Advertisers (''ANA'') (Comment 93) at 6–7. Some commenters argued in support of automatically including all corporate affiliates as operators. Others thought that all affiliates with identical privacy policies should be considered operators, or, alternatively, that operators should be required to disclose that an affiliate has a different privacy policy and describe how it differs from the primary operator's. As noted in Section II.C.3.c, *infra*, the notice is required to describe the privacy policies of the various operators. One commenter suggested a consumer perception standard: that an affiliate would be considered an operator if a consumer would reasonably expect that the affiliated entities are part of one organization that shares information within itself. PMA (Comment 107) at 5. The Commission believes that the proposed standard, which places responsibility for compliance on the entities that control the information, is the most workable test for who is an operator.

[55] In the NPR, the Commission stated that operators are jointly responsible for implementing the requirements of the Rule. 64 FR at 22752. In an investigation into a potential Rule violation, the Commission will examine all the facts and circumstances in determining the appropriate party or parties to pursue. The Commission likely will not pursue an entity that is an ''operator,'' but has not facilitated or participated in, and has no reason to know of, any Rule violations.

services.[56] If such companies collect personal information directly from children who click on ads placed on websites or online services directed to children, then they will be considered operators who must comply with the Act, unless one of the exceptions applies.[57] Moreover, if such companies collect personal information from visitors who click on their ads at general audience sites, and that information reveals that the visitor is a child, then they will be subject to the Act. In addition, if they do not collect information from children directly, but have ownership or control over information collected at a host children's site, they will be considered operators. If, however, no personal information is collected or maintained by such companies, either directly or through the host website, then they will not be deemed to be operators.

Some commenters sought greater clarity regarding the meaning of ''actual knowledge'' that a particular visitor is a child and inquired whether an operator of a general audience site has any duty to investigate the age of its visitors.[58] Actual knowledge will be present, for example, where an operator learns of a child's age or grade from the child's registration at the site or from a concerned parent who has learned that his child is participating at the site. In addition, although the COPPA does not require operators of general audience sites to investigate the ages of their site's visitors, the Commission notes that it will examine closely sites that do not directly ask age or grade, but instead ask ''age identifying'' questions, such as ''what type of school do you go to: (a) elementary; (b) middle); (c) high school; (d) college.'' Through such questions, operators may acquire actual knowledge that they are dealing with children under 13.

Finally, one commenter sought assurance that an operator would not be liable if his site contained a link to another site that was violating the Rule.[59] If the operator of the linking site is not an operator with respect to the second site (that is, if there is no ownership or control of the information collected at the second site according to the factors laid out in the NPR), then the operator will not be liable for the violations occurring at the second site.

7. Definition of ''Parent''

The Act and the proposed Rule defined ''parent'' as ''includ[ing] a legal guardian.''[60] The Commission received two comments regarding this definition, both of which sought additional guidance concerning the Rule's application in non-traditional family situations.[61] The Commission believes that the proposed definition is sufficiently flexible to account for a variety of family structures and situations, including situations where a child is being raised by grandparents, foster parents, or other adults who have legal custody. Therefore, the Commission retains the definition of parent contained in the proposed Rule.

8. Definition of ''Personal Information''

The definition of ''personal information'' is another critical part of the Rule because it specifies the type of information covered by the Rule. The proposed definition included a number of different types of individually identifiable information, including name, address, and phone number; e-mail address; and other types of information that could be used to locate an individual either online or offline.[62] The proposed definition also covered non-individually identifiable information (*e.g.*, information about a child's hobbies or toys) that is associated with an identifier.[63]

One commenter asked the Commission to clarify that operators are not required to provide parental notice or seek parental consent for collection of non-individually identifiable information that is not and will not be associated with an identifier.[64] The Commission believes that this is clear in both the Act and the Rule.

Several commenters sought further guidance on whether the use of screen names would trigger the Act's requirements.[65] If a screen name is not associated with any individually identifiable information, it is not considered ''personal information'' under this Rule.[66]

Another commenter criticized the proposed Rule on the grounds that it encourages operators to set up sites using screen names.[67] This commenter argued that it is important to have accountability online—*i.e.*, that it is important for operators to be able to identify and take action against visitors who post inappropriate information or harass other online visitors. The Commission agrees that these are important considerations, but notes that the Rule does not foreclose operators from taking such precautions. Operators are free to request parental consent to collect such information. Moreover, the exception to the requirement of prior parental consent under section 312.5(c)(5)(i) of the Rule allows operators to collect the child's online contact information for this very purpose.[68]

One commenter noted that there are some persistent identifiers that are automatically collected by websites and can be considered individually identifying information, such as a static IP address or processor serial number.[69] If this type of information were considered ''personal information,'' the commenter noted, then nearly every child-oriented website would automatically be required to comply with the Rule, even if no other personal information were being collected. The Commission believes that unless such identifiers are associated with other individually identifiable personal information, they would not fall within the Rule's definition of ''personal information.''

Several commenters asked whether information stored in cookies falls within the definition of personal information.[70] If the operator either collects individually identifiable information using the cookie or collects non-individually identifiable information using the cookie that is

[56] Media Inc., AdForce, Inc., DoubleClick, Inc., Engage Technologies, Inc., Flycast Communications Corp., and Real Media, Inc. (Comment 92) at 4–8.

[57] It may be appropriate for such companies to provide a joint notice with the operator of the host website.

[58] *See* PMA (Comment 107) at 6; Attorneys General (Comment 114) at 7. See also MLG Internet (Comment 119) at 1–2.

[59] MaMaMedia, Inc. (''MaMaMedia'') (Comment 85) at 7.

[60] 15 U.S.C. 6501(7); 64 FR at 22752, 22764.

[61] Ass'n of Educational Publishers (''EdPress'') (Comment 130) at 2; Highlights (Comment 124) at 1.

[62] 64 FR at 22752–22753, 22764.

[63] *Id.*

[64] *See* National Retail Federation (''NRF'') (Comment 95) at 2.

[65] ZapMe! (Comment 76) at 8–9; KidsOnLine.com (Comment 108) at 1–2; TRUSTe (Comment 97) at 3.

[66] One commenter also asked whether operators would be required to ensure that a screen name chosen by a child did not contain individually identifiable information. TRUSTe (Comment 97) at 3. Operators do not have a specific duty to investigate whether a screen name contains such information. However, an operator could give children warnings about including such information in screen names, especially those that will be disclosed in a public forum such as a chat room.

[67] KidsOnLine.com (Comment 108) at 1–2.

[68] *See also* 15 U.S.C. 6502(b)(2)(E)(i). As noted above, an operator who wishes to collect name and online contact information under this exception may not use or disclose that information for any other purpose. An operator, however, who collects other personal information and links it with online contact information collected under this exception would be in violation of the Rule unless the operator provided parental notice and obtained verifiable parental consent for the collection of all of that information.

[69] CDT (Comment 81) at 16. *See also* E.A. Bonnett (Comment 126) at 2–3.

[70] *See, e.g.*, Consumers Union (Comment 116) at 4.

combined with an identifier, then the information constitutes ''personal information'' under the Rule, regardless of where it is stored.

After reviewing the comments, the Commission has decided to retain the definition of ''personal information'' with slight modifications. In response to the suggestion of one commenter, one item was added to subparagraph (f) of the definition: a photograph of the individual, when associated with other information collected online that would enable the physical or online contacting of the individual.[71] The Commission is also making slight modifications to ensure consistency within the definition.

9. Definition of ''Third Party''

The proposed Rule defined the term ''third party'' as ''any person who is neither an operator with respect to the collection of personal information * * * nor a person who provides support for the internal operations of the website or online service.'' [72] Under the Rule, an operator is required to provide notice of its practices with respect to the disclosure of information to third parties and to allow parents to choose whether the operator may disclose their children's information to third parties.[73] Because third parties are not operators, they are not responsible for carrying out the provisions of the Rule.

Comments regarding this definition raised issues similar to those raised in response to the proposed definition of ''operator''—specifically, when and whether corporate affiliates would be considered ''operators'' or ''third parties.'' As noted above, the Commission believes that the most appropriate test for determining an entity's status as an operator or third party is to look at the entity's relationship to the data collected, using the factors listed in the NPR.[74] If an entity does not meet the test for operator, that entity will be considered a third party.

One commenter asked that the Commission require third parties to comply with the Rule.[75] However, the statute applies only to the practices of the operator, and the Commission does not have the authority to extend liability to third parties.

After reviewing the comments, the Commission has made minor revisions to the definition of ''third party'' to maintain consistency across the Rule. These revisions consist of adding the words ''and maintenance'' following ''collection,'' and clarifying that, in order to be excluded from the definition, a person who provides internal support for the website may not disclose or use information protected under this Rule for any other purpose.

10. The Definition of ''Obtaining Verifiable Parental Consent''

The proposed Rule included a definition of ''obtaining verifiable parental consent'' that was substantially similar to the definition contained in the COPPA.[76] The term was defined to mean ''making any reasonable effort (taking into consideration available technology) to ensure that before personal information is collected from a child, a parent of the child'' receives notice of the operator's information practices and consents to those practices. The Commission received no comments suggesting modification to this definition, and therefore retains the proposed definition.

11. Definition of ''Website or Online Service Directed to Children''

In the proposed Rule, the Commission listed a number of factors that the Commission would consider in determining whether a site would be ''directed to children,'' including, among other things, the site's ''subject matter, visual or audio content, age of models, language or other characteristics of the website or online service. * * *''[77] The Commission also stated in the proposed Rule that it would consider competent and reliable empirical evidence regarding audience composition as well as evidence regarding the intended audience of the site.[78] In addition, under the proposed Rule, a general audience website would not be deemed to be directed to children simply because it referred or linked to another website or online service that is directed to children.[79] Finally, if a general audience site has a distinct children's ''portion'' or ''area,'' then the operator would be required to provide the protections of the Rule for visitors to that portion of the site.[80]

Several commenters asked for more guidance about the factor analysis laid out in this definition.[81] One commenter asked that the Commission clarify that the presence of only one of the listed factors would not cause a site to be classified as ''directed to children''; rather that *all* of the factors would be taken into account.[82] In response, the Commission notes that the proposed definition makes it clear that the Commission will look at the overall character of the site—and not just the presence or absence of one or more factors—in determining whether a website is directed to children.

Another commenter noted that operators should not be able to construct a ''veil of ignorance'' where the operator can determine through questions whether a visitor is a child without specifically asking for the visitor's age.[83] As discussed above in Section II.A.6 concerning the definition of ''operator,'' the Commission will closely examine such sites to determine whether they have actual knowledge that they are collecting information from children. A similar concern was raised with respect to sites that ask for age ranges that include both children and teens (*e.g.*, a ''15 and under'' category).[84] Because it is simple for operators to craft a ''12 and under'' age range, the Commission will look closely at sites that do not offer such a range if it appears that their operators are trying to avoid compliance with the Rule.

B. Section 312.3: Regulation of Unfair or Deceptive Acts or Practices in Connection With the Collection, Use, and/or Disclosure of Personal Information From and About Children on the Internet

Section 312.3 of the proposed Rule set out the Rule's general requirements, which were detailed in the later provisions.[85] The Commission received no comments that directly pertained to section 312.3 of the proposed Rule, which was a restatement of the requirements laid out in the Act,[86] and therefore retains it without change. Comments regarding the sections

[71] Aftab & Savitt (Comment 118) at 4. This commenter also asked the Commission to remove the phrase ''collected online'' from this definition in order to cover information that is submitted to an operator offline, then posted online by the operator. While we are cognizant of the risks posed by such practices, the Commission believes that the COPPA does not apply to information submitted to an operator offline. *See* Section II.A.2, *supra*, concerning the definition of ''collection.''

[72] 64 FR at 22753, 22764.

[73] *See* Sections II.C.3.d, and II.D.1, *infra*.

[74] *See* Section II.A.6, *supra;* 64 FR at 22752.

[75] CME/CFA et al. (Comment 80) at 6, 11.

[76] *See* 64 FR 22753, 22764; 15 U.S.C. 6501(9).

[77] 64 FR 22753, 22764.

[78] *Id*.

[79] *Id*.

[80] *Id*.

[81] JuniorNet Corp. (''JuniorNet'') (Comment 100) at 2; Int'l Digital Software Ass'n (''IDSA'') (Comment 103) at 2; CDT (Comment 81) at 20–21; MLG Internet (Comment 119) at 2; Time Warner (Comment 78) at 4, 5.

[82] JuniorNet (Comment 100) at 2.

[83] Consumers Union (Comment 116) at 4–5.

[84] CME/CFA et al. (Comment 80) at 7; Attorneys General (Comment 114) at 7. *See also* TRUSTe (Comment 97) at 2.

[85] 64 FR at 22753, 22764.

[86] 15 U.S.C. 6502(b)(1).

implementing its requirements are discussed in the relevant sections below.

C. Section 312.4: Notice

1. Section 312.4(a): General Principles of Notice

The COPPA mandates that an operator provide notice on its website and to parents of ''what information is collected from children by the operator, how the operator uses such information, and the operator's disclosure practices regarding such information.'' [87] The proposed Rule set out general principles of notice, followed by a specific set of guidelines for the online placement and content of those notices, to ensure that parents receive all the information that they would find material when reviewing a site.[88] As noted in the NPR, the operator's notice will form the basis for a parent's decision whether to give the operator consent to collect, use, and/or disclose personal information from his or her child.[89] In order to provide informed consent, a parent must have a clear idea of what the operator intends to do.[90] Therefore, the proposed Rule required an operator's notice to ''be clearly and understandably written,'' [91] be complete, and * * * contain no unrelated, confusing, or contradictory materials.'' [92] The Commission believes that these are the core principles underlying a consent-based system and, therefore, retains this section in the final Rule.[93]

2. Section 312.4(b)(1): Notice on the Website or Online Service—Placement of the Notice

Section 312.4(b)(1) of the proposed Rule set forth the requirements for online placement of the notice of the operator's information practices. It required operators to place a link to the notice on the home page of the website or online service such that a typical visitor would see the link without having to scroll down from the initial viewing screen.[94] In addition, the proposed Rule required operators to post a link to that notice in a similar manner at each place on the website or online service where information is collected from children.[95]

A large number of commenters noted that with the multitude of Web browsers available and the advent of ever-smaller machines that can access the Internet, it may not be technically feasible to ensure that the link to the notice can be seen without scrolling down from the initial viewing screen.[96] The Commission acknowledges that the proposed Rule's requirement regarding the placement of the online notices may not be a workable standard. Therefore, the Commission has modified section 312.4(b)(1)(ii) to require that a link to the notice be placed ''in a clear and prominent place and manner on the home page of the website or online service.'' ''Clear and prominent'' means that the link must stand out and be noticeable to the site's visitors through use, for example, of a larger font size in a different color on a contrasting background. The Commission does not consider ''clear and prominent'' a link that is in small print at the bottom of the home page, or a link that is indistinguishable from a number of other, adjacent links.

Some commenters noted that general audience sites with distinct children's areas should be allowed to post the link to the children's privacy policy at the home page of the children's area, rather than the home page of the overall site.[97] The Commission believes that this is a sensible approach to providing notice. Parents who are reviewing the operator's practices with respect to children would likely go directly to the children's area; therefore, operators of sites with distinct children's areas must post a prominent link at the home page of that area.[98]

Further, in response to comment, section 312.4(b)(1)(iii) has been modified to require that a link to the notice be placed ''at each area on the website or online service where children directly provide, or are asked to provide, personal information and in close proximity to the requests for information in each such area.'' The comment noted—and the Commission agrees—that it makes sense to require that the link be in close proximity to the initial request for information in an area so that visitors do not have to scroll up or down the page to find the link.[99] In response to comments, the Commission also changed the requirement of notice at each ''place'' where children provide information to notice at each such ''area'' in order to make clear that there does not need to be a link accompanying each question, but simply at each separate area where such information is collected.[100]

3. Section 312.4 (b)(2) and (c)(1)(i)(B): Content of the Notice

Section 312.4(b)(2) of the proposed Rule details the information that operators must include in their notice on the site. That information was also required to be included in the notice to the parent under Section 312.4(c)(1)(i)(B).[101] Under the proposed Rule, operators were required to include in their notices, among other things: (1) names and contact information for all operators; (2) the types of personal information collected through the site and how such information is collected; (3) how the personal information would be used; (4) whether the personal

[87] 15 U.S.C. 6502(b)(1)(A)(i). One commenter stated that Congress included these general guidelines in the Act as a performance standard, rather than intending them to be a source of detailed regulations. Yahoo! Inc, theglobe.com, inc., DoubleClick, Inc. (''Yahoo et al.'') (Comment 73) at 2. Congress, however, specifically delegated to the Commission the authority to issue regulations to implement the Act.

[88] Sections 312.4(a), (b); 64 FR at 22753–56, 22764–65.

[89] 64 FR at 22754–55.

[90] The Commission notes that it has authority under this section, as well as under Section 5 of the Federal Trade Commission Act, to take action against operators whose notices are deceptive or misleading.

[91] CME/CFA et al. (Comment 80) at 9; The McGraw-Hill Companies (''McGraw-Hill'') (Comment 104) at 6. One commenter asked whether the Commission would apply a particular standard in evaluating how a notice is written. Jeff Sovern, St. John's University School of Law (''Sovern'') (Comment 33) at 3–4. Traditionally, the Commission has applied a ''reasonable consumer'' standard in evaluating whether a notice is clearly and understandably written. Because the notices required by the Act are intended for parents, the Commission will look at whether they are written such that a reasonable parent can read and comprehend them.

[92] 64 FR at 22754.

[93] Two commenters voiced support for these general principles. *See* Attorneys General (Comment 114) at 7; Kraft (Comment 67) at 1.

[94] 64 FR at 22754.

[95] *Id.* Several commenters supported the use of other mechanisms for providing notice, such as pop-up or interstitial pages, which typically appear temporarily when visitors move from one part of the site to another. America Online, Inc. (''AOL'') (Comment 72) at 11; NRF (Comment 95) at 3; iCanBuy.com (Comment 101) at 2. The Commission notes that pop-up or interstitial pages will only satisfy the notice requirements of the Rule if they are clear, prominent, and easily accessible to users, *i.e.*, they do not disappear after the initial viewing or users can re-access them through a clear and prominent link on the home page.

[96] *See, e.g.*, Am. Advertising Fed. (''AAF'') (Comment 87) at 2; ANA (Comment 93) at 5; Dell Computer Corp. (''Dell'') (Comment 102) at 3–4; McGraw-Hill (Comment 104) at 7; Time Warner (Comment 78) at 9; Viacom (Comment 79) at 6–7.

[97] ANA (Comment 93) at 5; MPA (Comment 113) at 3–4; DMA (Comment 89) at 22–23; McGraw-Hill (Comment 104) at 7.

[98] One comment argued that the notice requirements would require operators of general audience sites to have two physically separate privacy policies—one for adults and one for children. Kraft (Comment 67) at 4. Operators are free to combine the privacy policies into one document, as long as the link for the children's policy takes visitors directly to the point in the document where the operator's policies with respect to children are discussed, or it is clearly disclosed at the top of the notice that there is a specific section discussing the operator's information practices with regard to children.

[99] Mars, Inc. (''Mars'') (Comment 86) at 10.

[100] *See, e.g.*, AOL (Comment 72) at 8–11.

[101] 64 FR at 22754–56, 22765.

information would be disclosed to third parties, the types of businesses in which those third parties are engaged, whether the third parties have agreed to take steps to protect the information, and a statement that parents have the right to refuse to consent to the disclosure of their child's personal information to third parties; (5) that the operator may not condition a child's participation in an activity on the provision of more personal information than is necessary to participate in the activity; and (6) that the parent may review, make changes to, or have deleted the child's personal information.[102] Many of the comments addressing these sections expressed concern that they required the inclusion of too much information in the notices. As discussed below, the Commission believes that most of the information required in the proposed Rule would be material to parents in deciding whether to consent to their child's participation in a site. However, in order to reduce the length of the notice, the Commission has eliminated certain information that it has determined would be of limited benefit to parents.

a. Section 312.4(b)(2)(i). This section of the proposed Rule required operators to include in the notice the name, address, phone number, and e-mail address of all operators collecting or maintaining personal information from children through the website or online service.[103] Some commenters objected to including this information in the notice because it would make the notice unwieldy. Operators can minimize the length of the notice by designating a single entity as a central contact point for any inquiries regarding the information practices of the site's operators. The Commission, however, believes that it is essential that all operators be identified in the notice, even if full contact information is not provided, so that parents know who will see and use their children's personal information. Therefore, the Commission has modified this provision accordingly. Operators who do not wish to designate a single contact may still minimize the length of the notice by including in the notice on the site a hyperlink to a separate page listing the information.[104]

Several comments also noted that data-sharing relationships in the online world change quickly, sometimes on a weekly basis,[105] and that it would be burdensome for operators to revise their notices with each change, as the proposed Rule required, particularly in the case of the notice to the parent.[106] While the Commission believes that it is reasonable to expect operators to keep the notice on the site current, it agrees that it would be burdensome for operators to send numerous updated notices to parents. Therefore, as discussed in Section II.C.4, below, it has modified the Rule to require a new notice to the parent only where there will be a *material change* in the collection, use, and/or disclosure of personal information from the child. Thus, for example, if the operator plans to disclose the child's personal information to a new operator with different information practices than those disclosed in the original notice, then a new consent would be required.[107]

b. Section 312.4(b)(2)(ii). Under this section of the proposed Rule, operators were required to disclose the types of personal information collected from children and whether that information is collected directly or passively.[108] In the NPR, the Commission clarified that this section did not require operators to disclose to parents every specific piece of information collected from children, but rather the *types* or *categories* of personal information collected, like name, address, telephone number, social security number, hobbies, and investment information.[109] The Commission cautioned operators to use categories that were descriptive enough that parents could make an informed decision about whether to consent to the operator's collection and use of the information.[110]

Some commenters noted that the proposed Rule required operators to provide too much detail in the notice concerning the types of information collected from children.[111] These commenters felt that a more general notice would give the operator more flexibility to change its activities without having to return to the parent for additional consent.[112] The Commission believes that a more general notice may not reveal to parents that the operator collects information that the parent does not want discussed or divulged, like personal financial information. Therefore, the Commission is retaining this portion of the Rule. However, as noted above, these concerns should be alleviated by the Commission's amendment to the Rule regarding ''material changes.'' [113]

c. Section 312.4(b)(2)(iii). Section 312.4(b)(2)(iii) of the proposed Rule required operators to notify parents about how their child's personal information ''is or may be used by the operator, including but not limited to fulfillment of a requested transaction, recordkeeping, marketing back to the child, or making it publicly available through a chat room or by other means.'' [114] In the NPR, the Commission noted that operators must provide enough information for parents to make informed decisions, without listing every specific or possible use of the information.[115] Many commenters expressed the view that the proposed Rule would require an operator to provide such detail that they would inevitably have to send new notices and obtain new consents for every minor change in the operator's practices.[116] Again, these concerns should be alleviated by the Rule amendment regarding ''material changes.'' *See* Section II.C.4, *infra.*

Because this section of the proposed Rule referred only to ''the operator,'' one commenter asked how websites should address situations in which there are multiple operators collecting information through the site but who use children's personal information in different ways.[117] Specifically, the commenter asked whether each operator was required to post a separate notice, or whether a single notice could be used. Where there are multiple operators with different information

[102] *Id.*

[103] 64 FR at 22754, 22765.

[104] In response to two comments, the Commission notes that simply providing a hyperlink to the home pages of the other operators, however, would not provide adequate notice for parents. DMA (Comment 89) at 23–24; AOL (Comment 72) at 12. It would not only be burdensome for parents, but some entities that would be categorized as ''operators'' (*i.e.*, those ''on whose behalf'' personal information was collected) may not even have websites.

[105] PMA (Comment 107) at 7–8; DMA (Comment 89) at 23–24. *See also* McGraw-Hill (Comment 104) at 7.

[106] 64 FR at 22755. In the NPR, the Commission stated that additional notices to the parent would be required if the operator wished to disclose the child's personal information to parties not covered by the original consent, including parties created by a merger or other change in corporate structure.

[107] Marketing diet pills, for example, would be a materially different line of business than marketing stuffed animals.

[108] 64 FR at 22754, 22765.

[109] 64 FR at 22754.

[110] *Id.* For example, stating ''We collect your child's name, e-mail address, information concerning his favorite sports, hobbies, and books'' would be sufficient under the Rule. It would not be necessary for the operator to state ''We ask for your child's name and e-mail address, and whether he likes to play baseball, soccer, football, or badminton. * * *''

[111] McGraw-Hill (Comment 104) at 6–7; AAF (Comment 87) at 2.

[112] *Id.*

[113] *See* Section II.C.4, *infra.* In addition, as noted in note 9, *supra*, the Commission plans to develop educational materials to assist operators in complying with the Rule.

[114] 64 FR at 22754–55, 22765.

[115] 64 FR at 22754.

[116] *See supra* note 106 and accompanying text.

[117] Attorneys General (Comment 114) at 8.

practices, there should be one notice summarizing all of the information practices that will govern the collection, use, and/or disclosure of children's personal information through the site. Thus, the Commission has modified the Rule to clarify that a discussion of all policies governing the use of children's information collected through the site should be included in the notice.

d. Section 312.4(b)(2)(iv). Under this provision of the proposed Rule, an operator was required to disclose whether children's personal information was disclosed to third parties, and if so, the types of business in which those third parties were engaged, as well as whether those third parties had agreed to maintain the confidentiality, security, and integrity of the personal information obtained from the operator.[118] In addition, the operator was required to notify the parent that he or she had the option of consenting to the operator's collection and use of the child's information without consenting to the disclosure of that information to third parties.[119] After reviewing all the relevant comments, the Commission has determined that no changes to this section are necessary.

One commenter noted that the COPPA ''requires only that an operator describe its own practices. * * *'' [120] The Commission believes that the information required in this section of the proposed Rule falls within the rubric of ''the operator's disclosure practices for such information.'' [121] Parents need to know the steps an operator has taken to ensure that third parties will protect their children's data in order to provide meaningful consent.

Some commenters felt that providing information concerning the businesses engaged in by third parties would be overly burdensome.[122] Under this section, however, operators are not required to provide detailed information concerning third party businesses, but only to describe the ''*types* of business'' in which third parties who will receive children's information are engaged—for example, list brokering, advertising, magazine publishing, or retailing.[123] The Commission believes that it is not unduly burdensome to determine the general line of business of the companies with whom one does business. Moreover, this information will enable parents to provide meaningful consent to third party disclosures.

Commenters again pointed out that relationships between companies in the online environment change rapidly, which would make notices difficult to compose and keep current.[124] Changes in the identities of third parties would necessitate repeated notices to parents, burdening both the operator and the parent.[125] Another commenter suggested that rather than give notice of third parties' information practices, operators should be allowed simply to provide a warning to parents to review those practices.[126] Once again, these concerns should be alleviated by the fact that the disclosure is only of the *types* of businesses engaged in by third parties, and new notice and consent are required only if there has been a material change in the way that the operator collects, uses, and/or discloses personal information. *See* Section II.C.4, below.

Still other commenters stated that the Commission should require operators to disclose more detailed information regarding third parties' information practices than the proposed Rule required, including whether a third party has weaker standards than the operator.[127] The Commission believes that the proposed requirement—that operators state whether or not the third parties have agreed to maintain the confidentiality,[128] security, and integrity of children's data B strikes the appropriate balance between a parent's need for information and an operator's need for an efficient means of complying with the Rule.

Alternatively, one of these commenters requested that operators be prohibited from disclosing children's personal information to any third party unless that party not only complies with the Act, but also has the same privacy policy as the operator.[129] The Act explicitly applies to ''any website or online service directed to children that collects personal information from children or the operator of a website or online service that has actual knowledge that it is collecting personal information from a child.'' [130] Therefore, the Commission cannot extend liability to third parties.

e. Section 312.4(b)(2)(v). Under Section 312.4(b)(2)(v) of the proposed Rule, operators were required to state in their notices that the Act prohibits them from conditioning a child's participation in an activity on the child's disclosing more personal information than is reasonably necessary to participate in that activity.[131] One commenter objected to including such a statement in the notice, on the grounds that it does not provide parents with helpful information.[132] The Commission believes that this information is material to parents and will assist them in evaluating the reasonableness of an operator's requests for information. Therefore, the Commission has decided to retain this provision.

f. Section 312.4(b)(2)(vi). This section of the proposed Rule required operators to describe in the notice on the site parents' right to review personal information provided by their children.[133] It generally tracked the requirements in section 312.6 of the proposed Rule [134] by requiring notice of a parent's ability to review, make changes to, or have deleted the child's personal information. In the NPR, the Commission sought public comment on whether this information was needed in the notice on the site, or only in the notice to the parent.[135]

Some commenters believed that it was only necessary to include this information in the notice to the parent, because it is only relevant once parents have consented to the collection of their children's information.[136] Other commenters, however, felt notice of parents' right to review children's information should be included in the notice on the site so that parents can evaluate a site while surfing with their children.[137] The Commission also notes

[118] 64 FR at 22755.

[119] *Id.* For a more detailed discussion of withholding consent to the disclosure of personal information to third parties, *see* Section II.D.1, *infra*.

[120] DMA (Comment 89) at 24, citing 15 U.S.C. 6502(b)(1)(A)(i).

[121] 15 U.S.C. 6502(b)(1)(A)(i).

[122] *See e.g.,* AAF (Comment 87) at 3; CBBB (Comment 91) at 11; PMA (Comment 107) at 8; TRUSTe (Comment 97) at 1.

[123] 64 FR at 22755.

[124] TRUSTe (Comment 97) at 1–2; McGraw-Hill (Comment 104) at 7; AAF (Comment 87) at 3; PMA (Comment 107) at 8.

[125] *Id.*

[126] CBBB (Comment 91) at 11. The Commission believes that requiring parents to search out this information, which may not even be available or accessible, would be unduly burdensome.

[127] CME/CFA et al. (Comment 80) at 23–24; Electronic Privacy Information Center (''EPIC'') (Comment 115) at 8–9; Attorneys General (Comment 114) at 8.

[128] The Commission expects that third parties who have agreed to maintain the confidentiality of information received from operators will not disclose that information further.

[129] CME/CFA et al. (Comment 80) at 23. *See also* CDT (Comment 81) at 23.

[130] 15 U.S.C. 6502(b)(1)(A).

[131] 15 U.S.C. 6502(b)(1)(C); 64 FR at 22755, 22765, citing 15 U.S.C. 6502(b)(1)(C). *See also* 64 FR at 22758, 22766.

[132] Mars (Comment 86) at 4.

[133] 64 FR at 22755, 22765.

[134] 64 FR at 22757–58, 22766. For a detailed discussion of section 312.6, *see* Section II.E, *infra*.

[135] *See* 64 FR at 22762.

[136] DMA (Comment 89) at 19–20; PMA (Comment 107) at 8–9 (operator should be able to choose whether to include this information in the notice).

[137] Attorneys General (Comment 114) at 8–9; E.A. Bonnett (Comment 126) at 4; CBBB (Comment 91)

that if the parent accidentally deletes or misplaces the notice received from the operator, he or she would likely turn to the notice on the site for information on reviewing the child's information. If that information were not in the notice on the site, the parent may be foreclosed from exercising the right to review the child's information. Therefore, the Commission has retained this provision.

4. Section 312.4(c): Notice to a Parent

This provision of the proposed Rule required operators to ''make reasonable efforts, taking into account available technology, to ensure that a parent of a child receives notice of an operator's practices with regard to the collection, use, and/or disclosure of the child's personal information, including any collection, use, and/or disclosure to which the parent has not previously consented.'' [138] After reviewing the relevant comments, the Commission has amended this provision to require new notice to the parent only when there is a material change in the way the operator collects, uses, and/or discloses personal information from the child.

In the NPR, the Commission noted that ''reasonable efforts'' to provide a parent with notice under this section could include sending the notice to the parent by postal mail or e-mail, or having the child print out a form to give to the parent. These methods were intended to be non-exclusive examples.[139] The Commission also noted that operators must send the parent an updated notice and request for consent ''for any collection, use, or disclosure of his or her child's personal information not covered by a previous consent.'' [140] Examples of situations where new notice and request for consent would be needed included if the operator wished to use the information in a manner that was not included in the original notice, such as disclosing it to parties not covered by the original consent, including parties created by a merger or other corporate combination.[141]

Many commenters argued that the Commission's interpretation concerning when a new notice and request for consent would be required was burdensome and unnecessary.[142] Given the high rate of merger activity in this industry, the commenters asserted, operators would be required to send many additional notices to parents.[143] Moreover, commenters noted that many mergers do not change the nature of the business the operator engages in or how the operator uses personal information collected from children. Therefore, many additional notices to parents under the proposed interpretation of this provision would not provide parents with meaningful information.

The Commission agrees with these comments. In order to balance an operator's need for efficiency and parents' need for relevant information, the Commission has amended the Rule to require new notice and consent only when there is a *material change* in how the operator collects, uses, or discloses personal information from children. For example, if the operator obtained consent from the parent for the child to participate in games which required the submission of limited personal information but now wishes to offer chat rooms to the child, new notice and consent will be required. In addition, if an operator (*e.g.*, a toy company) merged with another entity (*e.g.*, a pharmaceutical company) and wished to use a child's personal information to market materially different products or services than those described in the original notice (*e.g.*, diet pills rather than stuffed animals), new notice and consent would be required. Likewise, new notice and consent would be required to disclose the information to third parties engaged in materially different lines of business than those disclosed in the original notice (*e.g.*, marketers of diet pills rather than marketers of stuffed animals). On the other hand, if the operator had parental consent to disclose the child's personal information to marketers of stuffed animals, it does not need to obtain a new consent to disclose that information to other marketers of stuffed animals.

One commenter suggested that the Rule also requires the operator to obtain parental confirmation that the notice was received, either through a return e-mail or a business reply postcard.[144] The Commission believes that this proposal would burden parents and operators without adding significantly to the protection of children online. In most cases, the operator's receipt of parental consent will serve as confirmation that the parent received the notice.[145] Likewise, in most instances, if the parent does not receive the notice, then the operator simply will not receive consent.

One commenter suggested that the Commission permit the notice to the parent to take the form of an e-mail with an embedded hyperlink to the notice on the site.[146] In response, the Commission notes that the notice to the parent must contain additional information that is not required in the notice on the site.[147] However, as long as the additional, required information is clearly communicated to parents in the e-mail, and the hyperlink to the notice on the site is clear and prominent, operators may include the hyperlink to the notice on the site in an e-mail to parents.

a. Section 312.4(c)(1) (i) and (ii): information in the notice to a parent. The proposed Rule required an operator's notice to a parent to include all the information included in the notice on the site (section 312.4(c)(1)(i)(B)), as well as additional information. In cases that do not implicate one of the exceptions to prior parental consent under section 312.5(c), an operator must tell the parent that he or she wishes to collect personal information from the child (section 312.4(c)(1)(i)(A)) and may not do so unless and until the parent consents, and the operator must describe the means by which the parent can provide that consent (section 312.4(c)(1)(ii)).[148]

In the NPR, the Commission requested public comment on whether there was additional information that

at 12; CME/CFA et al. (Comment 80) at 24; TRUSTe (Comment 97) at 1–2.

[138] 64 FR at 22755, 22765.

[139] *Id.* One commenter requested that we include this information in the text of the Rule. DMA (Comment 89) at 27. The Commission believes that the performance standard enunciated in this provision is appropriate in light of the operator's need for flexibility and the additional protections that are provided by the parental consent requirement. As discussed below, the Rule provides more specific guidance as to the appropriate mechanisms for obtaining parental consent *See* Section II.D.2, *infra.*

[140] 64 FR at 22755, 22765

[141] *Id.*

[142] *See, e.g.*, AOL (Comment 72) at 14–15; DMA (Comment 89) at 26; Kraft (Comment 67) at 2, 5–6. *See also* CBBB (Comment 91) at 13–14.

[143] *Id.*

[144] CME/CFA et al. (Comment 80) at 24–25. Similarly, one commenter noted that many parents share an e-mail account with their children. A & E Television Networks (''AETN'') (Comment 90) at 17–18. In these situations, the commenter argued, it would be impossible for the operator to determine whether the notice has been received by the parent. *Id.* In many cases, however, the children will have the incentive to give the notice to the parent in order to obtain parental consent. Further, as noted above, in most cases, the operator's receipt of parental consent will confirm that the parent has received the notice.

[145] *See* Section II.D.2 *infra*, for a detailed discussion of the requirements for obtaining verifiable parental consent under Section 312.5 of the Rule.

[146] Mars (Comment 86) at 12.

[147] For example, the notice to the parent must contain information concerning how to provide parental consent (section 312.4(c)(1)(ii)).

[148] 64 FR at 22755, 22765. One commenter thought that the notice should also inform parents that they have the option of denying consent. CME/CFA et al. (Comment 80) at 12. The Commission believes that a right of refusal is implied in a request for consent, and therefore is not modifying this provision.

should be included in the notice.[149] One commenter suggested that the notice include a statement recommending that parents warn their children not to post personal information in chat rooms or other public venues.[150] While the Commission does not believe this information should be required in the notice under the COPPA, it strongly encourages parents, operators, and educators to teach children about the dangers of posting personal information in public fora. After reviewing the comments concerning these provisions, the Commission believes that no changes are necessary.

b. Section 312.4(c)(1)(iii) and (iv): Notices under the multiple-contact exception, section 312.5(c)(3), and the child safety exception, section 312.5(c)(4). In cases where an operator wishes to collect a child's name and online contact information for purposes of responding more than once to a specific request of the child under Section 312.5(c)(3), or for the purpose of protecting the safety of a child participating on the website or online service under Section 312.5(c)(4), the operator was required to provide notice to the parent, with an opportunity to opt out of future use or maintenance of the child's personal information. Section 312.4(c)(1) (iii) and (iv) required the operator to notify the parent of the operator's intended use of the information, the parent's right to refuse to permit further contact with the child, or further use or maintenance of the information, and that ''if the parent fails to respond to the notice, the operator may use the information for the purpose(s) stated in the notice.'' [151] The Commission received only one comment regarding this provision [152] and has determined that no changes are necessary.

Because the types of contact with children covered under section 312.5(c)(3) and (4) do not require a parent's affirmative consent, the operator must clearly notify the parent that, in these instances, if the parent fails to respond to the notice, the operator may use the information for the purpose stated in the notice.[153] The Commission expects operators to process in a timely manner responses from parents prohibiting the use of their children's information.

D. Section 312.5: Verifiable Parental Consent

1. Section 312.5(a): General Requirements

Section 312.5(a) of the proposed Rule set forth two requirements: (1) That operators obtain verifiable parental consent before any collection, use, or disclosure of personal information from children, including any collection, use and/or disclosure to which the parent had not previously consented; and (2) that the operator give the parent the option to consent to collection and use of the child's personal information without consenting to its disclosure to third parties.[154] In the NPR, the Commission also stated that, because the Act required parental consent *prior to any* collection, use, *and/or* disclosure, the parental consent requirement applied to the subsequent use or disclosure of information already in possession of an operator as of the effective date of the proposed Rule.[155]

Commenters generally supported the principle of prior parental consent.[156] However, several argued that, by requiring parental consent for future use of information collected before the effective date of the Rule, the Commission was attempting to apply the Act retroactively.[157] They also stated that it would be extremely costly and burdensome to obtain consent for information collected years ago, especially in instances where they were unaware of a child's past or current age or had no information on how to contact the parents.[158] The Commission is persuaded that the Act should not be interpreted to cover information collected prior to its effective date. While the Act clearly gives parents control over the use and disclosure of information, and not just its collection,[159] it also appears to contemplate that such control be exercised only with regard to information ''collected'' under the Act—*i.e.*, collected after the Act's effective date.[160] Further, the Commission believes that it could be difficult and expensive for operators to provide notice and consent for information collected prior to the Rule's effective date. Therefore, the Commission has eliminated this requirement from the Rule.

The Commission notes, however, that notwithstanding any prior relationship that an operator has with the child, any collection of ''personal information'' by the operator after the effective date is covered by the Rule. Thus, for example, if an operator collected a child's name and e-mail address before the effective date, but sought information regarding the child's street address after the effective date, the later collection would trigger the Rule's requirements. Similarly, if after the effective date, an operator continued to offer activities involving the ongoing collection and disclosure of personal information from children (*e.g.*, a chatroom or message board), or began offering such activities for the first time, notice and consent would be required for all participating children regardless of whether they had previously registered or participated at the site.

The Commission also notes that, for information collected prior to the effective date of the Rule, it retains the authority to pursue unfair or deceptive acts or practices under Section 5 of the Federal Trade Commission Act. Thus, the Commission will continue to examine information practices in use before the effective date of the COPPA for deception and unfairness, and will

[149] 64 FR at 22762.

[150] CBBB (Comment 91) at 13.

[151] 64 FR at 22756, 22765.

[152] CME/CFA et al. (Comment 80) at 12 (generally requesting more information in the notices).

[153] 64 FR at 22757, 22765–66.

[154] 64 FR at 22756, 22765.

[155] *Id.* at 22751.

[156] *See, e.g.*, Gail Robinson (Comment 132); Tessin J. Ray (Comment 131); BAWSELADI (Comment 133); Deb Drellack (Comment 20); Valorie Wood (Comment 36); Deanie Billings (Comment 37); Nancy C. Zink (Comment 38); Susan R. Robinson (Comment 42); Joyce Patterson (Comment 43); Elaine Bumpus (Comment 44); Greg Anderson (Comment 46); Deanna (Comment 47); Mark E. Clark (Comment 48); Sue Bray (Comment 50); Cindy L. Hitchcock (Comment 55); Stephanie Brown (Comment 50); Samantha Hart (Comment 59); Tammy Howell (Comment 59); Jean Hughes (Comment 60); dinky (Comment 61); PrivaSeek (Comment 112) at 2; CDT (Comment 81) at 25; Consumers Union (Comment 116) at 1; EPIC (Comment 115) at 5, 9; FreeZone (IRFA comment 01) at 2; Kidsonline.com (IRFA comment 02) at 1; AAF (Comment 87) at 2; CBBB (Comment 91) at 1–2; CARU (Workshop comment 08) at 3; AAAA (Comment 134) at 2, 5; Mars (Comment 86) at 1; Time Warner (Comment 78) at 10; Viacom (Comment 79) at 9–10; Children's Television Workshop (''CTW'') (Comment 84) at 2, 6. *See also* 144 Cong. Rec. at S11659 (List of Supporters of Children's Internet Privacy Language).

[157] DMA (*citing Landgraf* v. *U.S. Film Products*, 511 U.S. 244 (1994)). *See also* EdPress (Comment 130) at 2; AAF (Comment 87) at 3–4; ANA (Comment 93) at 3–4; Grolier Enterprises (Comment 111) at 4; IDSA (Comment 103) at 7–8; McGraw-Hill (Comment 104) at 5; MPA (Comment 113) at 4; NRF (Comment 95) at 1–2; Time Warner Inc. (Comment 78) at 3–4; Walt Disney Company and Infoseek Corp. (''Disney, et al.'') (Comment 82) at 12–13.

[158] IDSA (Comment 103) at 7; TRUSTe (Comment 97) at 2–3.

[159] *See, e.g.*, 15 U.S.C. 6502(b)(1)(B)(ii) (giving parents the opportunity at any time to refuse to permit further use, disclosure, or maintenance of information collected from their children); 15 U.S.C. 6502(b)(1)(A)(ii) (requiring operators to obtain verifiable parental consent for the collection, use, and/or disclosure of personal information from children).

[160] *See* 144 Cong. Rec. at S11658 (Statement of Sen. Bryan) (stating that parents can opt out of further collection, use, or maintenance of their child's information and that ''[t]he opt out * * * operates as a revocation of consent that the parent has previously given'').

pursue enforcement in appropriate circumstances.[161]

Many commenters also objected to the requirement that operators obtain a new parental consent for any changes to the collection, use, and/or disclosure practices which were the subject of a previous consent.[162] As in the notice section of the Rule,[163] they argued that notification of minor changes would be extremely burdensome, especially in light of constant changes taking place in the online world, and unnecessary to achieve the purposes of the COPPA.[164] As noted above, the Commission agrees that the proposed requirement is unduly broad and would be overly burdensome, and is therefore amending the Rule to make clear that a new parental consent is required only if there is a material change in the operator's collection, use, and/or disclosure practices.

Finally, some commenters objected to the proposed Rule's requirement that parents be given an opportunity to provide consent for the collection and use of information without consenting to its disclosure to third parties.[165] Commenters argued that this requirement is not included in the COPPA and that it interferes with an operator's right under the COPPA to terminate service to a child whose parent refuses to permit further use, maintenance, or collection of the data.[166] Other commenters supported this requirement as important to the protection of children's privacy.[167]

The Commission believes that giving parents a choice about whether information can be disclosed to third parties implements the clear goals of the COPPA to give parents more control over their children's personal information, limit the unnecessary collection and dissemination of that information, and preserve children's access to the online medium.[168] The Act requires consent for the collection, use, or disclosure of information,[169] thus expressing the intent that parents be able to control all of these practices. Although the Act does not explicitly grant parents a separate right to control disclosures to third parties, the Commission believes that this is a reasonable and appropriate construction of the Act, particularly in light of the rulemaking record and other considerations.

Indeed, the record shows that disclosures to third parties are among the most sensitive and potentially risky uses of children's personal information.[170] This is especially true in light of the fact that children lose even the protections of the Act once their information is disclosed to third parties.[171] The Commission believes that these risks warrant providing parents with the ability to prevent disclosures to third parties without foreclosing their children from participating in online activities. In addition, the Act prohibits collecting more information than is reasonably necessary to participate in an activity,[172] showing Congressional intent to limit information practices (such as disclosures to third parties) that do not facilitate a child's experience at the site. Finally, the Commission believes that allowing parents to limit disclosures to third parties will increase the likelihood that they will grant consent for other activities and therefore preserve children's access to the medium.[173]

Thus, the Commission believes that providing parents with a choice about whether their children's information can be disclosed to third parties is within the authority granted by the COPPA, consistent with the rulemaking record, and important to the protection of children's privacy. The Commission is therefore retaining this provision.

2. Section 312.5(b): Mechanisms

Section 312.5(b) of the proposed Rule required that operators make reasonable efforts to obtain verifiable parental consent, taking into consideration available technology.[174] Consistent with the language of the COPPA, the proposed Rule further clarified that the methods used to obtain verifiable parental consent must be reasonably calculated, in light of available technology, to ensure that the person providing consent is the child's parent.[175] In the NPR, the Commission provided examples of methods that might satisfy these standards, and sought comment on the feasibility, costs, and benefits of those methods, as well as any others that the Commission should consider.[176] To gather additional relevant information, the Commission held a workshop devoted solely to this issue.[177]

While commenters and participants at the workshop generally supported the concept of prior parental consent, they differed on what would constitute a verifiable mechanism under this provision. In particular, there was considerable debate over whether e-mail based mechanisms could provide adequate assurance that the person providing consent was the child's parent.

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[161] *See GeoCities,* Docket No. C–3849 (Final Order Feb. 12, 1999); *Liberty Financial Cos., Inc.,* Docket No. C–3891 (Final Order Aug. 12, 1999). *See also* Staff Opinion Letter, July 17, 1997, issued in response to a petition filed by the Center for Media Education, at <*www.ftc.gov/os/1997/9707/cenmed.htm*>.

[162] IDSA (Comment 103) at 5–6; CBBB (Comment 91) at 13–14; DMA (Comment 89) at 26; Aftab & Savitt (Comment 118) at 5; ANA (Comment 93) at 6–7.

[163] *See* Section II.C.4, *supra.*

[164] One commenter supported this provision on the basis that not requiring it would render parental consent meaningless. Attorneys General (Comment 114) at 10. However, even one commenter who supported the requirement still expressed concern that parents might be ''badgered'' by too many of these requests. CME/CFA et al. (Comment 80) at 13.

[165] Section 312.5(a)(2). *See, e.g.,* DMA (Comment 89) at 25; NRF (Comment 95) at 4; McGraw-Hill (Comment 104) at 7; PMA (Comment 107) at 11.

[166] ANA (Comment 93) at 6; IDSA (Comment 103) at 4–5; DMA (Comment 89) at 25; PMA (Comment 107) at 11 (all referring to section 312.6(c) of the proposed Rule and 15 U.S.C. 6502(b)(3)). The purpose of that provision was to enable operators to offer some online activities that require children to provide personal information, *e.g.,* chat rooms, which may require the operator to collect an e-mail address for security purposes. Under that provision, operators may bar children whose parents have revoked consent for the operator's use of the necessary information from participating in those activities. The Commission does not believe that disclosure to outside parties—other than those, such as fulfillment services, that provide support for the internal operations of the website—is reasonably necessary for an operator to provide online activities.

[167] EPIC (Comment 115) at 9–10; Junkbusters (Comment 66) at 1. *See also* CDT (Comment 81) at 25; CME/CFA et al. (Comment 80) at 13; Sovern (Comment 33) at 4; Mars (Comment 86) at 12–13; TRUSTe (Comment 97) at 2.

[168] *See, e.g.,* 144 Cong. Rec. at S11657, S11658 (Statement of Sen. Bryan).

[169] 15 U.S.C. 6502(b)(1)(A)(ii).

[170] *See* CME/CFA et al. (Comment 80) at 26–27; Mars (Comment 86) at 13; Kraft (Comment 67) at 4–5; Viacom (Comment 79) at 13–14. *See also* Attorneys General (Comment 114) at 4 (*citing* 1997 survey showing that 97% of parents whose children use the Internet believe that website operators should not sell or rent children's personal information).

[171] Thus, for example, parents cannot access information in the possession of third parties, or require that it be deleted, as they can for operators subject to the Rule. *See* 15 U.S.C. 6502(b)(1)(B)(ii),(iii). Nor can they prohibit future use of information in the possession of third parties. *Compare* 15 U.S.C. 6502(b)(1)(B)(ii). In fact, parents are likely to be unaware of the identities and specific information practices of many of the third parties that obtain their children's information. *See* Section II.C.3.d, *supra* (operators need only disclose types of business engaged in by third parties and whether those third parties have agreed to maintain the confidentiality, security, and integrity of personal information received from operator).

[172] 15 U.S.C. 6502(b)(1)(C) (prohibiting an operator from conditioning participation on the disclosure of more information than necessary to participate in an activity).

[173] One study found that 97% of parents online did not want their children's information disclosed to third parties, suggesting that those parents would be more likely to grant consent if they could limit such disclosures. Louis Harris & Associates and Dr. Alan F. Westin, ''Commerce, Communication, and Privacy Online: A National Survey of Computer Users,'' 1997, at 75.

[174] 64 FR at 22756, 22765.

[175] *Id.*; 15 U.S.C. 6501(9).

[176] 64 FR at 22756.

[177] 64 FR at 34595.

Because of concerns that a child using e-mail could pretend to be a parent and thereby effectively bypass the consent process,[178] some commenters favored methods that would provide additional confirmation of the parent's identity.[179] These include use of a form to be signed by the parent and returned to the operator by postal mail or fax (''print-and-send''); (2) use of a credit card in connection with a transaction; (3) having the parent call a toll-free number staffed with trained personnel; (4) use of e-mail accompanied by a valid digital signature; and 5) other electronic methods that are currently available or under development.

Some commenters took the position that print-and-send was the method least subject to falsification;[180] they also noted that, because it is used by schools, most parents are familiar with it.[181] In addition, participants at the workshop noted that industry members currently use print-and-send to ensure that they are obtaining parental permission in certain circumstances—for example, when obtaining consent to publish a child's art work or letter, or to send a contest winner a prize.[182] Commenters also supported the use of credit cards in obtaining parental consent on the grounds that few, if any, children under the age of 13 have access to credit cards.[183] With regard to the use of a toll-free number, commenters and workshop participants noted that, with proper training, employees can easily learn to differentiate between children and adult callers, and that parents prefer this method.[184] Commenters also supported use of digital signatures to obtain consent, stating that they would effectively verify identity and are currently available.[185] Finally, testimony at the workshop showed that there are a number of other electronic products and services that are available now, or under development, that could be used to confirm a parent's identity and obtain consent. These included services that would provide a parent with a digital signature, password, PIN number, or other unique identifier after determining that the person seeking the identifier is an adult.[186]

Many commenters, however, criticized some of these methods for the costs and burdens they are likely to impose on operators. Regarding print-and-send, one commenter cited a figure of $2.81 per child to process mailed or faxed parental consent forms.[187] Another noted an 80% decline in online subscriptions to its magazine when it switched from an online subscription model to a form that had to be downloaded and mailed.[188] Still others pointed out that there is no way to authenticate a signature to be sure that it is actually the parent who has signed the form.[189]

Regarding the use of credit cards, commenters noted that operators would be charged a fee for each transaction,[190] that not every parent has a credit card,[191] and that some parents do not

[178] This is of particular concern where a child shares an e-mail account with a parent, which is a common practice. *See* CME/CFA et al. (Comment 80) at 28; APA (Comment 106) at 2; Attorneys General (Comment 114) at 11; AETN (Comment 90) at 17–18. In fact, one workshop participant reported that 40% of its registered parents shared an e-mail address with their children. Aledort/Disney (Workshop Tr.153). Another participant reported that 10–20% of its registered parents shared the same e-mail address as their children. Herman/iCanBuy.com (Workshop Tr 153–54).

[179] CME/CFA et al. (Comment 80) at 28; APA (Comment 106) at 1–2; Nat'l Ass'n of Elementary School Principals (''NAESP'') (Comment 96) at 1; CARU (Workshop comment 08) at 1–2; Consumers Union (Comment 116) at 5–6. *See also* Attorneys General (Comment 114) at 11 (supporting the traditional offline consent methods). One commenter stressed the need for a high standard for parental consent because children under the age of 13 do not have the developmental capacity to understand the nature of a website's request for information and its implications for privacy. APA (Comment 106) at 1–2.

[180] CBBB (Comment 91) at 18; CARU (Workshop comment 08) at 2; NAESP (Comment 96) at 1.

[181] NAESP (Comment 96) at 1. This commenter noted that young children rarely falsify their parents' signatures. *Id. See also* Douglas L. Brown (Comment 21); Don and Annette Huston (Comment 22).

[182] Bagwell/MTV Networks Online (Workshop Tr. 30, 35); Randall/MaMaMedia (Workshop Tr. 28); Aledort/Disney (Workshop Tr. 151); FreeZone Network (IRFA comment 01) at 2; Aftab & Savitt (Comment 118) at 6. One comment identified four children's websites that have implemented offline consent mechanisms pursuant to the CARU guidelines. CARU (Workshop comment 08) at 2; *see also* CBBB (Comment 91) at 23.

[183] AOL (Comment 72) at 18–19; iCanBuy.com (Comment 101) at 1; Mars (Comment 86) at 13. Among other things, credit cards can be used to set up a ''master account'' for the parent with an e-mail address to be used exclusively by the parent. Curtin/AOL (Workshop Tr. 36–7); Aftab (Comment 117) at 3. *See also* KidsOnLine.com (Comment 108) at 3; Talk City (Comment 110) at 3 (supporting the use of a credit card as a method of consent).

[184] CARU (Workshop comment 08) at 2; CME/CFA et al. (Comment 80) at 14; Aftab (Workshop Tr. at 52).

[185] *See* Brandt/VeriSign (Workshop Tr. 199–202) and (Comment 99) at 1–4 (stating that one year to 18 months would be sufficient time for testing and adoption of digital technology applications); Teicher/CyberSmart! (Workshop Tr. 191–92, 199); Lucas/PrivaSeek (Workshop Tr. 244–45, 299–300) and (Comment 112) at 4 (noting that the next step is the adoption of digital signatures by online businesses so that they can be made widely available to consumers); Hill/ZeroKnowledge (Workshop Tr. 269–73); Johnson/Equifax Secure, Inc. (Workshop Tr. 250–59).

[186] For example, one workshop participant described a service now under development which would use schools to assist in issuing a digital certificate to a child after obtaining parental consent. Teicher/CyberSmart! (Workshop Tr. 190–94; 196–97; 199). Another announced that his portal site would soon launch an e-mail authentication system that could verify the age or profession of a person, and then assign that person an e-mail address associated with his age or status, *e.g., John.doe@validadult.com; Mary.teacher@validteacher.com*. Ismach/BizRocket.com (Workshop comment 12) at 1–3; (Workshop Tr. 231–232). Still another has developed a permission-based infomediary service that will enable consumers to set their preferences as to how their information may be disclosed online. PrivaSeek (Comment 112) at 1. Under this service, which is expected to be launched by the end of the year, a parent could be assigned a password or digital signature following initial verification. The charge to participating websites is anticipated to be $0.10-$0.20 per name. Lucas/PrivaSeek (Workshop Tr. 242–49); PrivaSeek (Comment 112) at 1.

In addition, another company is currently providing digital credentials (a certificate, PIN or password) to consumers after authenticating their identity. The company estimates that the cost for sites to use this service is $3 to $4 per customer. Johnson/Equifax Secure (Workshop Tr. 249–59). Another company offers a service that enables a child to make purchases, with a parent's permission, at participating websites. Parents use a credit or debit card to establish an account and then authorize the sites to be accessed and the amounts to spend. Herman/iCanBuy.com (Workshop Tr. 185–190). Yet another company is also planning to launch (by spring 2000) a free verification service that uses both credit and bank cards in conjunction with algorithms to verify the validity of the card numbers. The card number would be checked at the consumer's browser and would not be collected or transferred over the Internet, addressing some consumers' concerns about using credit cards online. Oscar Batyrbaev (Comment 125) at 1; Batyrbaev/eOneID.com (Workshop Tr. 235–39). Parents without online access will be able to obtain verification by telephone. *Id.*

Finally, another online company will provide parents and children with digital pseudonyms that, following initial verification using a digital signature, can be used to verify identity. Hill/ZeroKnowledge (Workshop Tr. 268–73). *See also* Brandt/VeriSign (Workshop Tr. 195–96, 199–202).

[187] Clarke/KidsCom.com (Workshop Tr. 22). *See also* Cartoon Network et al. (Comment 77) at 8 (estimating that cost to open and sort written consent forms is about $0.08 to $0.31 per child). Another comment estimated that the cost per consent by fax and mail, including overhead, were $0.94 and $0.89, respectively. Zeeks.com (IRFA comment 05) at Attachment (''Compliance Cost Estimate'').

[188] Time Warner (Comment 78) at 11. Other commenters stated that offline methods might be inconvenient or labor-intensive for parents. Dell (Comment 102) at 2; Cartoon Network et al. (Comment 77) at 6; DMA (Comment 89) at 6–8; Grolier (Comment 111) at 1–2.

[189] Richard Storey (Comment 02) at 1; PMA (Comment 107) at 3–4, 10; PrivaSeek Inc. (Comment 112) at 3.

[190] Disney et al. (Comment 82) at 8; MPA (Comment 113) at 5; DMA (Comment 89) at 7. Two comments stated that credit cards cost up to $3 per verification to process. Cartoon Network et al. (Comment 77) at 10–11; DMA (Comment 89) at 7. One company experienced costs ranging from $2 to $3 per verification. Aftab (Workshop Tr. 17).

[191] McGraw-Hill (Comment 104) at 3; Cartoon Network et al. (Comment 77) at 9; KidsOnLine.com (Comment 108) at 3; DMA (Comment 89) at 7. Some commenters also thought consumers might be troubled by the privacy implications of divulging personal information for the purpose of granting consent. Brian Burke (Comment 05); Disney et al. (Comment 82) at 9; PrivaSeek (Comment 112) at 3; Cartoon Network et al. (Comment 77) at 9–10; PMA

like to use credit cards online.[192] One credit card company opposed the use of credit cards in this manner because it could foster unauthorized use and undermine systems used to detect fraud.[193] Commenters also noted that the use of a toll-free number would require operators to hire personnel just to answer phones, and would therefore be costly.[194] Finally, a number of commenters contended that while digital signatures and other electronic methods may be promising alternatives, they are not yet widely available, and therefore are impracticable as current methods of compliance.[195]

In response to a request for comment on whether e-mail alone would satisfy the Act's requirements, commenters presented a variety of views. A number of commenters opposed use of e-mail on the grounds that it is easily subject to circumvention by children.[196] While a significant number of commenters advocated the use of e-mail,[197] most of them acknowledged that taking additional steps in conjunction with e-mail would increase the likelihood that the consent was submitted by the parent and not the child.[198] Such steps would include: the use of PIN numbers or passwords;[199] sending follow-up e-mails to the parent to increase the likelihood that the parent will see the request for consent;[200] or allowing e-mail consent only if the parent and child have different e-mail addresses.[201] Still others recommended including in the e-mail questions to which the child would be unlikely to know the answer.[202]

Finally, many commenters urged the Commission to temporarily adopt a standard under which the consent mechanism required would depend upon how the operator intended to use the information (*i.e.*, a ''sliding scale'').[203] Such an approach would permit operators to obtain consent at a reasonable cost until secure electronic mechanisms become more widely available and affordable. Generally, these commenters advocated use of an e-mail based mechanism for purposes of consenting to an operator's *internal* use of information, such as an operator's marketing to a child based on the child's preferences, but a ''higher'' method of consent, such as use of a credit card or print-and-send form, for purposes of consenting to activities that present greater risks to children.[204] In comments and at the workshop, commenters cited public postings by children (*e.g.*, in chat rooms and on bulletin boards), as well as disclosures of information to third parties, as activities that pose such risks.[205] Other commenters opposed the ''sliding scale'' on the ground that it could permit the use of consent mechanisms that fall short of the COPPA's requirements.[206]

In determining whether a particular method of obtaining consent is ''verifiable'' under the COPPA, the Commission must consider: (1) whether the method ensures that it is the parent providing the consent; and (2) whether the method is a ''reasonable effort,'' taking into consideration available technology. In determining what is a ''reasonable effort'' under the COPPA, the Commission believes it is also appropriate to balance the costs imposed by a method against the risks associated with the intended uses of the information collected. Weighing all of these factors in light of the record, the Commission is persuaded that temporary use of a ''sliding scale'' is an appropriate way to implement the requirements of the COPPA until secure electronic methods become more available and affordable.

The record shows that certain methods of consent—print-and-send, credit card, toll-free number with trained personnel, and digital signature—provide appropriate assurances that the person providing consent is the child's parent, and thus satisfy the first part of the inquiry.[207] In addition, testimony at the Commission's workshop shows that a number of electronic products and services, which could also be used to verify a parent's identity and obtain consent, are currently available or under development.[208] The record also shows, however, that some of these methods may be costly and others may not be widely available at the present time.

(Comment 107) at 110; EPIC (Comment 115) at 10; DMA (Comment 89) at 7; Viacom (Comment 79) at 11.

[192] Cartoon Network et al. (Comment 77) at 9–11; DMA (Comment 89) at 7; PMA (Comment 107) at 10; Viacom (Comment 79) at 11.

[193] Visa USA, Inc. (Comment 75) at 2. The Commission recognizes that there may be risks in using credit cards for this purpose, but notes that this method is already being used for similar purposes—for example, to verify that a person is over 18 for purposes of obtaining access to adult materials online. *See* amicus of Senators Oxley and Coates; eOneID.com (Workshop comment 09) at Appendix A.

[194] Alison J. Richards (Comment 105) at 1; MPA (Comment 113) at 5; Cartoon Network et al. (Comment 77) at 11–2. One commenter estimated that the cost for telephone consents would be $0.97 for an automated answering system, the tapes of which would then need to be manually swept to weed out children and enter data into the system. Zeeks.com (IRFA Comment 05) at Attachment (''Compliance Cost Estimate''). Another commenter estimated the cost of a live operator to be $55 per hour plus training costs. Cartoon Network et al. (Comment 77) at 12.

[195] Richard Storey (Comment 02) at 1; Viacom (Comment 79) at 12; Disney et al. (Comment 82) at 8–9; DMA (Comment 89) at 5; Alison J. Richards (Comment 105) at 1; Amazon.com (Comment 109) at 3; Cartoon Network et al. (Comment 77) at 13–15; Grolier (Comment 111) at 1; CBBB (Comment 91) at 16–17.

[196] Attorneys General (Comment 114) at 11; Robert F. Reid (Comment 06); Joseph C. DeMeo (Comment 08); Patrick O'Heffernan (Comment 17); NAESP (Comment 96) at 1; APA (Comment 106) at 2; Consumers Union (Comment 116) at 5; CME/CFA et al. (Comment 80) at 15.

[197] Cartoon Network et al. (Comment 77) at 15–18; Disney et al. (Comment 82) at 7–9; Time Warner (Comment 78) at 10–11; DMA (Comment 89) at 5–6. Several commenters stated that Congress must have intended e-mail to be used for consent purposes because the Act allows online contact information to be collected for the purpose of seeking parental consent. *Id.* (*citing* 15 U.S.C. 6502(b)(2)(B)). Some commenters stated that, in their experience, parents preferred to use e-mail to grant consent. Bagwell/MTV Networks Online (Workshop Tr. 33–34); Aftab (Workshop Tr. 31).

[198] *See* Aledort/Disney (Workshop Tr. 149–51); Bruening/TRUSTe (Workshop Tr. 39); CARU (Workshop comment 08) at 2; Viacom (Comment 79) at 13; Cartoon Network et al. (Comment 77) at 17; NRF (Comment 95) at 4.

[199] AAAA (Comment 134) at 2; ANA (Comment 93) at 2; Talk City (Comment 110) at 3.

[200] Disney et al. (Comment 82) at 9; DMA (Comment 89) at 6.

[201] AAAA (Comment 134) at 2; ANA (Comment 93) at 2; NRF (Comment 95) at 4; MPA (Comment 113) at 5; DMA (Comment 89) at 6. The Commission notes that, because children can easily obtain multiple e-mail addresses from free e-mail services, this method may not ensure verifiability.

[202] NRF (Comment 95) at 4; Cartoon Network et al. (Comment 77) at 17; Time Warner (Comment 78) at 11; DMA (Comment 89) at 6. The Commission notes that this method could pose problems if it requires operators to verify the ''answer'' to the questions, or if the child is reasonably sophisticated.

[203] *See, e.g.*, Cartoon Network et al. (Comment 77) at 18 (suggesting that sliding scale sunset in five years); DMA (Workshop comment 02) at 1–3 (suggesting that the Commission reexamine the scale after a specific period of time or at a point when technology has changed); Viacom (Comment 79) at 9–10, 12–14 (five year sunset date); Kraft (Comment 67) at 5; Bagwell/MTV Networks Online (Workshop Tr. 32–33); CBBB (Comment 91) at 15–18; CTW (Comment 84) at 6–7; CARU (Workshop Comment 08) at 1–2; Mars (Comment 86) at 13–14; PMA (Comment 107) at 4, 11. *See also* Herman/iCanBuy.com (Workshop Tr. 209) (if adopted, should sunset within 12–18 months); Teicher/CyberSmart! (Workshop Tr. 199) (predicting significant changes in technology that would permit sunset within 18 months).

[204] Bagwell/MTV Networks Online (Workshop Tr. 32–33); Kraft (Comment 67) at 5.

[205] Kraft (Comment 67) at 4–5; Cartoon Network et al. (Comment 77) at 18; ANA (Comment 93) at 2; CBBB (Comment 91) at 15–18; PMA (Comment 107) at 11; CARU (Workshop Comment 08) at 1; Viacom (Comment 79) at 13; and Bagwell/MTV Networks Online (Workshop Tr. 33). The legislative history also reflects special concern for children's safety in such online fora as chat rooms, home pages, and pen-pal services in which children may make public postings of identifying information. *See* 144 Cong. Rec. S11657 (Statement of Sen. Bryan).

[206] *See, e.g.*, CME/CFA et al. (Comment 80) at 7.

[207] Print-and-send and digital signatures were listed as acceptable consent mechanisms in Senator Bryan's Floor Statement. *See* 144 Cong. Rec. S11657.

[208] *See* note 186, *supra*, describing such services.

Therefore, under the second prong of the inquiry, the Commission believes that, until reliable electronic methods of verification become more available and affordable, these methods should be required only when obtaining consent for uses of information that pose the greatest risks to children.

Thus, under the ''sliding scale,'' the more reliable methods of consent will be required for activities involving chat rooms, message boards, disclosures to third parties, and other ''disclosures'' as defined in Section 312.2 of the Rule.[209] As noted above, these methods include the methods identified in the NPR (print-and-send, credit card, toll-free number, and digital signatures),[210] as well as other reliable verification products and services to the extent that they are currently available. To minimize costs, the Rule makes clear that such methods also include the use of e-mail, as long as it is accompanied by a PIN or password obtained through one of the above procedures.[211]

For internal uses of information, operators will be permitted to use e-mail to obtain consent, as long as some additional steps are taken to provide assurances that the parent is providing the consent. Based on the comments, the Commission is persuaded that e-mail alone does not satisfy the COPPA because it is easily subject to circumvention by children.[212] The additional steps include sending a delayed confirmatory e-mail to the parent following receipt of consent, or obtaining a postal address or telephone number from the parent[213] and confirming the parent's consent by letter or telephone call.[214] If such consent mechanisms are used, the operator must notify parents that they can revoke any consent given in response to the earlier e-mail.

Based on evidence in the record, the Commission believes that use of a ''sliding scale'' is necessary only in the short term, and that, with advances in technology, companies will soon be able to use more reliable verifiable electronic methods in all of their transactions.[215] Indeed, as noted above, the record shows that a number of products and services, including digital signatures, will soon be more widely available to facilitate verifiable parental consent at reasonable cost. The Commission therefore plans to phase out the ''sliding scale'' two years from the effective date of the Rule (*i.e.*, April 2002), unless presented with evidence showing that the expected progress in available technology has not occurred.[216] The Commission will conduct a review of this issue, using notice and comment, approximately eighteen months from the effective date of the Rule (*i.e.*, in October 2001).

The Commission believes that temporary adoption of this ''sliding scale'' fulfills the statutory requirement that efforts to provide ''verifiable parental consent'' be ''reasonable.'' It provides operators with cost-effective options until more reliable electronic methods become available and affordable, while providing parents with the means to protect their children.

3. Section 312.5(c): Exceptions to Prior Parental Consent

The COPPA sets forth five exceptions to the general requirement that operators obtain verifiable parental consent before collecting personal information from children.[217] These limited exceptions were intended to facilitate compliance with the Rule, allow for seamless interactivity in a wide variety of circumstances, and enable operators to respond to safety concerns.[218] Indeed, many of the concerns raised by the commenters, are, in fact, addressed in these exceptions.[219]

This subsection of the proposed Rule permitted an operator, without prior parental consent, to collect: (1) a parent's or child's name and online contact information to seek parental consent or to provide parental notice;[220] (2) a child's online contact information in order to respond on a one-time basis to a specific request of the child (e.g., to provide one-time homework help or to send a document);[221] (3) a child's online contact information in order to respond directly more than once to a specific request of the child (e.g., to provide an online magazine subscription, or a contest entry and subsequent award)[222] when such information is not used to contact the child beyond the scope of that request, and the operator provides the parent with notice and an opportunity to opt-out;[223] and (4) the name and online contact information of the child to the extent reasonably necessary to protect the safety of a child participating on the website.[224] Furthermore, under the proposed Rule, the operator may collect, use, or disseminate such information as necessary to protect the security or the integrity of the site or service, to take precautions against liability, to respond to judicial process, or, to the extent permitted under other provisions of law,

[209] *See also* 15 U.S.C. 6501(4).

[210] 64 FR at 22756.

[211] For example, there may be verifying services available to operators that would verify a parent's identity and then provide the parent with a PIN or password for use with e-mail. Upon receipt of the parent's consent via e-mail, an operator could confirm the parent's identity with the verifying service. Similarly, as noted above, an operator could use e-mail, as long as it were sent through an account set up by an adult using a credit card (a ''master account''), and reserved for the adult's use. *See* note 184, *supra*.

[212] Attorneys General (Comment 114) at 11; Robert F. Reid (Comment 06); Joseph C. DeMeo (Comment 08); Patrick O'Hefferman (Comment 17); NAESP (Comment 96) at 1; APA (Comment 106) at 2; Consumers Union (Comment 116) at 5; CME/CFA et al. (Comment 80) at 28. In particular, where a parent and child share the same e-mail account, as is often the case, a child may easily pretend to be the parent and provide consent for himself. *See* note 179, *supra*.

[213] The Commission expects that operators will keep confidential any information obtained from parents in the course of obtaining parental consent or providing for parental review of information collected from a child.

[214] One variation on this approach would require not only a confirmatory e-mail to the parent, but also a response from the parent confirming the consent. Aledort/Disney (Workshop Tr. 149–150). *See also* Disney (Workshop comment 06) at 12. Using this method, one workshop participant reported that 33% of parents granted consent; 30% declined consent; and 37% never responded. Aledort/Disney (Workshop Tr. 152).

[215] Likewise, with advances in technology, the use of e-mail (without the more reliable methods of verification) may no longer be regarded as a ''reasonable effort'' under the Rule.

[216] Comments and testimony at the workshop showed that digital signatures and other reliable electronic methods are likely to be widely available and affordable within approximately a year to eighteen months from the July 1999 the workshop. *See* Brandt/VeriSign (Workshop Tr. 199–202). *See also* note 188, *supra* (other secure electronic methods are available now or will be available within a year from the date of the workshop). Thus, the proposed Rule's longer timetable for implementing the ''sliding scale''—two years from the Rule's effective date or almost *three* years from the date of the workshop—should provide ample time for these mechanisms to develop and become widely available.

[217] 15 U.S.C. 6502(b)(2).

[218] *See* 144 Cong. Rec. S11658 (Statement of Sen. Bryan).

[219] *See, e.g.*, Section II.A.8, *supra*, regarding the use of the exception to maintain website security.

[220] Section 312.5(c)(1).

[221] Section 312.5(c)(2). This exception also requires that the operator not use the information to recontact the child and that the operator delete the information from its records. If the website wishes to retain the child's e-mail address for future homework assistance, then it would fall into the scope of the exception in section 312.5(c)(3) and require parental notice and opt-out. Moreover, if the operator wishes to use the information collected under this—or any other—exception for other purposes, then the operator must follow the notice and consent requirements of the Rule.

[222] Section 312.5(c)(3). Sending an electronic postcard where the website retains the online contact information until the postcard is opened would fall under this exception. However, where the operator's postcard system sends the requested postcard without maintaining the online contact information, this collection would fall under section 312.5(c)(2).

[223] Section 312.5(c)(3).

[224] Section 312.5(c)(4). For example, operators may collect online contact information from children participating in their chat rooms in order to report to authorities a child's claim that he is being abused.

to provide information to law enforcement agencies or for an investigation related to public safety.[225] A workshop participant noted that these exceptions include some of the most popular and common online activities.[226]

A number of commenters had specific suggestions with regard to modifying the exceptions.[227] However, the Commission believes that the exceptions, which closely track the statutory language, strike the appropriate balance between an operator's legitimate need to collect information without prior parental consent and the safety needs of children. It is therefore retaining the language of the exceptions as proposed.

4. Response to Comments Requesting an Exception for Information Collection in the Educational Setting

Numerous commenters raised concerns about how the Rule would apply to the use of the Internet in schools.[228] Some commenters expressed concern that requiring parental consent for online information collection would interfere with classroom activities, especially if parental consent were not received for only one or two children.[229] In response, the Commission notes that the Rule does not preclude schools from acting as intermediaries between operators and parents in the notice and consent process, or from serving as the parents' agent in the process. For example, many schools already seek parental consent for in-school Internet access at the beginning of the school year. Thus, where an operator is authorized by a school to collect personal information from children, after providing notice to the school of the operator's collection, use, and disclosure practices, the operator can presume that the school's authorization is based on the school's having obtained the parent's consent.

Operators may wish to work with schools to educate parents about online educational activities that require websites to collect personal information in the school setting. To ensure effective implementation of the Rule, the Commission also intends to provide guidance to the educational community regarding the Rule's privacy protections.

E. Section 312.6: Right of Parent To Review Personal Information Provided by Child

Section 312.6 of the proposed Rule set forth the requirements for providing parental access to personal information collected from the child, including what information must be disclosed and how the parent could be properly identified.[230] In the NPR, the Commission sought comment regarding methods of identification, particularly in non-traditional family situations, and technological advances under development that might ease the process.[231]

1. Access to Information

The proposed Rule contemplated a two-step approach to parental review under §§ 312.6(a) (1) and (3). First, upon request of a properly identified parent, the operator was required to tell the parent what types of personal information have been collected from the child (*e.g.*, ''Your child has given us his name, address, e-mail address, and a list of his favorite computer games''). Second, if requested, the operator was required to provide the specific personal information collected from the child.[232]

One commenter suggested that operators be required to provide parents with the option of directly requesting the specific information collected.[233] As was explained in the NPR, operators, after obtaining proper identification, can in fact skip the first step relating to disclosure of the types of information collected, and simply allow parents to review the specific information.[234] Section 312.6(a) was not intended to mandate unnecessary steps, but rather to allow for flexibility for all parties. In some instances, parents may be satisfied with learning the types of information collected and may not need to see the specific personal information provided by the child. Similarly, if a parent asks only for the specific information collected from the child, the operator need not first provide a general list of the categories of information collected.[235]

Another commenter called for operators to provide information within a reasonable time or within a specified number of days, and suggested that information should be provided to parents on an ongoing basis.[236] The Commission declines to prescribe a specific time period applicable to all parental requests for information, but expects that operators will respond to such requests promptly and without imposing undue burdens on parents. In addition, the Commission believes that requiring operators to provide information to the parent on an ongoing basis would be unduly burdensome for both operators and parents, who may not need or want this information from the operator.

2. Parent's Right To Review Information Provided by the Child

Sections 312.6(a)(2) and (3) of the proposed Rule allowed parents to review, change, and delete personal information collected from their children.[237] Many commenters objected to granting parents the right to change information,[238] asserting that it was unduly burdensome and went beyond the language of the Act.[239] Other commenters noted that a right to alter data is much broader than the right to correct data,[240] and expressed concern that parents might use this right to

[225] Section 312.5(c)(5). Thus, an operator may collect limited information in order to protect the security of its site, for example, from hackers.

[226] Sehgal-Kolbet/CARU (Workshop Tr. 40–41). *See also* CARU (Workshop comment 08) at 2–3.

[227] For example, some commenters suggested that the Rule define ''a reasonable time'' for obtaining consent and deleting information under section 312.5(c)(1). PMA (Comment 107) at 12; Mars (Comment 86) at 14; CBBB (Comment 91) at 19; CME/CFA et al. (Comment 80) at 14. *See also* CDT (Comment 81) at 27. The Commission believes that the time period for obtaining consent may vary depending on the mechanism used; however, it expects operators to delete information obtained under this exception in a timely manner.

[228] Association of American Publishers (''AAP'') (Comment 70) at 4–5; EdPress (Comment 130) at 1–2; MaMaMedia (Comment 85) at 3–4; ZapMe! (Comment 76) at 4–5; ALA (Comment 68) at 2–3.

[229] *Id.*

[230] 64 FR at 22757–58, 22766.

[231] 64 FR at 22762–63.

[232] 64 FR at 22757–22758.

[233] CME/CFA et al. (Comment 80) at 16.

[234] 64 FR at 22758 n.11. However, as noted in the discussion of parental verification below, the Commission has modified the Rule to require proper identification only for access to the child's specific personal information, not for the types of information collected, as originally proposed.

[235] One commenter suggested that parental access be limited in cases where the operator has collected minimal personal information, such as an e-mail address for the sole purpose of sending a periodic newsletter or similar mailing, to a simple confirmation that the child is on the mailing list. AOL (Comment 72) at 19. In response, the Commission notes that the COPPA requires access to all information collected from children, regardless of the circumstances. *See* 15 U.S.C. 6502(b)(1)(B).

[236] Sovern (Comment 33) at 5.

[237] 64 FR at 22757–58, 22766.

[238] *See* NRF (Comment 95) at 4; DMA (Comment 89) at 17–19; ANA (Comment 93) at 6; MPA (Comment 113) at 5–6. *See also* McGraw-Hill (Comment 104) at 8.

[239] Commenters also asserted that allowing parents to change the information provided by their children threatens the confidentiality, security, and integrity of information in the operator's possession, putting the operator in jeopardy of violating section 312.8 of the Rule. *See* NRF (Comment 95) at 4; DMA (Comment 89) at 17–19; MPA (Comment 113) at 5–6. *See* also McGraw-Hill (Comment 104) at 8; Section II.G, *infra*. Two commenters also stated that this provision was unnecessary in light of the parent's right under section 312.6(a)(2) to prohibit further collection, use, and maintenance of information and to have information deleted. NRF (Comment 95) at 4; MPA (Comment 113) at 5–6.

[240] DMA (Comment 89) at 17–18; MPA (Comment 113) at 5–6.

change or delete grades or test scores at educational sites in conflict with federal education statutes and state policies.[241]

Based on the comments, the Commission is revising the Rule to eliminate the proposed Rule's requirement that parents be allowed to change information provided by their children. Even in the absence of a regulatory requirement, however, the Commission believes that operators may choose to permit parents to correct data given operators' strong incentives to maintain accurate information.[242] The Commission also agrees that the opportunity to refuse to permit further use or to delete information under section 312.6(a)(2) adequately protects the interests of the child and parent in this context.

One commenter noted that a child may not want a parent to know about certain information—for example where the child is seeking guidance regarding problems with the parent.[243] The Act does not give the Commission the authority, however, to exempt certain kinds of information from the right of parental review.

Another commenter asked the Commission to consider whether a parent's request to delete data should also extend to third parties who have received that information from the operator.[244] As noted above, the Act covers the actions of ''operators,'' not third parties. However, the Commission encourages operators to structure their contractual arrangements with third parties to require compliance with requests for deletion where practicable.

One commenter asked whether and how long an operator would be required to maintain personal information for review.[245] More specifically, the commenter requested that the Commission revise the Rule to include a statement that an operator is not required to maintain all personal information collected from the child indefinitely in anticipation of a subsequent request for review by a parent.[246] This is particularly important, noted the commenter, where an operator wishes to delete personal information quickly—for example when monitoring a chat room or message board.[247] The Commission does not believe it is necessary to so modify the Rule, but reiterates that if a parent seeks to review his child's personal information after the operator has deleted it, the operator may simply reply that it no longer has any information concerning that child.

Another commenter asserted that Congress did not intend that an operator be required to scour all of its databases for all personal information about a child, whether collected online or offline, in response to a request from the parent.[248] As currently amended, the Rule applies only to personal information submitted online,[249] and, therefore, a parent's access rights under the Act do not generally extend to data collected offline.[250] Nevertheless, if an operator maintains the information such that its source (online or offline) cannot be determined, the Commission would expect the operator to allow the parent to review all of the information. Similarly, if the operator has collected information prior to the effective date of the Rule, but maintains it in a database with information collected online after the effective date in such a way that its source cannot be determined, then the operator should allow the parent access to all of the information.

3. Right To Prohibit Further Use and Collection of the Child's Information

Section 312.6(a)(2) of the proposed Rule allowed parents to refuse to permit the operator's further use or collection of the child's personal information and to direct the operator to delete the information.[251] One commenter asserted that, according to the legislative history, the parental opt-out serves as a revocation of previous consent but does not preclude the operator from seeking consent from the parent for the same or different activities in the future.[252] Therefore, this commenter suggested revising the provision to specify that the refusal was limited to activities covered ''under the consent previously given.'' [253] The Commission agrees with the commenter's interpretation of this provision, but believes that such a modification is not necessary. The Act requires operators to allow parents to refuse to permit further use or future collection of personal information from their children.[254] Operators, however, are free to request a new consent from a parent if the child seeks to participate at the site in the future.[255]

4. Parental Verification

The COPPA requires operators to provide parents with ''a means that is reasonable under the circumstances for the parent to obtain any personal information collected from [the] child.'' [256] In recognition of the danger inherent in requiring an operator to release a child's personal information, the Commission, in section 312.6(a) of the proposed Rule, required operators to ensure that the person seeking to review such information was the child's parent, taking into account available technology, without unduly burdening the parent.[257] In the NPR, the Commission suggested appropriate means of complying with this provision, including using a password in conjunction with the parental consent process.[258]

Some commenters contended that parental verification was not necessary for access to the types or categories of personal information collected from the child under § 312.6(a)(1).[259] The Commission agrees, particularly since the same types or categories of information must already be disclosed

[241] AAP (Comment 70) at 4; McGraw-Hill (Comment 104) at 4, 8.

[242] One commenter observed that sites should be willing to permit changes as a matter of good customer service if any information is inaccurate. NRF (Comment 95) at 4. Similarly, another commenter noted that it, and many other organizations, already permit customers to correct data in some way. McGraw-Hill (Comment 104) at 8.

[243] MPA (Comment 113) at 5.

[244] Attorneys General (Comment 114) at 9.

[245] AOL (Comment 72) at 19.

[246] Such a statement was included in the NPR. 64 FR at 22758 n.12.

[247] AOL (Comment 72) at 19–20.

[248] IDSA (Comment 103) at 6–7.

[249] *See* Section II.A.2, *supra*.

[250] Operators must, however, allow parents to review information that was collected online but maintained offline.

[251] 64 FR at 22757–58, 22766. The Commission expects that operators will act upon requests under section 312.6(a)(2) in a timely fashion, especially with regard to chat and third party disclosures, where safety concerns are often heightened.

[252] DMA (Comment 89) at 19–20.

[253] Id.

[254] 15 U.S.C. 6502(b)(1)(B)(ii).

[255] Section 312.6(c) of the Rule retains the Act's proviso that an operator may terminate service to a child whose parent has refused to permit the operator's further use or collection of information from the child, or has directed the operator to delete the child's information. 15 U.S.C. 6502(b)(3). As noted in the NPR, the operator's right to terminate service to a child is limited by section 312.7 of the Rule, which prohibits operators from conditioning a child's participation in a game, the offering of a prize, or another activity on the child disclosing more personal information than is reasonably necessary to participate in the activity. 64 FR at 22758, 22766. Section 312.7 tracks the language of the statute. *See* 15 U.S.C. 6502(b)(1)(C). *See also* CME/CFA et al. (Comment 80) at 35–36 (supporting this reading of the Act).

[256] 15 U.S.C. 6502(b)(1)(B)(iii).

[257] 64 FR at 22757, 22766. *See also* 15 U.S.C. 6502(b)(1)(B) (requiring ''proper identification'' of parents).

[258] 64 FR at 22758. The other method suggested was using a photocopy of the parent's driver's license.

[259] CDT (Comment 81) at 29–30. *See also* Time Warner (Comment 78) at 13–14; DMA (Comment 89) at 17 (stringent identification requirements not necessary). One commenter stated that assuming an operator collects the same categories of information from visitors, access requirements could be met with a website form that tells parents the data categories maintained. CDT (Comment 81) at 29–30. The Commission believes that this method would be appropriate in cases where the request for information takes place online.

in the operator's notice.[260] Accordingly, the Rule has been modified to eliminate the requirement of parental identification for review of the types of information collected from children.[261] However, under § 312.6(a)(3), proper parental identification will be required for access to the specific information collected from a child.

Another commenter suggested that parents seeking review under this section should be required to provide operators with their children's identifying information (in the categories that the operator collects) in order to prove identity.[262] The operator would then disclose only the non-individually identifiable information (*e.g.,* hobbies) that the operator had collected from the child.[263] The commenter believed that this would prevent a non-parent from obtaining information from the operator that would enable him to contact the child offline.[264] However, this procedure would not, in fact, prevent access to a child's information by someone other than the parent, because many of the child's relatives and friends would be able to provide individually identifying information such as a telephone number or address. Moreover, the Act requires parental access to ''any'' personal information collected from the child.[265] The Commission therefore cannot limit the disclosures as suggested.

A number of commenters addressed the methods of verification that could be used to identify parents who seek access to their children's specific personal information. Several supported the option of using a password-protected e-mail or other secure method, which was specifically suggested in the NPR.[266] Another commenter noted that, in order to discourage requests from non-parents, requests for information could be made in writing, with confirmation sent to the home address.[267] The Commission recognizes that a number of methods might be appropriate for parental verification under this section, and allows the operator the flexibility to choose among them. Consistent with the verifiable parental consent requirements for ''disclosures'' under the Rule, acceptable methods would include print-and-send, use of a credit card in connection with a transaction, use of a toll-free number staffed by trained personnel, digital signatures, and use of an e-mail accompanied by a PIN number or a password obtained through one of the verification methods listed above.[268]

One commenter considered photocopies of a driver's license to be unnecessarily invasive, viewing a password system as preferable.[269] While the Commission agrees that submission of a driver's license may not be preferable to some parents, it should be retained as an option.

The Commission did not receive much feedback on technological advances under development that might ease the process of parental identification. Two commenters referred to digital signatures but noted they are not yet generally available.[270] The World Wide Web Consortium's Platform for Privacy Preferences Project (P3P) was also cited as a technology under development that might be used by operators and parents in the future.[271] As noted above, the Commission will continue to monitor technological advances that might play a useful role in identifying parents.[272]

5. Good Faith and Reasonable Procedures Under Section 312.6(b)

Section 312.6(b) of the proposed Rule, which tracked the language of the Act, stated that disclosures under section 312.6(a)(3) that were made in good faith and by following reasonable procedures would not give rise to liability under any Federal or State law.[273] Nonetheless, several commenters raised concerns about liability.[274] Two commenters called for specific examples of precautions that industry could take to protect itself against liability under other laws.[275] Comments also indicated that verification methods that would satisfy section 312.6(a)(3) should be listed in the Rule itself in order to provide certainty regarding the reasonableness of an operator's action under that provision.[276] One commenter asserted that parental requests for information should be in writing so the operator has a record to show good faith compliance with the Rule.[277]

The Commission recognizes the potential risks associated with the access provision and the related concerns about liability. The Commission believes, however, that the language of the Rule, which is identical to the language set forth in the Act,[278] strikes the proper balance in protecting the interests of the child, operator, and parent. An operator can assume that if it employs reasonable procedures to implement section 312.6(a)(3), including those listed above and in the NPR,[279] an inadvertent, good faith disclosure of a child's information to someone who purports to be a parent will not give rise to liability under any Federal or State laws.

Finally, one commenter stated that reasonable procedures for disclosure should account for situations where the consenting parent is unavailable as a result of death, divorce, or desertion.[280] The Commission understands that family situations can change and that circumstances may arise where it will be necessary to provide access to a party other than the consenting parent.[281] The Rule is not intended to preclude disclosures in such circumstances as long as they satisfy the ''good faith'' and ''reasonable procedures'' standards.

[260] *See also* 64 FR at 22758 n.13 (stating that it may be acceptable for an operator to use a less stringent method of parental identification when giving out the types of information collected from children).

[261] However, operators responding to requests under § 312.6(a)(1) may not reveal the names of any children from whom they have collected personal information. This change should also address the concerns of other commenters who felt the Commission's proposed approach to parental review was cumbersome and confusing. EPIC (Comment 115) at 5; Highlights (Comment 124) at 2–3.

[262] CDT (Comment 81) at 29–30.

[263] *Id.*

[264] *Id.*

[265] *See* 15 U.S.C. 6503(b)(1)(B).

[266] CDT (Comment 81) at 29; CME/CFA et al. (Comment 80) at 34 (supporting such a system until digital signatures become widely available); CBBB (Comment 91) at 22–24. *See* 64 FR at 22758 and n.14.

[267] MPA (Comment 113) at 4–5.

[268] As noted in note 213, *supra,* the Commission expects that operators will keep confidential any information obtained from parents in the process of obtaining consent or providing for parental review of information collected from a child.

[269] EPIC (Comment 115) at 5–6. Another commenter found requiring photocopies of drivers' licenses to be problematic since they may reveal additional personal information to the operator (such as parents' social security numbers) which parents should not be required to disclose. CME/CFA et al. (Comment 80) at 35. One commenter identified practicality and feasibility problems in connection with requiring a driver's license. CBBB (Comment 91) at 22.

[270] CME/CFA et al. (Comment 80) at 35; CBBB (Comment 91) at 16, 23–24.

[271] CBBB (Comment 91) at 23–24.

[272] *See* note 186, *supra* (discussing products and services that are available or under development).

[273] 64 FR at 22757–58, 22766. *See also* 15 U.S.C. 6502(a)(2).

[274] *See generally* DMA (Comment 89) at 15–16; Time Warner (Comment 78) at 12–13; EdPress (Comment 130) at 2.

[275] DMA (Comment 89) at 16; Time Warner (Comment 78) at 13.

[276] DMA (Comment 89) at 17; Time Warner (Comment 78) at 13.

[277] DMA (Comment 89) at 17.

[278] *See* 15 U.S.C. 6502(a)(2).

[279] 64 FR at 22757–58.

[280] CME/CFA et al. (Comment 80) at 16.

[281] It should be noted that the Rule's definition of ''parent'' in section 312.2 provides some flexibility in addressing changing family situations. *See* Section II.A.7, *supra.*

F. Section 312.7: Prohibition Against Conditioning a Child's Participation on Collection of Personal Information

Section 312.7 of the proposed Rule, which tracks the language of the Act and is retained in the final Rule, prohibited operators from conditioning a child's participation in a game, the offering of a prize, or another activity on the child's disclosing more personal information than is reasonably necessary to participate in such activity.[282] This section prohibits operators from tying the provision of personal information to such popular and persuasive incentives as prizes or games, while preserving children's access to such activities.

G. Section 312.8: Confidentiality, Security, and Integrity of Personal Information Collected From Children

Under section 312.8 of the proposed Rule, operators were required to establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of personal information collected from children.[283] More specifically, operators must have adequate policies and procedures for protecting children's personal information from loss, misuse, unauthorized access, or disclosure. In the NPR, the Commission offered a number of options that operators could use to implement this provision,[284] and sought comment regarding practices that are commonly used, practices that provide the strongest protection, and the costs of implementation.[285] After reviewing the comments, the Commission has decided to retain this provision, which tracks the requirements of the Act.[286]

Commenters suggested procedures for complying with this provision, including: using secure web servers and firewalls;[287] deleting personal information once it is no longer being used;[288] limiting employee access to data[289] and providing those employees with data-handling training;[290] and carefully screening the third parties to whom such information is disclosed.[291] The Commission agrees that these are appropriate measures to take under this provision.

One commenter noted that security procedures requiring special hardware, software, and/or encryption are costly.[292] The Commission is mindful of the potential costs of complying with the Rule, and thus, allows operators to choose from a number of appropriate methods of implementing this provision.

H. Section 312.9: Enforcement

This section of the proposed Rule stated that a violation of the Commission's rules implementing the COPPA would be treated as a violation of a rule defining an unfair or deceptive act or practice prescribed under section 18(a)(1)(B) of the Federal Trade Commission Act, 15 U.S.C. 57a(a)(1)(B). The Commission has modified this provision to incorporate the final citation form for relevant provisions of the Act.[293]

I. Section 312.10: Safe Harbors

1. In General

This section of the Rule provides that an operator's compliance with Commission-approved self-regulatory guidelines serves as a safe harbor in any enforcement action for violations of this Rule.[294] As the Commission noted in the NPR, this section serves as an incentive for industry self-regulation; by allowing flexibility in the development of self-regulatory guidelines, it ensures that the protections afforded children under this Rule are implemented in a manner that takes into account industry-specific concerns and technological developments.[295] To receive safe harbor treatment, an operator can comply with any Commission-approved guidelines. The operator need not independently apply for approval if in fact the operator is fully complying with guidelines already approved by the Commission that are applicable to the operator's business.[296]

In an enforcement action, the Commission has the burden of proving non-compliance with the Rule's requirements. The standards enunciated in the Rule thus remain the benchmark against which industry's conduct will ultimately be judged. Compliance with approved guidelines, however, will serve as a safe harbor in any enforcement action under the Rule. That is, if an operator can show full compliance with approved guidelines, the operator will be deemed in compliance with the Rule. The Commission retains discretion to pursue enforcement under the Rule if approval of the guidelines was obtained based upon incomplete or inaccurate factual representations, or if there has been a substantial change in circumstances, such as the failure of an industry group to obtain approval for a material modification to its guidelines.[297]

2. Criteria for Approval of Self-Regulatory Guidelines

Section 312.10(b)(1) of the proposed Rule stated that, in order to be approved by the Commission, self-regulatory guidelines must require subject operators to implement the protections afforded children under the proposed Rule.[298] Two commenters were concerned that this provision was not sufficiently flexible to serve as an incentive for self-regulation. They expressed the view that the Rule should not dictate the content of self-regulatory guidelines.[299] Another commenter stated that the Commission should allow a wide range of self-regulation.[300] The Commission believes that the language of the proposed Rule conveyed less flexibility in this regard than was originally intended. The Rule therefore clarifies that promulgators of self-

[282] 64 FR at 22758, 22766; 15 U.S.C. 6502(b)(1)(C). One commenter supporting this provision stated that children should not be enticed to turn over personal information. CDT (Comment 81) at 30.

[283] 64 FR at 22758–59, 22766.

[284] Protections identified in the NPR included: designating an individual in the organization to be responsible for maintaining and monitoring the security of the information; requiring passwords for access to the personal information; creating firewalls; utilizing encryption; implementing access control procedures in addition to passwords; implementing devices and procedures to protect the physical security of the data processing equipment; storing the personal information collected online on a secure server that is not accessible from the Internet; installing security cameras and intrusion-detection software to monitor who is accessing the personal information; or installing authentication software to determine whether a user is authorized to enter through a firewall. 64 FR at 22758.

[285] 64 FR at 22763.

[286] *See* 15 U.S.C. 6502(b)(1)(D).

[287] Attorneys General (Comment 114) at 12; CME/CFA et al. (Comment 80) at 36.

[288] Attorneys General (Comment 114) at 12; CME/CFA et al. (Comment 80) at 36; CDT (Comment 81) at 30.

[289] Attorneys General (Comment 114) at 12; CME/CFA et al. (Comment 80) at 36.

[290] CME/CFA et al. (Comment 80) at 36.

[291] *Id.* at 17.

[292] iCanBuy.com (Comment 101) at 4.

[293] *See* 15 U.S.C. 6502(c).

[294] Seventeen commenters addressed this provision of the proposed Rule. MaMaMedia (Comment 85) at 3–4; IDSA (Comment 103) at 7; ANA (Comment 93) at 2–3; MLG Internet (Comment 119) at 2; AAAA (Comment 134) at 4; Consumers Union (Comment 116) at 6; SNAP/CollegeEdge (Comment 123) at 1; Mars (Comment 86) at 15–16; CBBB (Comment 91) at 27–37; TRUSTe (Comment 97) at 2; Bonnett (Comment 126) at 6; DMA (Comment 89) at 27–29; CME/CFA, et al. (Comment 80) at 37; McGraw-Hill (Comment 104) at 8–9; PrivacyBot.com (Comment 32) (unpaginated); Disney (Comment 82) at 10; EPIC (Comment 115) at 6–7.

[295] 64 FR at 22759.

[296] *Id.*

[297] *Id.*

[298] *Id.*

[299] DMA (Comment 89) at 27 (stating that, rather than prescribe the content of self-regulatory guidelines, the Commission should approve guidelines based upon their ''overall merits''); MLG Internet (Comment 119) at 2 (stating that the Commission should allow self-regulatory groups to create rules that meet the COPPA's goals).

[300] Mars (Comment 86) at 16.

regulatory guidelines may comply with this section by requiring subject operators to implement ''substantially similar requirements that provide the same or greater protections for children as those contained in sections 312.2–312.8 of the Rule.'' [301] Under section 312.10(c) of the Rule, the burden remains with persons seeking Commission approval of guidelines to demonstrate that the guidelines in fact meet this standard.

In a similar vein, some commenters believed that the particular assessment mechanisms and compliance incentives listed as options in sections 312.10(b)(2) and 312.10(b)(3), respectively, of the proposed Rule were, in fact, mandatory practices.[302] In the NPR, the Commission sought to clarify that these sections set out performance standards and that the listed methods were only suggested means for meeting these standards.[303] In light of the confusion evidenced by the comments, the Commission has amended these sections to make this express.[304]

Thus, section 312.10(b)(2) of the Rule makes explicit that its requirement that guidelines include an effective, mandatory mechanism for the independent assessment of subject operators' compliance is a performance standard. Similarly, section 312.10(b)(3) of the Rule states that its requirement that guidelines include effective incentives for subject operators' compliance is a performance standard. Both section 312.10(b)(2) and 312.10(b)(3) of the Rule include suggested means of meeting their respective performance standards and provide that those performance standards may be satisfied by other means if their effectiveness equals that of the listed alternatives. The Commission believes that the Rule therefore provides the flexibility sought by the commenters.

In the NPR, the Commission stated that operators could not rely solely on self-assessment mechanisms to comply with section 312.10(b)(2).[305] Commenters were divided on the issue of whether the Commission should permit self-assessment as a means of measuring operators' compliance with self-regulatory guidelines. Some believed that self-assessment, without more, is not an adequate means of measuring compliance.[306] Others believed that the Commission should not impose an independent assessment requirement on operators that choose not to join third-party compliance programs, as long as their information practices satisfy the COPPA.[307]

On balance, the Commission believes that a performance standard that incorporates independent assessment is appropriate and necessary. Under the safe harbor provision, the Commission looks to the promulgators of guidelines, in the first instance, to ensure that those guidelines are effectively implemented. The Commission believes that independent assessment is the best way to ensure that operators are complying with the guidelines.[308] The Commission notes, however, that the Rule does not prohibit the use of self-assessment as one part of an organization's efforts under section 312.10(b)(2) to measure subject operators' compliance with the Rule, nor does it preclude individual operators who have not joined third-party programs from assessing their own compliance. The Rule does, however, prohibit the use of self-assessment as the *only* means of measuring compliance with self-regulatory guidelines.

Several commenters suggested that the Commission require that self-regulatory guidelines include an array of specific practices not listed in the proposed Rule. Such practices include, for example: comprehensive information practice reviews as a condition of membership in self-regulatory programs,[309] annual compliance affidavits to be submitted by subject operators to self-regulatory organizations,[310] quarterly monitoring of operators' information practices by self-regulatory groups,[311] public reporting of disciplinary actions taken by trade groups against subject operators in publications other than trade publications,[312] and referral to the Commission of all violations of approved guidelines [313] or all failures to comply with a self-regulatory group's disciplinary dictates.[314] Many of these ideas have merit, and self-regulatory groups may wish to include some or all of them in their proposed guidelines. The Commission does not, however, believe that it should require adoption of any specific practice or practices as a prerequisite to certification under the Rule. Self-regulatory groups or other promulgators of guidelines are best suited to determine the appropriateness of such measures, in light of the Rule's requirements. The Commission will review the adequacy of the proposed enforcement programs in considering specific safe harbor requests.

3. Request for Commission Approval of Self-Regulatory Guidelines

Section 312.10(c)(1)(iii) of the proposed Rule required that persons seeking approval of guidelines submit a statement to the Commission demonstrating that their proposed guidelines, including assessment mechanisms and compliance incentives, comply with the proposed Rule.[315] One commenter suggested that the Commission eliminate this requirement.[316] The Commission believes that the burden of demonstrating compliance properly rests on proponents of Commission approval and that the guideline approval process will benefit from proponents' explanations of their rationale for approval. Therefore, the Commission has retained this requirement in the Rule.

Section 312.10 of the proposed Rule did not include a provision governing

[301] Of course, promulgators of guidelines may also require subject operators to implement the precise information practices set forth in the Rule.

[302] DMA (Comment 89) at 28; PrivacyBot.com (Comment 32) (unpaginated). One commenter expressed the view that by requiring self-regulatory groups affirmatively to monitor their members' compliance, rather than take action only in response to consumer complaints, the proposed Rule in effect deputizes industry organizations to police their members on the Commission's behalf. DMA (Comment 89) at 28. However, the Commission believes that, to the contrary, the Rule's safe harbor provisions allow industry to craft effective alternatives to Commission enforcement.

[303] 64 FR at 22759.

[304] One commenter was concerned that section 312.10(b)(2) could be read to require ''manual,'' but not ''automated'' means of independently assessing subject operators' compliance with self-regulatory guidelines. PrivacyBot.com (Comment 32) (unpaginated) and (IRFA comment 03) at 2.

[305] 64 FR at 22759.

[306] CME/CFA et al. (Comment 80) at 37; CBBB (Comment 91) at 31.

[307] McGraw-Hill (Comment 104) at 9. *See also* Mars (Comment 86) at 15 (stating that the Commission should permit self-assessment).

[308] One commenter suggested that the Commission award safe harbor status only to non-profit self-regulatory programs or for-profit groups whose self-regulatory decisions are insulated from owner or investor control. CBBB (Comment 91) at 33–34. The Commission believes it is unnecessary to so limit eligibility for safe harbor status and further believes that the test for eligibility should be the substance of self-regulatory guidelines, rather than the corporate structure of their promulgators.

[309] CBBB (Comment 91) at 29–30.

[310] *Id.* at 32.

[311] E.A. Bonnett (Comment 126) at 6.

[312] CME/CFA et al. (Comment 80) at 37.

[313] *Id.*

[314] CBBB (Comment 91) at 32.

[315] 64 FR at 22759–60. One commenter requested that the Commission clarify the status under the Freedom of Information Act of proprietary information submitted to the Commission under this section. CBBB (Comment 91) at 37. The Commission believes this is unnecessary, as such information would be protected from disclosure under section 6(f) of the Federal Trade Commission Act and Exemption 4 of the Freedom of Information Act, to the extent that it constitutes ''trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential.'' FTCA Section 6(f), 15 U.S.C. 46(f); FOIA Exemption 4, 5 U.S.C. 552(b)(4).

[316] CBBB (Comment 91) at 36.

approval of changes in previously approved self-regulatory guidelines. Several commenters suggested that the Commission amend the proposed Rule to include such a provision.[317] Therefore, section 312.10(c)(3) of the Rule now provides that promulgators of approved self-regulatory guidelines must submit proposed changes and all supporting documentation for review and approval by the Commission. The Commission recognizes, however, the need for efficiency in reviewing proposed changes to approved guidelines. Only changes in approved guidelines will be subject to public notice and comment, not the unaffected portions of the guidelines.[318] Section 312.10(c)(3) of the Rule also requires that proponents of changes in approved guidelines submit a statement describing how the proposed changes comply with the Rule and how they affect existing guideline provisions.

Other comments suggested that the Commission should shorten the 180-day period for Commission action on submissions,[319] specify a time period for public comment (e.g., 30–45 days),[320] ''toll'' (rather than restart, as proposed in the NPR) the 180-day period for Commission action in the event of an incomplete submission of supporting documents,[321] and make guidelines effective upon publication of the Commission's decision, rather than 45 days from publication in the **Federal Register** as stated in the NPR.[322] After considering the comments, the Commission agrees that the guidelines should become effective upon publication of Commission approval.[323] However, it declines to adopt a single, specific time period for public comment, as the appropriate period may well vary with the complexity and novelty of the guidelines submitted. Further, the Commission does not believe the 180-day time period should be shortened or tolled during the comment period, but notes that it intends to complete its review within the statutory period.

4. Records

Section 312.10(d)(1) of the proposed Rule required that industry groups or other persons seeking safe harbor treatment maintain consumer complaints for a period not to exceed three years.[324] As one commenter noted, however, the proposed Rule did not specify the length of time required for maintaining the other documents specified in this section, *e.g.*, records of disciplinary actions against subject operators and records of independent assessments of subject operators' compliance.[325] The Commission agrees that this inconsistency is unnecessarily confusing. Therefore, the Rule now clarifies that industry groups or other persons seeking safe harbor treatment must maintain all documents required by this section for a period of three years.

J. Section 312.11: Rulemaking Review

Section 312.11 of the proposed Rule retained the Act's requirement that the Commission initiate a review proceeding to evaluate the Rule's implementation no later than five years after the effective date of the Rule and report its results to Congress.[326] The Commission stated in the NPR that the review will address the Rule's effect on: practices relating to the collection and disclosure of children's information; children's ability to access information of their choice online; and the availability of websites directed to children. In addition, eighteen months after the effective date of the Rule, the Commission will conduct a review of available mechanisms for obtaining verifiable parental consent, as discussed above in Section II.D.

K. Paperwork Reduction Act

Pursuant to the Paperwork Reduction Act (as amended 44 U.S.C. 3507(d)), the Commission submitted the proposed Rule to the Office of Management and Budget (OMB) for review.[327] The OMB has approved the Rule's information collection requirements.[328] The Commission did not receive any comments that necessitate modifying its cost estimates for the Rule's notice requirements.[329]

L. Final Regulatory Flexibility Analysis

The NPR did not include an initial regulatory flexibility analysis (IRFA) under the Regulatory Flexibility Act[330] based on a certification that the proposed Rule would not have a significant economic impact on a substantial number of small entities. Nonetheless, the Commission invited public comment on the proposed Rule's effect on small entities to ensure that no significant impact would be overlooked.[331] The Commission received two responsive comments suggesting that it publish an IRFA.[332] While the Commission believed that such an analysis was not technically required, it issued an IRFA to provide further information and opportunity for public comment on the small business impact, if any, of the Rule.[333]

This final regulatory flexibility analysis (FRFA) incorporates the Commission's initial findings, as set forth in the NPR; addresses the comments submitted in response to the IRFA notice; and describes the steps the agency has taken in the final Rule to minimize the impact on small entities consistent with the objectives of the COPPA.

Succinct Statement of the Need for, and Objectives of, the Rule

The Rule prohibits unfair or deceptive acts or practices in connection with commercial websites' and online services' collection and use of personal information from and about children by: (1) Enhancing parental involvement in a child's online activities in order to protect the privacy of children in the online environment; (2) helping to protect the safety of children in online fora such as chat rooms, home pages, and pen-pal services in which children may make public postings of identifying information; (3) maintaining the security of children's personal information collected online; and (4) limiting the collection and disclosures of personal information without parental consent. The Commission was

[317] ANA (Comment 93) at 3; Mars (Comment 86) at 17; and MLG Internet (Comment 119) at 2.

[318] 64 FR at 22760.

[319] CBBB (Comment 91) at 36. This commenter suggested a 90-day review period.

[320] *Id.*

[321] *Id.*; Mars (Comment 86) at 17.

[322] CBBB (Comment 91) at 36.

[323] One commenter requested that the Commission maintain a list of parties interested in being contacted by the Commission when proposed guidelines are published in the **Federal Register** and on the Commission's website. EPIC (Comment 115) at 7. The Commission believes that publication of proposed guidelines is, as a general matter, sufficient notice of their submission for approval.

[324] 64 FR at 22760.

[325] CBBB (Comment 91) at 37.

[326] 15 U.S.C. 6506. Two commenters called for conducting the review in three years rather than five. CME/CFA et al. (Comment 80) at 17; CDT (Comment 81) at 31. The Commission believes that the COPPA's five year requirement is appropriate, but will consider undertaking a review sooner if warranted.

[327] The Commission's Supporting Statement submitted to OMB as part of the clearance process has been made available on the public record of this rulemaking. *See* Supporting Statement for Information Collection Provisions at <http://www.ftc.gov/os/1999/9906/childprivsup.htm>.

[328] The assigned OMB clearance number is 3084–0117.

[329] *See* 64 FR at 22761 (estimating total burden of 18,000 hours for first year, and 1800 hours for subsequent years).

[330] 5 U.S.C. 603.

[331] *See* 64 FR at 22761.

[332] Hons. George Gekas and James Talent, U.S. House of Representatives (Comment 74) at 4; U.S. Small Business Administration (Comment 128) at 4–5.

[333] 64 FR 40525.

required by the COPPA to issue implementing regulations.[334]

Summary of the Significant Issues Raised by the Public Comments in Response to the IRFA; Summary of the Assessment of the Agency of Such Issues; and Statement of Any Changes Made in the Rule as a Result of Such Comments

In the IRFA, the Commission sought comment regarding the impact of the proposed Rule and any alternatives the Commission should consider, with a specific focus on the effect of the Rule on small entities.[335] The Commission received five comments, which discussed issues also addressed in the Statement of Basis and Purpose, above, including notice, verifiable parental consent, security, and safe harbors.

1. New Notice and Request for Consent

One commenter contended that the requirement for new notice and consent for different uses of a child's personal information under the notice and consent sections of the proposed Rule threatened smaller operators that rely on mergers and marketing alliances to help build their business.[336] The commenter recommended that new notice and consent should be required only when there is a material change in intended uses or practices.[337] As explained in Section II.C.4 and II.D.1, above, the Commission has modified its position to require new notice and consent only if there is a material change in the collection, use, or disclosure of personal information from children.

2. Verifiable Parental Consent

Another commenter expressed concern that the proposed Rule's consent requirement would result in high compliance costs and a substantial reduction in traffic to small sites.[338] According to the commenter, a child's use of collaborative educational tools on the Internet should be treated differently from the collection and use of personal contact information by marketers. The commenter, who called for parental notification and opt-out for such collaborative uses, was especially concerned about the loss of business from schools.

The Commission does not have discretion under the statute to waive the requirement of verifiable parental consent.[339] As noted above in Section II.D.4, the Rule does not preclude schools from acting as intermediaries between operators and parents in the notice and consent process, or from serving as the parent's agent in the process. Thus, the Rule should not hinder businesses that provide services to schools.

The Commission is sensitive to commenters' concerns about increased costs and reduced traffic to sites. Accordingly, the Commission has temporarily adopted a sliding scale approach to verifiable parental consent to minimize burdens and costs for operators while still providing for parental control of children's personal information. As more fully described in Section II.D, inexpensive e-mail mechanisms may be used to obtain parental consent for the collection of information for internal uses, such as an operator's marketing to a child based on information collected about the child's preferences. Only where information is subject to ''disclosure'' under section 312.2 of the Rule will the other methods of consent be required and, even then, operators will have a range of mechanisms from which to choose. Further, even after the sliding scale is phased out two years from the Rule's effective date, operators will be able to choose from a number of consent methods, many of which are expected to be less costly and more widely available at that time.[340] Finally, for certain uses of children's personal information, no consent will be required at all under the exceptions to prior parental consent set forth in section 312.5(c) of the Rule.

3. Confidentiality, Security, and Integrity of Information

One commenter found the security methods identified in section 312.8 of the proposed Rule to be effective, but suggested that small entities should not be held to the same standards as larger entities when evaluating adequate protection under the Rule.[341] As noted earlier, the Rule allows operators flexibility in selecting security procedures in accordance with their particular needs.

4. Safe Harbors

A commenter suggested that section 312.10 of the proposed Rule should more clearly recognize the role automation can play in assessing an operator's compliance with privacy seal programs.[342] As explained above in Section II.I.2, section 312.10(b)(2) includes a performance standard requiring only that assessment mechanisms be effective, mandatory, and independent. In addition to the examples listed in the Rule, that performance standard may be satisfied by other equally effective means. Thus, the Rule does not preclude the use of automated assessment tools that meet the performance standard.

Description and Estimate of the Number of Small Entities to Which the Rule Will Apply or an Explanation of Why No Such Estimate Is Available

The Rule applies to any commercial operator of an online service or website directed to children or any commercial operator that has actual knowledge that it is collecting personal information from a child.[343] A precise estimate of the number of small entities that fall within the Rule is not currently feasible, in part, because the definition of a website directed to children turns on a number of factors that will require a factual analysis on a case-by-case basis.[344] In connection with the NPR, IRFA, and the public workshop on verifiable parental consent, the Commission has not received any comments providing an estimate of the number of small entities to which the Rule will apply.

Description of the Projected Reporting, Recordkeeping and Other Compliance Requirements of the Rule, Including an Estimate of the Classes of Small Entities That Will Be Subject to the Requirement and the Type of Professional Skills Necessary for Preparation of the Report or Record

The Commission incorporates by reference its description of the projected reporting, recordkeeping and other compliance requirements of the Rule, as

[334] 15 U.S.C. 6502.

[335] 64 FR at 40527–28.

[336] KidsOnLine.com (IRFA Comment 02) at 1.

[337] *Id.*

[338] Zeeks.com (IRFA Comment 05) at 2.

[339] *See* 15 U.S.C. 6502; section 312.3 of the Rule. Another commenter suggested that operators be permitted to collect some personal information to establish a relationship with the child in exchange for limited access to the site (such as games) without obtaining consent. KidsOnLine.com (IRFA Comment 02) at 2.

[340] *See supra* note 1868. As described more fully above, the Commission will undertake a review eighteen months after the effective date of the Rule to determine through public comment whether technology has progressed as expected. The impact on small businesses will again be carefully considered.

[341] KidsOnLine.com (IRFA Comment 02) at 1.

[342] PrivacyBot.com (IRFA Comment 03) at 2. This commenter noted that the examples listed the NPR appeared to call for manual assessment mechanisms.

[343] Section 312.3. The Rule does not apply to nonprofit entities. Section 312.2 (definition of ''operator'').

[344] Under section 312.2, in determining whether a commercial website or online service is directed to children, the Commission will consider its subject matter, visual or audio content, age of models, language or other characteristics of the website or online service, as well as whether advertising promoting or appearing on the website or online service is directed to children.

set forth in the IRFA.[345] The Office of Management and Budget has approved the information collection of the Rule[346] based on the Commission's earlier submission for clearance, which has been made available on the public record of this rulemaking.[347] The Commission has not received any comments that necessitate modifying its previous description of projected compliance requirements.

Description of the Steps the Agency Has Taken To Minimize the Significant Economic Impact on Small Entities, Consistent With the Stated Objectives of Applicable Statutes, Including a Statement of the Factual, Policy, and Legal Reasons for Selecting the Alternative Adopted in the Final Rule and Why Each of the Other Significant Alternatives to the Rule Considered by the Agency Which Affect the Impact on Small Entities Was Rejected

The Rule incorporates the many performance standards set forth in the statute.[348] Thus, operators are free to choose among a number of compliance methods based upon their individual business models and needs. Although the Rule's provisions impose some costs, the requirements of notice, verifiable parental consent, access, and security are mandated by the COPPA itself. The Commission has sought to minimize the burden on all businesses, including small entities, by adopting flexible standards;[349] however, it does not have the discretion to create exemptions from the Act based on an operator's size. Likewise, while the Rule attempts to clarify, consolidate, and simplify the statutory requirements for all entities,[350] the Commission has little discretion, if any, to mandate different methods or schedules for small entities that would undermine compliance with the Act.[351]

Nevertheless, throughout the rulemaking proceeding, the Commission has sought to gather information regarding the economic impact of the COPPA's requirements on all operators, including small entities. The NPR, for example, included a number of questions for public comment regarding the costs and benefits associated with notice and consent.[352] Similarly, the subsequent IRFA notice invited public comment specifically on the issue of small business impact.[353] In addition, the agenda for the public workshop on verifiable parental consent included topics designed to elicit economic impact information. In connection with the workshop, the Commission invited additional public comment.

The Commission has carefully considered responsive comments that suggested a variety of alternatives in developing the final Rule. The discussion below reviews some of the significant alternatives considered and the basis for the Commission's decisions with regard to certain notice, parental consent, access, security, and safe harbor requirements.

1. New Notice and Request for Consent

Many commenters contended that requiring operators to undertake new notice and consent under sections 312.4(c) and 312.5 for any use not covered by a parent's previous consent was burdensome and unnecessary.[354] The Commission is sensitive to the objections raised, particularly with respect to mergers, which occur often in this industry and which would trigger new notice and consent requirements even where there was no significant change in the operator's information practices. Eliminating this requirement altogether, however, would prevent parents from receiving material information that could affect their decisions regarding their child's online activities.[355]

In response to comments, including those of small businesses,[356] the Commission has modified the Rule to require new notice and consent only if there will be a material change in how the operator collects, uses, or discloses personal information from children.[357] This modification should substantially reduce the costs of compliance.

2. Verifiable Parental Consent

Throughout the rulemaking, the Commission has sought input on what mechanisms may be used to satisfy the COPPA's verifiable parental consent requirement. As described more fully in Section II.D. above, the Commission has temporarily adopted a ''sliding scale'' approach that depends upon the use of the child's personal information. This approach was recommended by many industry members seeking to preserve flexibility for operators while achieving the objectives of the Act.[358] To minimize burdens until more reliable electronic methods become more available and affordable, it allows use of e-mail for internal uses of personal information, as long as additional steps are taken to verify a parent's identity.

Some commenters had contended that use of e-mail alone should be an acceptable method of consent under section 312.5 of the Rule.[359] Commenters also criticized methods such as print-and-send, credit card, toll-free numbers, and digital signatures for the costs and burdens they might impose.[360] Based on the comments and workshop discussion, the Commission does not believe that use of e-mail alone adequately satisfies the statutory requirement that operators make reasonable efforts to obtain verifiable parental consent, taking into consideration available technology.[361] According to many commenters, e-mail is easily subject to circumvention by children.[362] In particular, where a child and parent share the same e-mail account, as is often the case, a child may easily pretend to be a parent and provide consent for himself.[363]

The Commission does not expect that declining to permit use of e-mail alone will impose significant costs in terms of foregone activities. Websites will be able to engage in many activities that do not trigger any prior consent requirements pursuant to the exceptions to parental consent set forth in section 312.5(c).[364] According to a workshop participant, these exceptions cover some of the most popular and common online activities,

[345] *See* 64 FR at 40526–27.

[346] The OMB clearance number is 3084–0117.

[347] *See* Supporting Statement for Information Collection Provisions at <http://www.ftc.gov/os/1999/9906/childprivsup.htm>.

[348] *See, e.g.,* sections 312.4(c), 312.5.

[349] *See* 5 U.S.C. 603(c)(3). The notice requirements, for example, have been designed to minimize the burdens on operators in a variety of ways. Section 312.4(b) of the Rule permits operators to post ''links'' to the required notices, rather than state the complete text. Similarly, in response to industry concerns about technical feasibility, the Commission has eliminated the requirement that the link must be seen without having to scroll down from the initial viewing screen. *See* Section II.C.2, *supra*.

[350] *See* 5 U.S.C. 603(c)(2).

[351] For example, the COPPA requires the online posting of privacy policies by websites and online services. A waiver for small entities of that prior notice requirement (*e.g.*, by permitting notice after the fact) would be inconsistent with the statutory mandate. *See* 15 U.S.C. 6502(b)(1)(A)(i).

[352] 64 FR at 22761–63.

[353] 64 FR 40525.

[354] *See supra* note 143.

[355] For example, an operator might initially use a child's information only for internal marketing purposes and then later undertake a new use involving disclosures to third parties. Such a change would likely be important to the parent's consent decision.

[356] *See* KidsOnLine.com (IRFA Comment 02) at 1.

[357] *See also* Section II.C.3.a, *supra* (discussing section 312.4(b)(2)(i) (content of notice)).

[358] *See supra* note 203 and accompanying text.

[359] *See supra* note 197 and accompanying text.

[360] *See supra* notes 187–195 and accompanying text.

[361] *See* 15 U.S.C. 6501(9).

[362] *See supra* note 196 and accompanying text.

[363] *See supra* note 178 and accompanying text.

[364] *See* Section II.D.3, *supra.* Prior parental consent is not required pursuant to these exceptions. However, in some instances, operators must provide parents with notice and an opportunity to opt out. *See* section 312.5(c)(3).

including newsletters, contests, and online magazine subscriptions.[365]

Moreover, where e-mail mechanisms are employed for internal uses under the sliding scale, the additional steps required under section 312.5 (such as sending a confirmatory e-mail to the parent following receipt of consent) should not be especially onerous given the availability and ease of automated technology.[366] Thus, the additional steps required should have no deterrent effect on operators (or parents).

Only for activities that entail ''disclosure'' of a child's personal information, as defined in the Rule, such as chat rooms, message boards, pen-pal services, and personal home pages, will the higher method of consent be triggered.[367] The comments and public workshop discussion provide considerable support for the principle that such activities warrant a higher level of protection, given the heightened safety concerns.[368] In order to ensure maximum flexibility within this upper tier of the sliding scale, a range of mechanisms will be acceptable under the Rule, including postal mail, facsimile, credit card in connection with a transaction, toll-free numbers, and digital signatures.[369] To minimize costs, once a parent has provided consent through one of these methods and obtained a PIN or password, an operator may subsequently obtain consent through an e-mail accompanied by such PIN or password.

In adopting the sliding scale for a two-year period following the Rule's effective date, the Commission has sought to minimize any burdens of compliance until advancements in technology provide more reliable electronic methods at low cost. Based on reports from industry members, the Commission expects that this will occur soon.[370] To assess whether such developments have in fact occurred as expected, the Commission will undertake a review, using notice and comment, approximately eighteen months after the Rule's effective date. All businesses, including small entities, will be given the opportunity to comment on economic impact issues at that time.

If technology progresses as expected, operators should have a wide variety of reasonable and effective options for providing verifiable parental consent. Therefore, phasing out the sliding scale should not impose undue burdens on operators seeking to comply with the Rule. Moreover, the Commission's amendment to the Rule requiring new notice and consent only in the case of Amaterial changes' to an operator's information practices should further reduce operators' burdens.

3. Parental Access to Information

In implementing the COPPA's parental access requirement,[371] the Commission has adopted flexible standards and sought to eliminate any unnecessary provisions in the Rule. For example, section 312.6(a)(3) requires that operators provide a means of review that ensures that the requestor is a parent, taking into account available technology, and that is not unduly burdensome to the parent. In response to comments that the proposed Rule's right to change information went beyond the statute and was onerous, the Commission has omitted that provision from the Rule. To eliminate unnecessary costs, the Rule also no longer requires parental verification for access to the types or categories of personal information collected from the child under section 312.6(a)(1). However, consistent with the COPPA, which recognized the safety concerns inherent in granting access to the child's specific information, proper parental verification will be required for access to that information under section 312.6(a)(3). As with verifiable parental consent, operators may choose from among a variety of verification methods, including both online and offline methods.[372]

4. Confidentiality, Security, and Integrity of Information

As required under the Act, the Rule seeks to ensure a baseline level of protection for children's personal information.[373] The Commission recognizes that certain security procedures may be more costly for smaller entities than larger entities.[374] Accordingly, section 312.8 allows operators flexibility in selecting reasonable procedures in accordance with their business models.[375]

5. Safe Harbors

The safe harbor provisions also utilize performance standards in order to minimize burdens and provide incentives for industry self-regulation, as required by the COPPA.[376] In response to concerns that the proposed Rule appeared inflexible, the Commission has clarified in section 312.10(b)(1) that promulgators of self-regulatory guidelines may comply with the safe harbor provisions by requiring subject operators to implement ''substantially similar requirements that provide the same or greater protections for children'' as those contained in the Rule. The Commission also has adopted performance standards for the assessment mechanisms and compliance incentives in sections 312.10(b)(2) and (b)(3). In addition to the examples listed in the Rule, these performance standards may be satisfied by other equally effective means. In order to maximize efficiency, the Rule further provides that only material changes in approved guidelines will be subject to the public notice and comment required under this section.

Final Rule

List of Subjects in 16 CFR Part 312

Children, Children's online privacy protection, Communications, Computer technology, Consumer protection, Data protection, Electronic mail, E-mail, Information practices, Internet, Online service, Privacy, Record retention, Safety, Trade practices, Website, Youth.

Accordingly, the Federal Trade Commission amends 16 CFR chapter I by adding a new Part 312 to read as follows:

PART 312—CHILDREN'S ONLINE PRIVACY PROTECTION RULE

[365] *See supra* note 226.

[366] A number of commenters recognized that taking additional steps would increase the likelihood that it is the parent who is providing consent, and some websites already undertake such measures. *See supra* notes 198–203 and accompanying text.

[367] To minimize burdens on general audience sites, the Commission has revised the Rule so that if a chat room monitor strips any posting of individually identifiable information before it is made public, the operator will not be deemed to have ''collected'' the child's personal information for purposes of the Rule. *See* Section II.A.2, *supra* (discussing section 312.2's definition of ''collects or collection''). Moreover, because the individually identifiable information has been deleted, the operator will not have ''disclosed'' that information under the Rule.

[368] *See supra* note 205 and accompanying text.

[369] *See* section 312.5(b).

[370] *See* Section II.D.2 and note 186, *supra*.

[371] *See* 15 U.S.C. 6502(b)(1)(B)(iii).

[372] The Commission will continue to monitor technological advances that might play a useful role in identifying parents for purposes of granting access. The Commission agrees with comments that it is currently premature to mandate the use of certain mechanisms still under development or not yet widely available. *See* CBBB (Comment 91) at 24.

[373] *See* 15 U.S.C. 6502(b)(1)(D).

[374] *See* KidsOnLine.com (IRFA Comment 02) at 1.

[375] *See* note 284, supra.

[376] *See* 15 U.S.C. 6503.

Authority: Secs. 15 U.S.C. 6501 *et seq.*

§ 312.1 Scope of regulations in this part.

This part implements the Children's Online Privacy Protection Act of 1998, (15 U.S.C. 6501, *et seq.*,) which prohibits unfair or deceptive acts or practices in connection with the collection, use, and/or disclosure of personal information from and about children on the Internet. The effective date of this part is April 21, 2000.

§ 312.2 Definitions.

Child means an individual under the age of 13.

Collects or collection means the gathering of any personal information from a child by any means, including but not limited to:

(a) Requesting that children submit personal information online;

(b) Enabling children to make personal information publicly available through a chat room, message board, or other means, *except where* the operator deletes all individually identifiable information from postings by children before they are made public, and also deletes such information from the operator's records; or

(c) The passive tracking or use of any identifying code linked to an individual, such as a cookie.

Commission means the Federal Trade Commission.

Delete means to remove personal information such that it is not maintained in retrievable form and cannot be retrieved in the normal course of business.

Disclosure means, with respect to personal information:

(a) The release of personal information collected from a child in identifiable form by an operator for any purpose, except where an operator provides such information to a person who provides support for the internal operations of the website or online service and who does not disclose or use that information for any other purpose. For purposes of this definition:

(1) *Release of personal information* means the sharing, selling, renting, or any other means of providing personal information to any third party, and

(2) *Support for the internal operations of the website or online service* means those activities necessary to maintain the technical functioning of the website or online service, or to fulfill a request of a child as permitted by § 312.5(c)(2) and (3); or

(b) Making personal information collected from a child by an operator publicly available in identifiable form, by any means, including by a public posting through the Internet, or through a personal home page posted on a website or online service; a pen pal service; an electronic mail service; a message board; or a chat room.

Federal agency means an agency, as that term is defined in Section 551(1) of title 5, United States Code.

Internet means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected world-wide network of networks that employ the Transmission Control Protocol/Internet Protocol, or any predecessor or successor protocols to such protocol, to communicate information of all kinds by wire, radio, or other methods of transmission.

Online contact information means an e-mail address or any other substantially similar identifier that permits direct contact with a person online.

Operator means any person who operates a website located on the Internet or an online service and who collects or maintains personal information from or about the users of or visitors to such website or online service, or on whose behalf such information is collected or maintained, where such website or online service is operated for commercial purposes, including any person offering products or services for sale through that website or online service, involving commerce:

(a) Among the several States or with 1 or more foreign nations;

(b) In any territory of the United States or in the District of Columbia, or between any such territory and

(1) Another such territory, or

(2) Any State or foreign nation; or

(c) Between the District of Columbia and any State, territory, or foreign nation. This definition does not include any nonprofit entity that would otherwise be exempt from coverage under Section 5 of the Federal Trade Commission Act (15 U.S.C. 45).

Parent includes a legal guardian.

Person means any individual, partnership, corporation, trust, estate, cooperative, association, or other entity.

Personal information means individually identifiable information about an individual collected online, including:

(a) A first and last name;

(b) A home or other physical address including street name and name of a city or town;

(c) An e-mail address or other online contact information, including but not limited to an instant messaging user identifier, or a screen name that reveals an individual's e-mail address;

(d) A telephone number;

(e) A Social Security number;

(f) A persistent identifier, such as a customer number held in a cookie or a processor serial number, where such identifier is associated with individually identifiable information; or a combination of a last name or photograph of the individual with other information such that the combination permits physical or online contacting; or

(g) Information concerning the child or the parents of that child that the operator collects online from the child and combines with an identifier described in this definition.

Third party means any person who is not:

(a) An operator with respect to the collection or maintenance of personal information on the website or online service; or

(b) A person who provides support for the internal operations of the website or online service and who does not use or disclose information protected under this part for any other purpose.

Obtaining *verifiable consent* means making any reasonable effort (taking into consideration available technology) to ensure that before personal information is collected from a child, a parent of the child:

(a) Receives notice of the operator's personal information collection, use, and disclosure practices; and

(b) Authorizes any collection, use, and/or disclosure of the personal information.

Website or online service directed to children means a commercial website or online service, or portion thereof, that is targeted to children. *Provided, however,* that a commercial website or online service, or a portion thereof, shall not be deemed directed to children solely because it refers or links to a commercial website or online service directed to children by using information location tools, including a directory, index, reference, pointer, or hypertext link. In determining whether a commercial website or online service, or a portion thereof, is targeted to children, the Commission will consider its subject matter, visual or audio content, age of models, language or other characteristics of the website or

online service, as well as whether advertising promoting or appearing on the website or online service is directed to children. The Commission will also consider competent and reliable empirical evidence regarding audience composition; evidence regarding the intended audience; and whether a site uses animated characters and/or child-oriented activities and incentives.

§ 312.3 Regulation of unfair or deceptive acts or practices in connection with the collection, use, and/or disclosure of personal information from and about children on the Internet.

General requirements. It shall be unlawful for any operator of a website or online service directed to children, or any operator that has actual knowledge that it is collecting or maintaining personal information from a child, to collect personal information from a child in a manner that violates the regulations prescribed under this part. Generally, under this part, an operator must:

(a) Provide notice on the website or online service of what information it collects from children, how it uses such information, and its disclosure practices for such information (§ 312.4(b));

(b) Obtain verifiable parental consent prior to any collection, use, and/or disclosure of personal information from children (§ 312.5);

(c) Provide a reasonable means for a parent to review the personal information collected from a child and to refuse to permit its further use or maintenance (§ 312.6);

(d) Not condition a child's participation in a game, the offering of a prize, or another activity on the child disclosing more personal information than is reasonably necessary to participate in such activity (§ 312.7); and

(e) Establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of personal information collected from children (§ 312.8).

§ 312.4 Notice.

(a) *General principles of notice.* All notices under §§ 312.3(a) and 312.5 must be clearly and understandably written, be complete, and must contain no unrelated, confusing, or contradictory materials.

(b) *Notice on the website or online service.* Under § 312.3(a), an operator of a website or online service directed to children must post a link to a notice of its information practices with regard to children on the home page of its website or online service and at each area on the website or online service where personal information is collected from children. An operator of a general audience website or online service that has a separate children's area or site must post a link to a notice of its information practices with regard to children on the home page of the children's area.

(1) *Placement of the notice.* (i) The link to the notice must be clearly labeled as a notice of the website or online service's information practices with regard to children;

(ii) The link to the notice must be placed in a clear and prominent place and manner on the home page of the website or online service; and

(iii) The link to the notice must be placed in a clear and prominent place and manner at each area on the website or online service where children directly provide, or are asked to provide, personal information, and in close proximity to the requests for information in each such area.

(2) *Content of the notice.* To be complete, the notice of the website or online service's information practices must state the following:

(i) The name, address, telephone number, and e-mail address of all operators collecting or maintaining personal information from children through the website or online service. *Provided that:* the operators of a website or online service may list the name, address, phone number, and e-mail address of one operator who will respond to all inquiries from parents concerning the operators' privacy policies and use of children's information, as long as the names of all the operators collecting or maintaining personal information from children through the website or online service are also listed in the notice;

(ii) The types of personal information collected from children and whether the personal information is collected directly or passively;

(iii) How such personal information is or may be used by the operator(s), including but not limited to fulfillment of a requested transaction, recordkeeping, marketing back to the child, or making it publicly available through a chat room or by other means;

(iv) Whether personal information is disclosed to third parties, and if so, the types of business in which such third parties are engaged, and the general purposes for which such information is used; whether those third parties have agreed to maintain the confidentiality, security, and integrity of the personal information they obtain from the operator; and that the parent has the option to consent to the collection and use of their child's personal information without consenting to the disclosure of that information to third parties;

(v) That the operator is prohibited from conditioning a child's participation in an activity on the child's disclosing more personal information than is reasonably necessary to participate in such activity; and

(vi) That the parent can review and have deleted the child's personal information, and refuse to permit further collection or use of the child's information, and state the procedures for doing so.

(c) *Notice to a parent.* Under § 312.5, an operator must make reasonable efforts, taking into account available technology, to ensure that a parent of a child receives notice of the operator's practices with regard to the collection, use, and/or disclosure of the child's personal information, including notice of any material change in the collection, use, and/or disclosure practices to which the parent has previously consented.

(1) *Content of the notice to the parent.* (i) All notices must state the following:

(A) That the operator wishes to collect personal information from the child;

(B) The information set forth in paragraph (b) of this section.

(ii) In the case of a notice to obtain verifiable parental consent under § 312.5(a), the notice must also state that the parent's consent is required for the collection, use, and/or disclosure of such information, and state the means by which the parent can provide verifiable consent to the collection of information.

(iii) In the case of a notice under the exception in § 312.5(c)(3), the notice must also state the following:

(A) That the operator has collected the child's e-mail address or other online contact information to respond to the child's request for information and that the requested information will require more than one contact with the child;

(B) That the parent may refuse to permit further contact with the child and require the deletion of the information, and how the parent can do so; and

(C) That if the parent fails to respond to the notice, the operator may use the information for the purpose(s) stated in the notice.

(iv) In the case of a notice under the exception in § 312.5(c)(4), the notice must also state the following:

(A) That the operator has collected the child's name and e-mail address or other online contact information to protect the safety of the child participating on the website or online service;

(B) That the parent may refuse to permit the use of the information and require the deletion of the information, and how the parent can do so; and

(C) That if the parent fails to respond to the notice, the operator may use the information for the purpose stated in the notice.

§ 312.5 Parental consent.

(a) *General requirements.* (1) An operator is required to obtain verifiable parental consent before any collection, use, and/or disclosure of personal information from children, including consent to any material change in the collection, use, and/or disclosure practices to which the parent has previously consented.

(2) An operator must give the parent the option to consent to the collection and use of the child's personal information without consenting to disclosure of his or her personal information to third parties.

(b) *Mechanisms for verifiable parental consent.* (1) An operator must make reasonable efforts to obtain verifiable parental consent, taking into consideration available technology. Any method to obtain verifiable parental consent must be reasonably calculated, in light of available technology, to ensure that the person providing consent is the child's parent.

(2) Methods to obtain verifiable parental consent that satisfy the requirements of this paragraph include: providing a consent form to be signed by the parent and returned to the operator by postal mail or facsimile; requiring a parent to use a credit card in connection with a transaction; having a parent call a toll-free telephone number staffed by trained personnel; using a digital certificate that uses public key technology; and using e-mail accompanied by a PIN or password obtained through one of the verification methods listed in this paragraph. *Provided that:* For the period until April 21, 2002, methods to obtain verifiable parental consent for uses of information other than the ''disclosures'' defined by § 312.2 may also include use of e-mail coupled with additional steps to provide assurances that the person providing the consent is the parent. Such additional steps include: sending a confirmatory e-mail to the parent following receipt of consent; or obtaining a postal address or telephone number from the parent and confirming the parent's consent by letter or telephone call. Operators who use such methods must provide notice that the parent can revoke any consent given in response to the earlier e-mail.

(c) *Exceptions to prior parental consent.* Verifiable parental consent is required prior to any collection, use and/or disclosure of personal information from a child except as set forth in this paragraph. The exceptions to prior parental consent are as follows:

(1) Where the operator collects the name or online contact information of a parent or child to be used for the sole purpose of obtaining parental consent or providing notice under § 312.4. If the operator has not obtained parental consent after a reasonable time from the date of the information collection, the operator must delete such information from its records;

(2) Where the operator collects online contact information from a child for the sole purpose of responding directly on a one-time basis to a specific request from the child, and where such information is not used to recontact the child and is deleted by the operator from its records;

(3) Where the operator collects online contact information from a child to be used to respond directly more than once to a specific request from the child, and where such information is not used for any other purpose. In such cases, the operator must make reasonable efforts, taking into consideration available technology, to ensure that a parent receives notice and has the opportunity to request that the operator make no further use of the information, as described in § 312.4(c), immediately after the initial response and before making any additional response to the child. Mechanisms to provide such notice include, but are not limited to, sending the notice by postal mail or sending the notice to the parent's e-mail address, but do not include asking a child to print a notice form or sending an e-mail to the child;

(4) Where the operator collects a child's name and online contact information to the extent reasonably necessary to protect the safety of a child participant on the website or online service, and the operator usesd reasonable efforts to provide a parent notice as described in § 312.4(c), where such information is:

(i) Used for the sole purpose of protecting the child's safety;

(ii) Not used to recontact the child or for any other purpose;

(iii) Not disclosed on the website or online service; and

(5) Where the operator collects a child's name and online contact information and such information is not used for any other purpose, to the extent reasonably necessary:

(i) To protect the security or integrity of its website or online service;

(ii) To take precautions against liability;

(iii) To respond to judicial process; or

(iv) To the extent permitted under other provisions of law, to provide information to law enforcement agencies or for an investigation on a matter related to public safety.

§ 312.6 Right of parent to review personal information provided by a child.

(a) Upon request of a parent whose child has provided personal information to a website or online service, the operator of that website or online service is required to provide to that parent the following:

(1) A description of the specific types or categories of personal information collected from children by the operator, such as name, address, telephone number, e-mail address, hobbies, and extracurricular activities;

(2) The opportunity at any time to refuse to permit the operator's further use or future online collection of personal information from that child, and to direct the operator to delete the child's personal information; and

(3) Notwithstanding any other provision of law, a means of reviewing any personal information collected from the child. The means employed by the operator to carry out this provision must:

(i) Ensure that the requestor is a parent of that child, taking into account available technology; and

(ii) Not be unduly burdensome to the parent.

(b) Neither an operator nor the operator's agent shall be held liable under any Federal or State law for any disclosure made in good faith and following reasonable procedures in responding to a request for disclosure of personal information under this section.

(c) Subject to the limitations set forth in § 312.7, an operator may terminate any service provided to a child whose parent has refused, under paragraph (a)(2) of this section, to permit the operator's further use or collection of personal information from his or her child or has directed the operator to delete the child's personal information.

§ 312.7 Prohibition against conditioning a child's participation on collection of personal information.

An operator is prohibited from conditioning a child's participation in a game, the offering of a prize, or another activity on the child's disclosing more personal information than is reasonably necessary to participate in such activity.

§ 312.8 Confidentiality, security, and integrity of personal information collected from children.

The operator must establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of personal information collected from children.

§ 312.9 Enforcement.

Subject to sections 6503 and 6505 of the Children's Online Privacy Protection Act of 1998, a violation of a regulation prescribed under section 6502 (a) of this Act shall be treated as a violation of a rule defining an unfair or deceptive act or practice prescribed under section 18(a)(1)(B) of the Federal Trade Commission Act (15 U.S.C. 57a(a)(1)(B)).

§ 312.10 Safe harbors.

(a) *In general.* An operator will be deemed to be in compliance with the requirements of this part if that operator complies with self-regulatory guidelines, issued by representatives of the marketing or online industries, or by other persons, that, after notice and comment, are approved by the Commission.

(b) *Criteria for approval of self-regulatory guidelines.* To be approved by the Commission, guidelines must include the following:

(1) A requirement that operators subject to the guidelines (''subject operators'') implement substantially similar requirements that provide the same or greater protections for children as those contained in §§ 312.2 through 312.9;

(2) An effective, mandatory mechanism for the independent assessment of subject operators' compliance with the guidelines. This performance standard may be satisfied by:

(i) Periodic reviews of subject operators' information practices conducted on a random basis either by the industry group promulgating the guidelines or by an independent entity;

(ii) Periodic reviews of all subject operators' information practices, conducted either by the industry group promulgating the guidelines or by an independent entity;

(iii) Seeding of subject operators' databases, if accompanied by either paragraphs (b)(2)(i) or (b)(2)(ii) of this section; or

(iv) Any other equally effective independent assessment mechanism; and

(3) Effective incentives for subject operators' compliance with the guidelines. This performance standard may be satisfied by:

(i) Mandatory, public reporting of disciplinary action taken against subject operators by the industry group promulgating the guidelines;

(ii) Consumer redress;

(iii) Voluntary payments to the United States Treasury in connection with an industry-directed program for violators of the guidelines;

(iv) Referral to the Commission of operators who engage in a pattern or practice of violating the guidelines; or

(v) Any other equally effective incentive.

(4) The assessment mechanism required under paragraph (b)(2) of this section can be provided by an independent enforcement program, such as a seal program. In considering whether to initiate an investigation or to bring an enforcement action for violations of this part, and in considering appropriate remedies for such violations, the Commission will take into account whether an operator has been subject to self-regulatory guidelines approved under this section and whether the operator has taken remedial action pursuant to such guidelines, including but not limited to actions set forth in paragraphs (b)(3)(i) through (iii) of this section.

(c) *Request for Commission approval of self-regulatory guidelines.*

(1) To obtain Commission approval of self-regulatory guidelines, industry groups or other persons must file a request for such approval. A request shall be accompanied by the following:

(i) A copy of the full text of the guidelines for which approval is sought and any accompanying commentary;

(ii) A comparison of each provision of §§ 312.3 through 312.8 with the corresponding provisions of the guidelines; and

(iii) A statement explaining:

(A) How the guidelines, including the applicable assessment mechanism, meet the requirements of this part; and

(B) How the assessment mechanism and compliance incentives required under paragraphs (b)(2) and (3) of this section provide effective enforcement of the requirements of this part.

(2) The Commission shall act upon a request under this section within 180 days of the filing of such request and shall set forth its conclusions in writing.

(3) Industry groups or other persons whose guidelines have been approved by the Commission must submit proposed changes in those guidelines for review and approval by the Commission in the manner required for initial approval of guidelines under paragraph (c)(1). The statement required under paragraph (c)(1)(iii) must describe how the proposed changes affect existing provisions of the guidelines.

(d) *Records.* Industry groups or other persons who seek safe harbor treatment by compliance with guidelines that have been approved under this part shall maintain for a period not less than three years and upon request make available to the Commission for inspection and copying:

(1) Consumer complaints alleging violations of the guidelines by subject operators;

(2) Records of disciplinary actions taken against subject operators; and

(3) Results of the independent assessments of subject operators' compliance required under paragraph (b)(2) of this section.

(e) *Revocation of approval.* The Commission reserves the right to revoke any approval granted under this section if at any time it determines that the approved self-regulatory guidelines and their implementation do not, in fact, meet the requirements of this part.

§ 312.11 Rulemaking review.

No later than April 21, 2005, the Commission shall initiate a rulemaking review proceeding to evaluate the implementation of this part, including the effect of the implementation of this part on practices relating to the collection and disclosure of information relating to children, children's ability to obtain access to information of their choice online, and on the availability of websites directed to children; and report to Congress on the results of this review.

§ 312.12 Severability.

The provisions of this part are separate and severable from one another. If any provision is stayed or determined to be invalid, it is the Commission's intention that the remaining provisions shall continue in effect.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 99–27740 Filed 11–2–99; 8:45 am]

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federal register

Wednesday
November 3, 1999

Part IV

Department of Health and Human Services

Office of the Secretary

45 CFR Parts 160 Through 164

Standards for Privacy of Individually Identifiable Health Information; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 160 through 164

RIN 0991–AB08

Standards for Privacy of Individually Identifiable Health Information

AGENCY: Office of the Assistant Secretary for Planning and Evaluation, DHHS.

ACTION: Proposed rule.

SUMMARY: This rule proposes standards to protect the privacy of individually identifiable health information maintained or transmitted in connection with certain administrative and financial transactions. The rules proposed below, which would apply to health plans, health care clearinghouses, and certain health care providers, propose standards with respect to the rights individuals who are the subject of this information should have, procedures for the exercise of those rights, and the authorized and required uses and disclosures of this information.

The use of these standards would improve the efficiency and effectiveness of public and private health programs and health care services by providing enhanced protections for individually identifiable health information. These protections would begin to address growing public concerns that advances in electronic technology in the health care industry are resulting, or may result, in a substantial erosion of the privacy surrounding individually identifiable health information maintained by health care providers, health plans and their administrative contractors. This rule would implement the privacy requirements of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996.

DATES: Comments will be considered if received as provided below, no later than 5 p.m. on January 3, 2000.

ADDRESSES: Submit electronic comments at the following web site: http://aspe.hhs.gov/admnsimp/.

Mail comments (1 original, 3 copies, and, if possible, a floppy disk) to the following address: U.S. Department of Health and Human Services, Assistant Secretary for Planning and Evaluation, Attention: Privacy-P, Room G–322A, Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201.

If you prefer, you may deliver your written comments (1 original, 3 copies, and, if possible, a floppy disk) to the following address: Room 442E, 200 Independence Avenue, SW, Washington, DC 20201.

See the **SUPPLEMENTARY INFORMATION** section for further information on comment procedures, availability of copies of this document and electronic access to this document.

FOR FURTHER INFORMATION CONTACT: Roxanne Gibson (202) 260–5083.

SUPPLEMENTARY INFORMATION: Comment procedures, availability of copies, and electronic access.

Comment procedures: All comments should include the full name, address and telephone number of the sender or a knowledgeable point of contact. Written comments should include 1 original and 3 copies. If possible, please send an electronic version of the comments on a 3½ inch DOS format floppy disk in Adobe Acrobat Portable Document Format (PDF) (preferred) HTML (preferred), ASCII text, or popular word processor format (Microsoft word, Corel WordPerfect).

Because of staffing and resource limitations, we cannot accept comments by electronic mail or facsimile (FAX) transmission, and all comments and content are to be limited to the 8.5 wide by 11.0 high vertical (also referred to as ''portrait'') page orientation. Additionally, it is requested that if identical/duplicate comment submissions are submitted both electronically and in paper form that each submission clearly indicate that it is a duplicate submission. In each comment, please specify the section of this proposed rule to which the comment applies.

Comments received in a timely fashion will be available for public inspection (by appointment), as they are received, generally beginning approximately three weeks after publication of a document in Room 442E of the Department's offices at 200 Independence Avenue, SW., Washington, DC 20201 on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: 202–260–5083).

After the close of the comment period, comments submitted electronically and written comments that we are technically able to convert will be posted on the Administrative Simplification web site (http://aspe.hhs.gov/admnsimp/).

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, PO Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by fax to (202) 512–2250. The cost for each copy is $8.00. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

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I. Background

A. Need for Privacy Standards.

[*Please label comments about this section with the subject: ''Need for privacy standards''*]

The maintenance and exchange of individually identifiable health information is an integral component of the delivery of quality health care. In order to receive accurate and reliable diagnosis and treatment, patients must provide health care professionals with accurate, detailed information about their personal health, behavior, and other aspects of their lives. Health care providers, health plans and health care clearinghouses also rely on the provision of such information to accurately and promptly process claims for payment and for other administrative functions that directly affect a patient's ability to receive needed care, the quality of that care, and the efficiency with which it is delivered.

Individuals who provide information to health care providers and health plans increasingly are concerned about how their information is used within the health care system. Patients want to know that their sensitive information will be protected not only during the course of their treatment but also in the future as that information is maintained and/or transmitted within and outside of the health care system. Indeed, a Wall Street Journal/ABC poll on September 16, 1999 asked Americans what concerned them most in the coming century. ''Loss of personal privacy'' was the first or second concern of 29 percent of respondents. All other issues, such a terrorism, world war, and global warming had scores of 23 percent or less.

Efforts to provide legal protection against the inappropriate use of individually identifiable health

information have been, to date, undertaken primarily by the States. States have adopted a number of laws designed to protect patients against the inappropriate use of health information. A recent survey of these laws indicates, however, that these protections are quite uneven and leave large gaps in their protection. See Health Privacy Project, ''The State of Health Privacy: An Uneven Terrain,'' Institute for Health Care Research and Policy, Georgetown University (July 1999) (http://www.healthprivacy.org).

A clear and consistent set of privacy standards would improve the effectiveness and the efficiency of the health care system. The number of entities who are maintaining and transmitting individually identifiable health information has increased significantly over the last 10 years. In addition, the rapid growth of integrated health care delivery systems requires greater use of integrated health information systems. The expanded use of electronic information has had clear benefits for patients and the health care system as a whole. Use of electronic information has helped to speed the delivery of effective care and the processing of billions of dollars worth of health care claims. Greater use of electronic data has also increased our ability to identify and treat those who are at risk for disease, conduct vital research, detect fraud and abuse, and measure and improve the quality of care delivered in the U.S.

The absence of national standards for the confidentiality of health information has, however, made the health care industry and the population in general uncomfortable about this primarily financially driven expansion in the use of electronic data. Many plans, providers, and clearinghouses have taken steps to safeguard the privacy of individually-identifiable health information. Yet they must currently rely on a patchwork of State laws and regulations that are incomplete and, at times, inconsistent. The establishment of a consistent foundation of privacy standards would, therefore, encourage the increased and proper use of electronic information while also protecting the very real needs of patients to safeguard their privacy.

The use of these standards will most clearly benefit patients who are, in increasing numbers, indicating that they are apprehensive about the use and potential use of their health information for inappropriate purposes. A national survey released in January 1999 indicated that one-fifth of Americans already believe that their personal health information has been used inappropriately. See California HealthCare Foundation, ''National Survey: Confidentiality of Medical Records,'' January 1999 (conducted by Princeton Survey Research Associates) (http://www.chcf.org). Of even greater concern, one-sixth of respondents indicated that they had taken some form of action to avoid the misuse of their information, including providing inaccurate information, frequently changing physicians, or avoiding care. The use of these standards will help to restore patient confidence in the health care system, providing benefits to both patients and those who serve them.

In order to administer their plans and provide services, private and public health plans, health care providers, and health care clearinghouses must assure their customers (such as patients, insurers, providers, and health plans) that the health care information they collect, maintain, use, or transmit will remain confidential. The protection of this information is particularly important where it is individually identifiable. Individuals have an important and legitimate interest in the privacy of their health information, and that interest is threatened where there is improper use or disclosure of the information. The risk of improper uses and disclosures has increased as the health care industry has begun to move from primarily paper-based information systems to systems that operate in various electronic forms. The ease of information collection, organization, retention, and exchange made possible by the advances in computer and other electronic technology afford many benefits to the health care industry and patients. At the same time, these advances have reduced or eliminated many of the logistical obstacles that previously served to protect the confidentiality of health information and the privacy interests of individuals.

Congress recognized the need for minimum national health care privacy standards to protect against inappropriate use of individually identifiable health information by passing the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191, which called for the enactment of a privacy statute within three years of the date of enactment. The legislation also called for the Secretary of Health and Human Services to develop and send to the Congress recommendations for protecting the confidentiality of health care information, which she did on September 11, 1997. The Congress further recognized the importance of such standards by providing the Secretary of Health and Human Services with authority to promulgate health privacy regulations in lieu of timely action by the Congress. The need for patient privacy protection also was recognized by the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry in its recommendations for a Consumer Bill of Rights and Responsibilities (November, 1997).

B. Statutory Background.

[*Please label comments about this section with the subject: ''Statutory background''*]

The Congress addressed the opportunities and challenges presented by the health care industry's increasing use of and reliance on electronic technology in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191, which was enacted on August 21, 1996. Sections 261 through 264 of HIPAA are known as the Administrative Simplification provisions. The major part of these Administrative Simplification provisions are found at section 262 of HIPAA, which enacted a new part C of title XI of the Social Security Act (hereinafter we refer to the Social Security Act as the ''Act'' and we refer to all other laws cited in this document by their names).

In section 262, Congress recognized and sought to facilitate the efficiencies and cost savings for the health care industry that the increasing use of electronic technology affords. Thus, section 262 directs HHS to issue standards to facilitate the electronic exchange of information with respect to financial and administrative transactions carried out by health plans, health care clearinghouses, and health care providers who transmit electronically in connection with such transactions. HHS proposed such standards in a series of Notices of Proposed Rulemaking (NPRM) published on May 7, 1998 (63 FR 25272 and 25320), and June 16, 1998 (63 FR 32784). At the same time, Congress recognized the challenges to the confidentiality of health information presented by the advances in electronic technology and communication. Section 262 thus also directs HHS to develop standards to protect the security, including the confidentiality and integrity, of such information. HHS issued an NPRM proposing security standards on August 12, 1998 (63 FR 43242).

Congress has recognized that privacy standards must accompany the electronic data interchange standards and that the increased ease of transmitting and sharing individually

identifiable health information must be accompanied by an increase in the privacy and confidentiality. In fact, a significant portion of the first Administrative Simplification section that was debated on the floor of the Senate in 1994 (as part of the Health Security Act) was made up of privacy provision. Although the requirement for the issuance of concomitant privacy standards remained as part of the bill passed by the House of Representatives, in conference the requirement for privacy standards was removed from the standard-setting authority of title XI (section 1173 of the Act) and placed in a separate section of HIPAA, section 264. Subsection (b) of section 264 required the Secretary of HHS to develop and submit to the Congress recommendations for:

(1) The rights that an individual who is a subject of individually identifiable health information should have.

(2) The procedures that should be established for the exercise of such rights.

(3) The uses and disclosures of such information that should be authorized or required.

The Secretary's Recommendations were submitted to the Congress on September 11, 1997, and are summarized below. Section 264(c)(1) provides that:

If legislation governing standards with respect to the privacy of individually identifiable health information transmitted in connection with the transactions described in section 1173(a) of the Social Security Act (as added by section 262) is not enacted by (August 21, 1999), the Secretary of Health and Human Services shall promulgate final regulations containing such standards not later than (February 21, 2000). Such regulations shall address at least the subjects described in subsection (b).

As the Congress did not enact legislation governing standards with respect to the privacy of individually identifiable health information prior to August 21, 1999, HHS has now, in accordance with this statutory mandate, developed proposed rules setting forth standards to protect the privacy of such information.

These privacy standards have been, and continue to be, an integral part of the suite of Administrative Simplification standards intended to simplify and improve the efficiency of the administration of our health care system.

Part C of title XI consists of sections 1171 through 1179 of the Act. These sections define various terms and impose several requirements on HHS, health plans, health care clearinghouses, and health care providers who conduct the identified transactions electronically.

The first section, section 1171 of the Act, establishes definitions for purposes of part C of title XI for the following terms: code set, health care clearinghouse, health care provider, health information, health plan, individually identifiable health information, standard, and standard setting organization.

Section 1172 of the Act makes the standard adopted under part C applicable to: (1) Health plans, (2) health care clearinghouses, and (3) health care providers who transmit health information in electronic form in connection with transactions referred to in section 1173(a)(1) of the Act (hereinafter referred to as the ''covered entities''). Section 1172 also contains requirements concerning the adoption of standards, including the role of standard setting organizations and required consultations, summarized below.

Section 1173 of the Act requires the Secretary to adopt standards for transactions, and data elements for such transactions, to enable health information to be exchanged electronically. Section 1173(a)(1) describes the transactions that are covered, which include the nine transactions listed in section 1173(a)(2) and other transactions determined appropriate by the Secretary. The remainder of section 1173 sets out requirements for the specific standards the Secretary is to adopt: unique health identifiers, code sets, security standards, electronic signatures, and transfer of information among health plans. Of particular relevance to this proposed rule is section 1173(d), the security standard provision. The security standard authority applies to both the transmission and the maintenance of health information and requires the entities described in section 1172(a) to maintain reasonable and appropriate safeguards to ensure the integrity and confidentiality of the information, protect against reasonably anticipated threats or hazards to the security or integrity of the information or unauthorized uses or disclosures of the information, and to ensure compliance with part C by the entity's officers and employees.

In section 1174 of the Act, the Secretary is required to establish standards for all of the above transactions, except claims attachments, by February 21, 1998. A proposed rule for most of the transactions was published in 1998 with the final rule expected by the end of 1999. The delay was caused by the deliberate consensus building process working with industry and the large number of comments received (about 17,000).

Generally, after a standard is established, it may not be changed during the first year after adoption except for changes that are necessary to permit compliance with the standard. Modifications to any of these standards may be made after the first year, but not more frequently than once every 12 months. The Secretary also must ensure that procedures exist for the routine maintenance, testing, enhancement and expansion of code sets and that there are crosswalks from prior versions.

Section 1175 of the Act prohibits health plans from refusing to process, or from delaying processing of, a transaction that is presented in standard format. It also establishes a timetable for compliance: each person to whom a standard or implementation specification applies is required to comply with the standard within 24 months (or 36 months for small health plans) of its adoption. A health plan or other entity may, of course, comply voluntarily before the effective date. The section also provides that compliance with modifications to standards or implementation specifications must be accomplished by a date designated by the Secretary, which date may not be earlier than 180 days from the notice of change.

Section 1176 of the Act establishes civil monetary penalties for violation of the provisions in part C of title XI of the Act, subject to several limitations. Penalties may not be more than $100 per person per violation and not more than $25,000 per person for violations of a single standard for a calendar year. The procedural provisions of section 1128A of the Act apply to actions taken to obtain civil monetary penalties under this section.

Section 1177 establishes penalties for any person that knowingly uses a unique health identifier, or obtains or discloses individually identifiable health information in violation of the part. The penalties include: (1) A fine of not more than $50,000 and/or imprisonment of not more than 1 year; (2) if the offense is ''under false pretenses,'' a fine of not more than $100,000 and/or imprisonment of not more than 5 years; and (3) if the offense is with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, a fine of not more than $250,000 and/or imprisonment of not more than 10 years. We note that these penalties do not affect any other penalties that may be imposed by other federal programs.

Under section 1178 of the Act, the requirements of part C, as well as any standards or implementation specifications adopted thereunder, preempt contrary State law. There are three exceptions to this general rule of preemption: State laws that the Secretary determines are necessary for certain purposes set forth in the statute; State laws that the Secretary determines address controlled substances; and State laws relating to the privacy of individually identifiable health information that are contrary to and more stringent than the federal requirements. There also are certain areas of State law (generally relating to public health and oversight of health plans) that are explicitly carved out of the general rule of preemption and addressed separately.

Section 1179 of the Act makes the above provisions inapplicable to financial institutions or anyone acting on behalf of a financial institution when ''authorizing, processing, clearing, settling, billing, transferring, reconciling, or collecting payments for a financial institution.'' Finally, as explained above, section 264 requires the Secretary to issue standards with respect to the privacy of individually identifiable health information transmitted in connection with the transactions described in section 1173(a)(1). Section 264 also contains a preemption provision that provides that contrary provisions of State laws that are more stringent than the federal standards, requirements, or implementation specifications will not be preempted.

C. Administrative Costs

Section 1172(b) of the Act provides that ''(a)ny standard adopted under this part (part C of title XI of the Act) shall be consistent with the objective of reducing the administrative costs of providing and paying for health care.'' As is more fully discussed in the Regulatory Impact and Regulatory Flexibility analyses below, we recognize that the proposed privacy standards would entail substantial initial and ongoing administrative costs for entities subject to the rules. However, as the analyses also indicate, even if the rules proposed below are considered in isolation, they should produce administrative and other cost savings that should more than offset such costs on a national basis. It is also the case that the privacy standards, like the security standards authorized by section 1173(d) of the Act, are necessitated by the technological advances in information exchange that the remaining Administrative Simplification standards facilitate for the health care industry. The same technological advances that make possible enormous administrative cost savings for the industry as a whole have also made it possible to breach the security and privacy of health information on a scale that was previously inconceivable. The Congress recognized that adequate protection of the security and privacy of health information is a *sine qua non* of the increased efficiency of information exchange brought about by the electronic revolution, by enacting the security and privacy provisions of the law. Thus, even if the rules proposed below were to impose net costs, which we do not believe they do, they would still be ''consistent with'' the objective of reducing administrative costs for the health care system as a whole.

D. Consultations

[*Please label comments about this section with the subject: ''Consultations''*]

The Congress explicitly required the Secretary to consult with specified groups in developing the standards under sections 262 and 264. Section 264(d) of HIPAA specifically requires the Secretary to consult with the National Committee on Vital and Health Statistics (NCVHS) and the Attorney General in carrying out her responsibilities under the section. Section 1172(b)(3) of the Act, which was enacted by section 262, requires that, in developing a standard under section 1172 for which no standard setting organization has already developed a standard, the Secretary must, before adopting the standard, consult with the National Uniform Billing Committee (NUBC), the National Uniform Claim Committee (NUCC), the Workgroup for Electronic Data Interchange (WEDI), and the American Dental Association (ADA). Section 1172(f) also requires the Secretary to rely on the recommendations of the NCVHS and consult with other appropriate federal and State agencies and private organizations.

We engaged in the required consultations including the Attorney General, NUBC, NUCC, WEDI and the ADA. We consulted with the NCVHS in developing the Recommendations, upon which this proposed rule is based. In addition we are continuing to consult with this committee by requesting the committee to review this proposed rule and provide comments, and recommendations will be taken into account in developing the final regulation. We consulted with representatives of the National Congress of American Indians, the National Indian Health Board, and the self governance tribes. We also met with representatives of the National Governors' Association, the National Conference of State Legislatures, the National Association of Public Health Statistics and Information Systems, and a number of other State organizations to discuss the framework for the proposed rule, issues of special interests to the States, and the process for providing comments on the proposed rule.

In addition to the required consultations, we met with numerous individuals, entities, and agencies regarding the regulation, with the goal of making these standards as compatible as possible with current business practices, while still enhancing privacy protection. Relevant federal agencies participated in an interagency working group, with additional representatives from all operating divisions and many staff offices of HHS. The following federal agencies and offices were represented on the interagency working group: the Department of Justice, the Department of Commerce, the Social Security Administration, the Department of Defense, the Department of Veterans Affairs, the Department of Labor, the Office of Personnel Management, and the Office of Management and Budget. The interagency working group developed the policies of the proposed rules set forth below.

E. Summary and Purpose of the Proposed Rule

[*Please label comments about this section with the subject: ''Summary and purpose''*]

The following outlines the provisions and operations of this proposed rule and is intended to provide a framework for the following preamble. A more detailed discussion of the authority, rationale, and implementation can be found in Section II of the preamble, Provisions of the Proposed Rule.

As described in more detail in preamble section I.B, above, the HIPAA requires the Secretary of HHS to promulgate a series of standards relating to the electronic exchange of health information. Collectively these are known as the Administrative Simplification provisions. In addition to those standards, the Secretary was required to develop and submit to the Congress recommendations for the privacy rights that an individual who is a subject of individually identifiable health information should have, the procedures that should be established for the exercise of such rights, and the

uses and disclosures of such information that should be authorized.

On September 11, 1997, the Secretary presented to the Congress her Recommendations for protecting the ''Confidentiality of Individually-Identifiable Health Information'' (the ''Recommendations''), as required by section 264 (a) of HIPAA. In those Recommendations, the Secretary called for new federal legislation to create a national floor of standards that provide fundamental privacy rights for patients, and that define responsibilities for those who use and disclose identifiable health information.

The Recommendations elaborated on the components that should be included in privacy legislation. These components included new restrictions on the use and disclosure of health information, the establishment of new consumer rights, penalties for misuse of information, and redress for those harmed by misuse of their information. The Recommendations served, to the extent possible under the HIPAA legislative authority, as a template for the rules proposed below. They are available on the HHS website at http://aspe.hhs.gov/admnsimp/pvcrec.htm.

The Secretary's Recommendations set forth the a framework for federal privacy legislation. Such legislation should:

- Allow for the smooth flow of identifiable health information for treatment, payment, and related operations, and for specified additional purposes related to health care that are in the public interest.
- Prohibit the flow of identifiable information for any additional purposes, unless specifically and voluntarily authorized by the subject of the information.
- Put in place a set of fair information practices that allow individuals to know who is using their health information, and how it is being used.
- Establish fair information practices that allow individuals to obtain access to their records and request amendment of inaccurate information.
- Require persons who hold identifiable health information to safeguard that information from inappropriate use or disclosure.
- Hold those who use individually identifiable health information accountable for their handling of this information, and to provide legal recourse to persons harmed by misuse.

We believed then, and still believe, that there is an urgent need for legislation to establish comprehensive privacy standards for all those who pay and provide for health care, and those who receive information from them.

This proposed rule implements many of the policies set forth in the Recommendations. However, the HIPAA legislative authority is more limited in scope than the federal statute we recommend, and does not always permit us to propose the policies that we believe are optimal. Our major concerns with the scope of the HIPAA authority include the limited number of entities to whom the proposed rule would be applicable, and the absence of strong enforcement provisions and a private right of action for individuals whose privacy rights are violated.

The Recommendations call for legislation that applies to health care providers and payers who obtain identifiable health information from individuals and, significantly, to those who receive such information from providers and payers. The Recommendations follow health information from initial creation by a health plan or health care provider, through various uses and disclosures, and would establish protections at each step: ''We recommend that everyone in this chain of information handling be covered by the same rules.'' However, the HIPAA limits the application of our proposed rule to health plans, health care clearinghouses, and to any health care provider who transmits health information in electronic form in connection with transactions referred to in section 1173(a)(1) of the Act (the ''covered entities''). Unfortunately, this leaves many entities that receive, use and disclose protected health information outside of the system of protection that we propose to create.

In particular, the proposed regulation does not directly cover many of the persons who obtain identifiable health information from the covered entities. In this proposed rule we are, therefore, faced with creating new regulatory permissions for covered entities to disclose health information, but cannot directly put in place appropriate restrictions on how many likely recipients of such information may use and re-disclose such information. For example, the Secretary's Recommendations proposed that protected health information obtained by researchers not be further disclosed except for emergency circumstances, for a research project that meets certain conditions, and for oversight of research. In this proposed rule, however, we cannot impose such restrictions. Additional examples of persons who receive this information include workers compensation carriers, researchers, life insurance issuers, employers and marketing firms. We also do not have the authority to directly regulate many of the persons that covered entities hire to perform administrative, legal, accounting, and similar services on their behalf, and who would obtain health information in order to perform their duties. This inability to directly address the information practices of these groups leaves an important gap in the protections provided by the proposed rule.

In addition, only those providers who engage in the electronic administrative simplification transactions can be covered by this rule. Any provider who maintains a solely paper information system would not be subject to these privacy standards, thus leaving another gap in the system of protection we propose to create.

The need to match a regulation limited to a narrow range of covered entities with the reality of information sharing among a wide range of entities leads us to consider limiting the type or scope of the disclosures permitted under this regulation. The disclosures we propose to allow in this rule are, however, necessary for smooth operation of the health care system and for promoting key public goals such as research, public health, and law enforcement. Any limitation on such disclosures could do more harm than good.

Requirements to protect individually identifiable health information must be supported by real and significant penalties for violations. We recommend federal legislation that would include punishment for those who misuse personal health information and redress for people who are harmed by its misuse. We believe there should be criminal penalties (including fines and imprisonment) for obtaining health information under false pretenses, and for knowingly disclosing or using protected health information in violation of the federal privacy law. We also believe that there should be civil monetary penalties for other violations of the law and that any individual whose rights under the law have been violated, whether negligently or knowingly, should be permitted to bring an action for actual damages and equitable relief. Only if we put the force of law behind our rhetoric can we expect people to have confidence that their health information is protected, and ensure that those holding health information will take their responsibilities seriously.

In HIPAA, Congress did not provide such enforcement authority. There is no private right of action for individuals to enforce their rights, and we are concerned that the penalty structure

does not reflect the importance of these privacy protections and the need to maintain individuals' trust in the system. For these and other reasons, we continue to call for federal legislation to ensure that privacy protection for health information will be strong and comprehensive.

1. Applicability

a. *Entities covered.* Under section 1172(a) of the Act, the provisions of this proposed rule apply to health plans, health care clearinghouses, and to any health care provider who transmits health information in electronic form in connection with transactions referred to in section 1173(a)(1) of the Act (the ''covered entities''). The terms health plan, health care provider, and health care clearinghouse are defined in proposed § 160.103.

As noted above, because we do not have the authority to apply these standards directly to any entity that is not a covered entity, the proposed rule does not directly cover many of the persons who obtain identifiable health information from the covered entities. Examples of persons who receive this information include contractors, third-party administrators, researchers, public health officials, life insurance issuers, employers and marketing firms. We would attempt to fill this gap in our legislative authority in part by requiring covered entities to apply many of the provisions of rule to the entities with whom they contract for administrative and other services. The proposed provision is outlined in more detail below in the discussion of business partners.

b. *Protected health information.* We propose to apply the requirements of this rule to the subset of individual identifiable health information which is maintained or transmitted by covered entities and which is or has been in electronic form. The provisions of the rule would apply to the information itself, referred to as protected health information in this rule, and not to the particular records in which the information is contained. Once information has been maintained or transmitted electronically by a covered entity, the protections would follow the information in whatever form, including paper records, in which it exists (while it is held by a covered entity).

We understand that our proposal would create a situation in which some health information would be protected while other similar information (e.g., health information contained in paper records that has not been maintained or transmitted electronically) would not be protected. We are concerned about the potential confusion that such a system might entail, but we believe that applying the provisions of the rule to information only in electronic form would result in no real protection for health care consumers. We have requested comment on whether we should extend the scope of the rule to all individually identifiable health information, including purely paper records, maintained by covered entities. Although we are concerned that extending our regulatory coverage to all records might be inconsistent with the intent of the provisions in the HIPAA, we believe that we do have the authority to do so and that there are sound rationale for providing a consistent level of protection to all individually identifiable health information held by covered entities.

2. General Rules

The purpose of our proposal is to define and limit the circumstances in which an individual's protected heath information may be used or disclosed by others. We are proposing to make the use and exchange of protected health information relatively easy for health care purposes, and more difficult for purposes other than health care.

Covered entities would be prohibited from using or disclosing protected health information except as provided in the proposed rule. Under the rule, covered entities could use or disclose protected health information with individual authorization, as provided in proposed § 164.508. Covered entities could use or disclose protected health information without authorization for treatment, payment and health care operations, as provided in § 164.506(a). (The terms ''treatment,'' ''payment'' and ''health care operations'' are defined in proposed § 164.504). Covered entities also would be permitted to use or disclose a patient's protected health information without authorization for specified public and public policy-related purposes, including public health, research, health oversight, law enforcement, and use by coroners, as provided in proposed § 164.510. Covered entities would be permitted to use and disclose protected health information when required to do so by other law, such as mandatory reporting under state law or pursuant to a search warrant.

Covered entities would be required by this rule to disclose protected health information for only two purposes: to permit individuals to inspect and copy protected health information about them, pursuant to proposed § 164.514, and for enforcement of this rule pursuant to proposed § 164.522.

Under our proposal, most uses and disclosures of an individual's protected health information would not require explicit authorization by the individual, but would be restricted by the provisions of the rule. As discussed in section II.C. of this preamble, we propose to substitute regulatory protections for the pro forma authorizations that are used today. The rules would create a sphere of privacy protection that includes covered entities who engage in treatment or payment, and the business partners they hire to assist them. While written consent for these activities would not be required, new restrictions on both internal uses and external disclosures would be put in place to protect the information.

Our proposal is based on the principle that a combination of strict limits on how plans and providers can use and disclose identifiable health information, adequate notice to patients about how such information will be used, and patients' rights to inspect, copy and amend protected health information about them, will provide patients with better privacy protection and more effective control over the dissemination of their information than alternative approaches to patient protection and control.

A central aspect of this proposal is the principle of ''minimum necessary'' disclosure. (See proposed § 164.506(a)). With certain exceptions, permitted uses and disclosures of protected health information would be restricted to the minimum amount of information necessary to accomplish the purpose for which the information is used or disclosed, taking into consideration practical and technological limitations (including the size and nature of the covered entity's business) and costs. While we recognize that there are legitimate uses of protected health information for which patient authorization should not be required, the privilege of this access carries with it an obligation to safeguard the information. Covered entities would be required to take steps to limit the amount of protected health information used or disclosed to the information necessary to meet the purpose of the use or disclosure. These policies could include limiting access to the information to a subset of employees who need to use the information in the course of their work, and limiting the amount of information disclosed from a record to the information needed by the recipient to fulfill the purpose of the disclosure.

We propose that individuals be able to request that a covered entity restrict the protected health information that

results from that encounter (with the exception of encounters for emergency treatment) from further use or disclosure for treatment, payment, and health care operations. (See proposed § 164.506(c)). Covered entities would not be required to agree to restrictions requested by individuals; the rule would only enforce a restriction that has been agreed to by the covered entity and the individual.

Today's health care system is a complex business involving multiple individuals and organizations engaging in a variety of commercial relationships. An individual's privacy should not be compromised when a covered entity engages in such normal business relationships. To accomplish this result, the rule would, with narrow exceptions, require covered entities to ensure that the business partners with which they share protected health information understand—through contract requirements '' that they are subject to standards regarding use and disclosure of protected health information and agree to abide by such rules. (See proposed § 164.506(e)). Other than for purposes of treatment consultation or referral, we would require a contract to exist between the covered entity and the business partner that would, among other specified provisions, limit the business partner's uses and disclosures of protected health information to those permitted by the contract and would impose certain security, inspection and reporting requirements on the business partner.

We do not intend to interfere with business relationships in the health care industry, but rather to ensure that the privacy of the information shared in these relationships is protected. Business partners would not be permitted to use or disclose protected health information in ways that would not be permitted by the covered entity itself.

3. Scalability

The privacy standards would need to be implemented by all covered entities, from the smallest provider to the largest, multi-state health plan. For this reason, we propose the privacy principles and standards that covered entities must meet, but leave the detailed policies and procedures for meeting these standards to the discretion of each covered entity. We intend that implementation of these standards be flexible and scalable, to account for nature of each covered entity's business, as well as the covered entity's size and resources. A single approach to implementation of these requirements would be neither economically feasible nor effective in safeguarding health information privacy. Instead, we would require that each covered entity assess its own needs and devise and implement privacy policies appropriate to its size, its information practices, and its business requirements. Examples of how implementation of these standards are scalable are provided in the relevant sections of this preamble. (See, also, the discussion in preamble sections II.C. and III.)

4. Uses and Disclosures With Individual Authorization

The rule would require that covered entities have authorization from individuals before using or disclosing their protected health information for any purpose not otherwise recognized by this rule. In § 164.508, we propose rules for obtaining authorizations. Authorizations are needed in a wide array of circumstances. Entities not covered by this rule often want access to individually identifiable health information . For example, a potential employer may require health information as part of a background check for security purposes, or the patient may request a plan or provider to disclose information to obtain eligibility for disability benefits or to an attorney for use in a law suit. Covered entities may also seek such an authorization in order to use protected health information for a purpose not otherwise permitted under this rule. For example, a health plan may wish to use a person's records for developing a marketing strategy.

The proposed authorization requirements are intended to ensure that an individual's authorization is truly voluntary. We would prohibit covered entities from conditioning treatment or payment on the individual agreeing to disclose information for other purposes. We also would require authorizations to clearly and specifically describe the information to be disclosed. If an authorization is sought so that a covered entity may sell, barter, or otherwise exchange the information for purposes other than treatment, payment, or health care operations, the covered entity would have to disclose this fact on the authorization form. We would also require authorizations to be revocable. We do not seek to limit the purposes for which authorization of records disclosure may be sought, but rather to ensure that these authorizations are voluntary, fair, and enforceable.

While the provisions of this proposed rule are intended to make authorizations for treatment and payment purposes unnecessary, some States may continue to require them. This rule would not supersede such State requirements generally, but would impose a new requirement that such State-mandated authorizations must be physically separate from an authorization for other purposes described in this rule.

5. Uses and Disclosures for Treatment, Payment and Health Care Operations

Under this rule, covered entities with limited exceptions would be permitted to use and disclose protected health information without individual authorization for treatment and payment purposes, and for related purposes that we have defined as health care operations. (See § 164.506.) We would construe the terms ''treatment'' and ''payment'' broadly. In section II.B. of this preamble, we describe the types of activities that would be considered health care operations.

6. Permissible Uses and Disclosures for Purposes Other Than Treatment, Payment and Health Care Operations

Individually identifiable health information is needed to support certain national priority activities, such as reducing health care fraud, improving the quality of treatment through research, protecting the public health, and responding to emergency situations. In many cases, the need to obtain authorization for use of health information would create significant obstacles in efforts to fight crime, understand disease, and protect public health. We examined the many uses that the health professions, related industries, and the government make of health information and we are aware of the concerns of privacy and consumer advocates about these uses.

After balancing privacy and other social values, we are proposing rules that would permit use or disclosure of health information without individual authorization for the following national priority activities and activities that allow the health care system to operate smoothly:

- Oversight of the health care system
- Public health functions
- Research
- Judicial and administrative proceedings
- Law enforcement
- Emergency circumstances
- To provide information to next-of-kin
- For identification of the body of a deceased person, or the cause of death
- For government health data systems
- For facility patient directories
- To banks, to process health care payments and premiums
- For management of active duty military and other special classes of individuals

• Where other law requires such disclosure and no other category of permissible disclosures would allow the disclosure

The rule would specify conditions that would need to be met in order for the use or disclosure of protected health information to be permitted for each of these purposes. (See § 164.514) We have proposed conditions tailored to the need for each type of use or disclosure, and to the types of organizations involved in each such activity. These uses and disclosures, and the conditions under which they may occur, are discussed in section II. F of this preamble.

The uses and disclosures that would be permitted under proposed rule would be just that—permissible. Thus, for disclosures that are not compelled by other law, providers and payers would be free to disclose or not, according to their own policies and ethical principles. We propose these rules as a basic set of legal controls, but ethics and professional practice may dictate more guarded disclosure policies. At the same time, nothing in this rule would provide authority for a covered entity to restrict or refuse to make a disclosure mandated by other law.

7. Individual Rights

We are proposing to establish several basic rights for individuals with respect to their protected health information. We propose that individuals be able to obtain access to protected health information about them, which would include a right to inspect and obtain a copy of such information. See proposed § 164.514. The right of access would extend to an accounting of disclosures of the protected health information for purposes other than treatment, payment, and health care operations. See proposed § 164.515.

In § 164.512, we also propose that individuals have a right to receive a written notice of information practices from covered entities. While the primary purpose of this notice would be to inform individuals about the uses and disclosures that a covered entity would intend to make with the information, the notice also would serve to limit the activities of the covered entity—an otherwise lawful use or disclosure that does not appear in the entity's notice would not be permitted. The covered entity's uses and disclosures could be stated in broad terms, but an entity would not be able to make a use or disclosure that is not included in its notice. The covered entity could modify its notice at any time and apply revised practices to existing and new information held by the covered entity.

In addition, we propose that individuals have the right to request amendment or correction of protected health information that is inaccurate or incomplete. See proposed § 164.516. We are proposing procedural requirements and deadlines to implement each of these individual rights.

8. Administrative Requirements and Policy Development and Documentation

In our Recommendations, we call for a federal law that requires holders of identifiable health information to implement safeguards to protect it from inappropriate access, use or disclosure. No legislation or rule can effectively specify how to do this for every holder of health information. But federal rules can and should require those who hold identifiable health information to develop and implement basic administrative procedures to protect that information and protect the rights of the individual with respect to that information.

To accomplish this goal, we propose that covered entities be required to designate a privacy official, develop a privacy training program for employees, implement safeguards to protect health information from intentional or accidental misuse, provide some means for individuals to lodge complaints about the covered entity's information practices, and develop a system of sanctions for employees and business partners who violate the entity's policies or procedures. (See proposed § 164.518.). We also propose, in § 164.520, to require covered entities to maintain documentation of their policies and procedures for complying with the requirements of this proposed rule. The purpose of these requirements is to ensure that covered entities make explicit decisions about who would have access to protected health information, how that information would be used within the entity, and when that information would or would not be disclosed to other entities.

9. Preemption

The HIPAA provides that the rule promulgated by the Secretary may not preempt state laws that are in conflict with the regulatory requirements and that provide greater privacy protections. The HIPAA also provides that standards issued by the Secretary will not supercede certain other State laws, including: State laws relating to reporting of disease or injury, child abuse, birth or death, public health surveillance, or public health investigation or intervention; State regulatory reporting; State laws which the Secretary finds are necessary to prevent fraud and abuse, to ensure appropriate State regulation of insurance, for State reporting on health care delivery or costs, or for other purposes; or, State laws which the Secretary finds address controlled substances. These provisions are discussed in more detail in preamble section II.I.1.

This proposed rule also must be read in conjunction with other federal laws and regulations that address the use and disclosure of health information. These issues are discussed in preamble section II.I.2.

In general, the rule that we are proposing would create a federal floor of privacy protection, but would not supercede other applicable law that provide greater protection to the confidentiality of health information. In general, our rule would not make entities subject to a state laws to which they are not subject today.

10. Enforcement

The HIPAA grants the Secretary the authority to impose civil monetary penalties against covered entities which fail to comply with the requirements of this rule, and also establishes criminal penalties for certain wrongful disclosures of protected health information. The civil fines are capped at $25,000 for each calendar year for each provision that is violated. The criminal penalties are graduated, increasing if the offense is committed under false pretenses, or with intent to sell the information or reap other personal gain. The statute does not provide for a private right of action for individuals.

We propose to create a complaint system to permit individuals to make complaints to the Secretary about potential violations of this rule. We also propose that covered entities develop a process for receiving complaints from individuals about the entities' privacy practices. (See § 164.522.) Our intent would be to work with covered entities to achieve voluntary compliance with the proposed standards.

11. Conclusion

Although the promise of these proposed standards cannot become reality for many patients because of the gaps in our authority, we believe they would provide important new protections. By placing strict boundaries around the ways covered entities could use and disclose information, these rules would protect health information at its primary sources: health plans and health care providers. By requiring covered entities to inform patients about how their information is being used and

shared, by requiring covered entities to provide access to that information, and by ensuring that authorizations would be truly voluntary, these rules would provide patients with important new tools for understanding and controlling information about them. By requiring covered entities to document their privacy practices, this rule would focus attention on the importance of privacy, and reduce the ways in which privacy is compromised through inattention or misuse.

With the Secretary's recommendations and these proposed rules, we are attempting to further two important goals: to allow the free flow of health information needed to provide and promote high quality health care, while assuring that individuals' health information is properly protected. We seek a balance that permits important uses of information privacy of people who seek care and healing. We believe our Recommendations find that balance, and have attempted to craft this proposed rule to strike that balance as well.

We continue to believe, however, that federal legislation is the best way to guarantee these protections. The HIPAA legislative authority does not allow full implementation of our recommended policies in this proposed rule. The legislation limits the entities that can be held responsible for their use of protected health information, and the ways in which the covered entities can be held accountable. For these and other reasons, we continue to call upon Congress to pass comprehensive federal privacy legislation. Publication of this proposed rule does not diminish our firm conviction that such legislation should be enacted as soon as possible.

II. Provisions of the Proposed Rule

We propose to establish a new subchapter C to title 45 of the Code of Federal Regulations. Although the rules proposed below would only establish two new parts (parts 160 and 164), we anticipate the new subchapter C will eventually contain three parts, part 160, 162, and 164, with parts 161 and 163 being reserved for future expansion, if needed. Part 160 will contain general requirements and provisions applicable to all of the regulations issued under sections 262 and 264 of Public Law 104–191 (the Administrative Simplification provisions of HIPAA). We anticipate that Part 162 will contain the Administrative Simplification regulations relating to transactions, code sets and identifiers. The new part 164 will encompass the rules relating to the security standards authorized by section 1173(d), the electronic signature standard authorized by section 1173(e), and the privacy rules proposed below.

The new part 164 will be composed of two subparts: subparts A and E, with B, C, and D being reserved. Subpart A will consist of general provisions and subpart E will consist of the final privacy rules. Because the new part 160 will apply to the privacy rules, as well as the other Administrative Simplification rules, it is set out below.

A. Applicability

[*Please label comments about this section with the subject: ''Applicability''*]

The discussion below describes the entities and the information that would be subject to the proposed regulation.

1. Covered Entities

The standards in this proposed regulation would apply to all health plans, all health care clearinghouses, and all health care providers that transmit health information in an electronic form in connection with a standard transaction. In this proposed rule, these entities are referred to as ''covered entities.'' See definition at proposed § 160.103.

A health plan is defined by section 1171 to be an individual or group plan that provides for, or pays the cost of, medical care. The statute expressly includes a significant group of employee welfare benefit plans, state-regulated insurance plans, managed care plans, and essentially all government health plans, including Medicare, Medicaid, the veterans health care program, and plans participating in the Federal Employees Health Benefits Program. See discussion of the definition in section II.B.

A health care provider would be a provider of services as defined in section 1861(u) of the Act, 42 U.S.C. 1395x, a provider of medical or other health services as defined in section 1861(s) of the Act, and any other person who furnishes, bills or is paid for health care services or supplies in the normal course of business. See discussion of the definition in section II.B. Health care providers would be subject to the provisions of the rule if they transmit health information in electronic form in connection with a standard transaction. Standard transactions include claims and equivalent encounter information, eligibility and enrollment transactions, premium payments, claims attachments, and others. See proposed § 160.103. Health care providers who themselves do not directly conduct electronic transactions would become subject to the provisions of the proposed rule if another entity, such as a billing agent or hospital, transmits health information in electronic form in connection with a standard transaction on their behalf.

A health care clearinghouse would be a public or private entity that processes or facilitates the processing of nonstandard data elements of health information into standard data elements. See section 1171(2) of the Act. For purposes of this rule, we would consider billing services, repricing companies, community health management information systems or community health information systems, ''value-added'' networks, switches and similar organizations to be health care clearinghouses for purposes of this part only if they actually perform the same functions as a health care clearinghouse. See discussion of the definition in section II.B.

2. Covered Information

We propose to apply the standards in this proposed regulation to individually identifiable health information that is or has been electronically transmitted or maintained by a covered entity, including such information when it is in non-electronic form (e.g., printed on paper) or discussed orally. In this proposed regulation, such information is referred to as ''protected health information.'' See discussion of the definition in section II.B. Under HIPAA, our authority to promulgate privacy standards extends to all individually identifiable health information, in any form, maintained or transmitted by a covered entity. For reasons discussed below, we are proposing to limit the application of the proposed standards to protected health information. Below we invite comment on whether we should apply the standards to a broader set of individually identifiable health information in the future.

Under the proposal, the standards apply to information, not to specific records. Thus, once protected health information is transmitted or maintained electronically, the protections afforded by this regulation would apply to the information in any form and continue to apply as the information is printed, discussed orally or otherwise changed in form. It would also apply to the original paper version of information that is at some point transmitted electronically. The authority for, and implications of, this scope are discussed in detail in this section, below.

This proposed regulation would not apply to information that has never been electronically maintained or transmitted by a covered entity.

a. *Legislative authority.* Under HIPAA, we have authority to promulgate a

privacy standard that applies to all individually identifiable health information transmitted or maintained by a covered entity, including information in a non-electronic form. We recognize that there may be an expectation that we would apply privacy standards only to information that is electronically maintained and transmitted. Our prior proposals under HIPAA have addressed only electronically maintained and transmitted information. See Notices of Proposed Rulemaking (NPRM) published on May 7, 1998 (63 FR 25272 and 25320), June 16, 1998 (63 FR 32784), and the proposed security standards published on August 12, 1998 (63 FR 43242).

In considering the appropriate reach of the proposed privacy standards, however, we determined that limiting the standards to electronic information would not be consistent with the requirement in HIPAA for the Secretary to address privacy, confidentiality and security concerns relating to individually identifiable health information.

The HIPAA statute, taken as a whole, contemplates an information protection system that assures the privacy, confidentiality and integrity of health information. Two provisions in subtitle F of HIPAA address privacy and confidentiality concerns: section 264, titled ''Recommendations with Respect to Privacy of Certain Health Information'' and section 1173(d), titled ''Security Standards for Health Information.'' See 42 U.S.C. 1320d–1320d–8, enacted as sections 262 and 264 of HIPAA.

In enacting HIPAA, Congress recognized that the increased accessibility of health information made possible by the widespread and growing use of electronic media and the new federal mandate for increased standardization of data, requires enhanced privacy and confidentiality protections. The House Report links privacy and security concerns stating: ''The standards adopted would protect the privacy and confidentiality of health information. Health information is considered relatively ''safe'' today, not because it is secure, but because it is difficult to access. These standards improve access and establish strict privacy protections.'' House Report No. 496, 104th Cong., 2d. Sess., at 99.

Section 264(c) authorizes the Secretary to protect the privacy of individually identifiable health information transmitted in connection with the standard transactions. Section 1173(d) authorizes the Secretary to prescribe requirements that address the security, integrity, and confidentiality of health information maintained or transmitted, in any form or medium, by the covered entities.

Neither the privacy authority in section 264(c) nor the security authority in 1173(d) exclusively limit the scope of protection to electronic information. Section 264(c) of HIPAA requires the Secretary to issue a regulation setting privacy standards for individually identifiable health information ''transmitted in connection with the transactions described in section 1173(a).'' This statutory language is not on its face limited to electronic transmissions of individually identifiable health information, although electronic transmissions of such information are clearly within its scope. Moreover, the section requires the regulations to address ''at least'' the subjects of the Secretary's Recommendations, which focus on individually identifiable health information, without reference to whether the information is electronic or not.

The security provision also is not limited by its terms to electronically maintained information. Rather, section 1173(d) applies throughout to ''health information,'' a statutorily defined term that clearly covers information in both its electronic and non-electronic forms.

In HIPAA, when Congress intended to limit health information to its electronic form, it did so explicitly. Section 1172(a)(3) of the statute says that the standards apply to health plans and to health care providers who transmit health information *in electronic form* in connection with the standard transactions (emphasis added); by contrast, the section 1173(d) requirements for information maintained or transmitted are not similarly qualified.

Further support for the premise that the standards may reach information that is maintained or transmitted non-electronically is found within section 1173(d) itself. That section explicitly distinguishes within one subsection (§ 1173(d)(1)(A)) between ''record systems used to maintain health information'' and ''*computerized* record systems.'' Thus, the conclusion may be drawn that the record systems covered by the § 1173(d) security standards are intended to include record systems other than those that are exclusively electronic or ''computerized.''

Finally, the section that generally defines the HIPAA standard transactions, section 1173(a), is not limited by its terms to transactions that are electronic. Rather, although all of the transactions described can be performed electronically, all take paper and some take oral forms as well. Indeed, the purpose of the standards, including the security and privacy standards, is stated as ''to enable electronic exchange.'' This purpose would not preclude (and in fact would support) requirements that relate to non-electronic media where they support the overall goal of enabling electronic information exchange. Thus, we believe that the statute authorizes a privacy regulation covering health information in any form or medium maintained or transmitted by the covered entities.

Although we believe that HIPAA authorizes the Secretary to issue regulations covering individually identifiable health information in any form, the proposed privacy standards in this NPRM are directed to protecting only individually identifiable health information that is or at some point has been electronically maintained or transmitted by a covered entity. Those standards do not cover health information that has never been in electronic form.

We are proposing this approach because we believe that it focuses most directly on the primary concern raised by HIPAA: the fact that growing use of computerization in health care, including the rapid growth of electronic transfers of health information, gives rise to a substantial concern about the confidentiality of the health care information that is part of this growing electronic commerce. At the same time, could not adequately address the confidentiality concerns associated with electronic transfers of health information unless we address the resulting uses and disclosures of such information, in whatever form. Indeed, the protection offered by this standard would be devoid of meaning if all non-electronic records and transmissions were excluded. In that event, access to ''protected'' health information would become merely a matter of obtaining the information in a paper or oral form. Such a narrow reading of the statute would lead to a system in which individually identifiable health information transmitted as part of a claim would be protected only until the information was printed or read aloud, at which point protection would disappear. Previously protected information could be freely printed and redistributed, regardless of limits on further electronic redistribution. The statutory language does not compel such an anomalous result.

In developing our proposal, we considered other approaches for determining the information that would be subject to the privacy standards. We

considered but rejected limiting the scope of the proposal to information in electronic form. For the reasons discussed above, such a narrow interpretation would render the standards nearly meaningless. We also considered applying the privacy standards to all individually identifiable health information in any form maintained or transmitted by a covered entity. There are clear advantages to this approach, including permitting covered entities to treat all individually identifiable health information under the same standards. We rejected that approach in favor of our proposed approach which we believe is more focused at the public concerns over health information confidentiality in an electronic communications age. We also were concerned about imposing additional burden with respect to health information that was less likely to present privacy concerns: paper records that are never reduced to electronic form are less likely to become disseminated broadly throughout the health care system. We invite comment on the approach that we are proposing and on whether alternate approaches to determining the health information that would be subject to this regulation would be more appropriate.

We also considered making use of other statutory authorities under which we impose general operating or management conditions for programs (e.g., Medicare, grant programs) to enhance these proposed privacy protections. Doing so could enable us to apply these privacy standards to a wider range of entities than are currently affected, such as health care providers who do not transmit standard transactions electronically. We use many other authorities now to impose confidentiality and privacy requirements, although the current rules lack consistency. It is not clear whether using these other authorities would create more uniform protections or expanded enforcement options. Therefore we request comment on the concept of drawing on other authorities to amplify the protections of these privacy standards.

b. *Application to records containing protected and unprotected health information.* Once transmitted or maintained electronically, protected health information is often mixed with unprotected health information in the same record. For example, under the proposed rules, information from a medical record that is electronically transmitted by a provider to a health plan and then returned to the original record would become protected health information, even though the rest of the information contained in the paper record may not be subject to these privacy rules.

We reiterate that under the proposed rule, the protections would apply to the information itself, not to the particular record in which it is contained or transmitted. Therefore, an entity could not maintain duplicate records and only apply the protections to the information contained in the record that is electronically maintained or transmitted. For example, once an individual's name and diagnostic code is transmitted electronically between covered entities (or business partners), that information must be protected by both the transmitting and receiving entities in every record, written, electronic or other, in which it appears.

We recognize that this approach may require some additional administrative attention to mixed records (records containing protected and unprotected health information) to ensure that the handling of protected health information conforms with these regulations. We considered ways to limit application of these protections to avoid such potential administrative concerns. However, these regulations would have little effect if not applicable to otherwise protected health information simply because it was combined with unprotected health information—any information could be lawfully disclosed simply by including some additional information. Likewise, these regulations would have no meaning if entities could then avoid applying the protections merely by maintaining separate duplicate records. A way to limit these rules to avoid application to mixed information without sacrificing basic protections is not apparent.

Unlike the potential issues inherent in the protection of oral information, there may be relatively simple ways to reduce possible confusion in protecting mixed records. The risk of inappropriate use or disclosure of protected health information in a mixed record can be eliminated simply by handling all information in mixed records as if it were protected. It also may be possible to develop a ''watermark'' analogous to a copyright label, designating which written information is protected. We welcome comments on how best to protect information in mixed records, without creating unnecessary administrative burdens.

Finally, we recognize that these rules may create awkward boundaries and enforcement ambiguities, and seek comment on how best to reduce these ambiguities while maintaining the basic protections mandated by the statute.

3. Interaction With Other Standards

The privacy standards in this proposed regulation would be closely integrated with other standards that have been proposed under the HIPAA Administrative Simplification title. This is particularly true with respect to the proposed security standards published on August 12, 1998 (63 FR 43242).

We understand that we are proposing a broader scope of applicability with respect to covered information under these privacy standards than we have previously proposed under the security standard. We intend to solicit additional comments regarding the scope of information that should be addressed under the security standard in the near future.

We also recognize that in this NPRM we are publishing slightly different definitions for some of the concepts that were defined in previously published NPRMs for the other standards. The differences resulted from the comments received on the previous NPRMs as well as the conceptual work done in the development of this NPRM. As we publish the final rules, we will bring all the definitions into conformance.

4. References to Other Laws

The provisions we propose in this rule would interact with numerous other laws. For example, proposed § 164.510 provides standards for certain uses or disclosures that are permitted in this rule, and in some cases references activities that are authorized by other applicable law, such as federal, State, tribal or territorial laws. In cases where this rule references ''law'' or ''applicable law'' we intend to encompass all applicable laws, decisions, rules, regulations, administrative procedures or other actions having the effect of law. We do not intend to exclude any applicable legal requirements imposed by a governmental body authorized to regulate in a given area. Where particular types of law are at issue, such as in the proposed provisions for preemption of State laws in subpart B of part 160, or permitted disclosures related to the Armed Forces in § 164.510(m), we so indicate by referring to the particular type of law in question (e.g., ''State law'' or ''federal law'').

When we describe an action as ''authorized by law,'' we mean that a legal basis exists for the activity. The phrase ''authorized by law'' is a term of art that includes both actions that are permitted and actions that are required by law. When we specifically discuss an action that is ''required'' or ''mandated,'' we mean that a law compels (or conversely, prohibits) the performance

of the activity in question. For example, in the health oversight context, disclosure of health information pursuant to a valid Inspector General subpoena, grand jury subpoena, civil investigative demand, or a statute or regulation requiring production of information justifying a claim would constitute a disclosure required by law.

B. Definitions. (§§ 160.103 and 164.504)

[*Please label comments about this section with the subject: ''Definitions''*]

Section 1171 of the Act defines several terms and our proposed rules would, for the most part, simply restate the law or adopt definitions previously defined in the other HIPAA proposed rules. In some instances, we propose definitions from the Secretary's Recommendations. We also propose some new definitions for convenience and efficiency of exposition, and others to clarify the application and operation of this rule. We describe the proposed definitions and discuss the rationale behind them, below.

Most of the definitions would be defined in proposed §§ 160.103 and 164.504. The definitions at proposed § 160.103 apply to all Administrative Simplification standards, including this privacy rule and the security standard. The definitions proposed in § 164.504 would apply only to this privacy rule. Certain other definitions are specific to particular sections of the proposed rule and are provided in those sections. The terms that are defined at proposed § 160.103 follow:

1. *Act*. We would define ''Act'' to mean the Social Security Act, as amended. This definition would be added for convenience.

2. *Covered entity*. This definition would be provided for convenience of reference and would mean the entities to which part C of title XI of the Act applies. These are the entities described in section 1172(a)(1): Health plans, health care clearinghouses, and health care providers who transmit any health information in electronic form in connection with a transaction referred to in section 1173(a)(1) of the Act (a ''standard transaction''). In the preamble we occasionally refer to health plans and the health care providers described above as ''covered plans,'' ''covered providers,'' or ''covered plans and providers.''

We note that health care providers who do not submit HIPAA transactions in standard form become covered by this rule when other entities, such as a billing service or a hospital, transmit standard electronic transactions on their behalf. The provider could not circumvent these requirements by assigning the task to its agent, since the agent would be deemed to be acting as the provider.

3. *Health care*. We would define the term ''health care'' as it is defined in the Secretary's Recommendations. Health care means the provision of care, services, or supplies to a patient and includes any: (1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, counseling, service, or procedure with respect to the physical or mental condition, or functional status, of a patient or affecting the structure or function of the body; (2) sale or dispensing of a drug, device, equipment, or other item pursuant to a prescription; or (3) procurement or banking of blood, sperm, organs, or any other tissue for administration to patients.

4. *Health care clearinghouse*. We would define ''health care clearinghouse'' as defined by section 1171(2) of the Act. The Act defines a ''health care clearinghouse'' as a ''public or private entity that processes or facilitates the processing of nonstandard data elements of health information into standard data elements.'' In practice, clearinghouses receive transactions from health care providers, health plans, other health care clearinghouses, or business partners of such entities, and other entities, translate the data from a given format into one acceptable to the entity receiving the transaction, and forward the processed transaction to that entity. There are currently a number of private clearinghouses that contract or perform this function for health care providers. For purposes of this rule, we would consider billing services, repricing companies, community health management information systems or community health information systems, ''value-added'' networks, switches and similar organizations to be health care clearinghouses for purposes of this part only if they actually perform the same functions as a health care clearinghouse.

We would note that we are proposing to exempt clearinghouses from a number of the provisions of this rule that would apply to other covered entities (see §§ 164.512, 164.514 and 164.516 below), because in most cases we do not believe that clearinghouses would be dealing directly with individuals. In many instances, clearinghouses would be considered business partners under this rule and would be bound by their contracts with covered plans and providers. See proposed § 164.506(e). We would adopt this position with the caveat that the exemptions would be void for any clearinghouse that had direct contact with individuals in a capacity other than that of a business partner.

5. *Health care provider*. Section 1171(3) of the Act defines ''health care provider'' as a ''provider of medical services as defined in section 1861(u) of the Act, a provider of medical or other health services as defined in section 1861(s) of the Act, and any other person who furnishes health care services or supplies.'' We are proposing to define ''health care provider'' as the Act does, and clarify that a health care provider is limited to any person or organization that furnishes, bills, or is paid for, health care services or supplies in the normal course of business. This definition would include a researcher who provides health care to the subjects of research, free clinics, and a health clinic or licensed health care professional located at a school or business.

Section 1861(u) of the Act contains the Medicare definition of a provider, which encompasses institutional providers, such as hospitals, skilled nursing facilities, home health agencies, and comprehensive outpatient rehabilitation facilities. Section 1861(s) of the Act defines other Medicare facilities and practitioners, including assorted clinics and centers, physicians, clinical laboratories, various licensed/certified health care practitioners, and suppliers of durable medical equipment. The last portion of the proposed definition encompasses appropriately licensed or certified health care practitioners or organizations, including pharmacies and nursing homes and many types of therapists, technicians, and aides. It also would include any other individual or organization that furnishes health care services or supplies in the normal course of business. An individual or organization that bills and/or is paid for health care services or supplies in the normal course of business, such as a group practice or an ''on-line'' pharmacy accessible on the Internet, is also a health care provider for purposes of this statute.

For a more detailed discussion of the definition of health care provider, we refer the reader to our proposed rule (Standard Health Care Provider Identifier) published on May 7, 1998, in the **Federal Register** (63 FR 25320).

6. *Health information*. We would define ''health information'' as it is defined in section 1171(4) of the Act. ''Health information'' would mean any information, whether oral or recorded in any form or medium, that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or

university, or health care clearinghouse; and that relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.

In this paragraph we attempt to clarify the relationship between the defined terms ''health information,'' ''individually identifiable health information'' and ''protected health information.'' The term ''health information'' encompasses the universe of information governed by the administrative simplification requirements of the Act. For example, under section 1173 of the Act, the Secretary is to adopt standards to enable the electronic exchange of all health information. However, protection of personal privacy is primarily a concern for the subset of health information that is ''individually identifiable health information,'' as defined by the Act (see below). For example, a tabulation of the number of students with asthma by school district would be health information, but since it normally could not be used to identify any individuals, it would not usually create privacy concerns. The definition of individually identifiable health information omits some of the persons or organizations that are described as creating or receiving ''health information.'' Some sections of the Act refer specifically to individually identifiable health information, such as section 1177 in setting criminal penalties for wrongful use or disclosure, and section 264 in requesting recommendations for privacy standards. Finally, we propose the phrase ''protected health information'' (§ 164.504) to refer to the subset of individually identifiable health information that is used or disclosed by the entities that are subject to this rule.

7. *Health plan*. We would define ''health plan'' essentially as section 1171(5) of the Act defines it. Section 1171 of the Act refers to several definitions in section 2791 of the Public Health Service Act, 42 U.S.C. 300gg–91, as added by Public Law 104–191. For clarity, we would incorporate the referenced definitions as currently stated into our proposed definitions.

As defined in section 1171(5), a ''health plan'' is an individual plan or group health plan that provides, or pays the cost of, medical care (see section 2791(a) of the Public Health Service Act (PHS Act)). This definition would include, but is not limited to, the 15 types of plans listed in the statute, as well as any combination of them. The term would include, when applied to public benefit programs, the component of the government agency that administers the program. Church plans and government plans are included to the extent that they fall into one or more of the listed categories.

Health plan'' includes the following singly or in combination:

a. ''Group health plan'' (as currently defined by section 2791(a) of the PHS Act). A group health plan is a plan that has 50 or more participants (as the term ''participant'' is currently defined by section 3(7) of ERISA) or is administered by an entity other than the employer that established and maintains the plan. This definition includes both insured and self-insured plans.

Section 2791(a)(1) of the PHS Act defines ''group health plan'' as an employee welfare benefit plan (as defined in current section 3(1) of ERISA) to the extent that the plan provides medical care, including items and services paid for as medical care, to employees or their dependents directly or through insurance, or otherwise.

b. ''Health insurance issuer'' (as currently defined by section 2791(b) of the PHS Act).

Section 2971(b) of the PHS Act defines a ''health insurance issuer'' as an insurance company, insurance service, or insurance organization that is licensed to engage in the business of insurance in a State and is subject to State law that regulates insurance.

c. ''Health maintenance organization'' (as currently defined by section 2791(b) of the PHS Act). Section 2791(b) of the PHS Act currently defines a ''health maintenance organization'' as a federally qualified health maintenance organization, an organization recognized as such under State law, or a similar organization regulated for solvency under State law in the same manner and to the same extent as such a health maintenance organization. These organizations may include preferred provider organizations, provider sponsored organizations, independent practice associations, competitive medical plans, exclusive provider organizations, and foundations for medical care.

d. Part A or Part B of the Medicare program (title XVIII of the Act).

e. The Medicaid program (title XIX of the Act).

f. A ''Medicare supplemental policy'' as defined under section 1882(g)(1) of the Act. Section 1882(g)(1) of the Act defines a ''Medicare supplemental policy'' as a health insurance policy that a private entity offers a Medicare beneficiary to provide payment for expenses incurred for services and items that are not reimbursed by Medicare because of deductible, coinsurance, or other limitations under Medicare. The statutory definition of a Medicare supplemental policy excludes a number of plans that are similar to Medicare supplemental plans, such as health plans for employees and former employers and for members and former members of trade associations and unions. A number of these health plans may be included under the definitions of ''group health plan'' or ''health insurance issuer,'' as defined in paragraphs ''a'' and ''b'' above.

g. A ''long-term care policy,'' including a nursing-home fixed indemnity policy. A ''long-term care policy'' is considered to be a health plan regardless of how comprehensive it is.

h. An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers. This includes plans that are referred to as multiple employer welfare arrangements (''MEWAs'').

i. The health care program for active military personnel under title 10 of the United States Code. See paragraph ''k'', below, for further discussion.

j. The veterans health care program under chapter 17 of title 38 of the United States Code. This health plan primarily furnishes medical care through hospitals and clinics administered by the Department of Veterans Affairs (VA) for veterans enrolled in the VA health care system.

k. The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) as defined in 10 U.S.C. 1072(4). We note that the Act's definition of ''health plan'' omits several types of health care provided by the Department of Defense (DOD). Sections 1171(5)(I) and 1171(5)(K) cover only the health care program for active duty personnel (see 10 U.S.C. 1074(a)) and the CHAMPUS program (see 10 U.S.C. 1079, 1086). What is omitted is health care provided in military treatment facilities to military retirees (see 10 U.S.C. 1074(b)), to dependents of active duty personnel and to dependents of retirees (see 10 U.S.C. 1076), to Secretarial designees such as members of Congress, Justices of the Supreme Court, and to foreign military personnel under NATO status of forces agreements. Health care provided by the DOD in military facilities to the aforementioned persons is not included as a ''health plan'' under HIPAA. However, these facilities would still be considered to be health care providers.

l. The Indian Health Service program under the Indian Health Care Improvement Act (25 U.S.C. 1601, *et.*

seq.). This program furnishes services, generally through its own health care providers, primarily to persons who are eligible to receive services because they are of American Indian or Alaskan Native descent.

m. The Federal Employees Health Benefits Program under 5 U.S.C. chapter 89. This program consists of health insurance plans offered to active and retired federal employees and their dependents. Although section 1171(5)(M) of the Act refers to the ''Federal Employees Health Benefit Plan,'' this and any other rules adopting administrative simplification standards will use the correct name, the Federal Employees Health Benefits Program. One health plan does not cover all federal employees; over 350 health plans provide health benefits coverage to federal employees, retirees, and their eligible family members. Therefore, we will use the correct name, The Federal Employees Health Benefits Program, to make clear that the administrative simplification standards apply to all health plans that participate in the Program.

n. An approved State child health plan for child health assistance that meets the requirements of section 2103 of the Act, which established the Children's Health Insurance Program (CHIP).

o. A Medicare Plus Choice organization as defined in 42 CFR 422.2, with a contract under 42 CFR part 422, subpart K.

p. Any other individual plan or group health plan, or combination thereof, that provides or pays for the cost of medical care. This category implements the language at the beginning of the statutory definition of the term ''health plan'': ''The term 'health plan' means an individual or group plan that provides, or pays the cost of, medical care * * * Such term includes the following, and any combination thereof * * *'' This statutory language is general, not specific. Moreover, the statement that the term ''health plan'' ''includes'' the specified plans implies that the term also covers other plans that meet the stated criteria. One approach to interpreting this introductory language in the statute would be to make coverage decisions about plans that may meet these criteria on a case-by-case basis. Instead we propose to clarify its coverage by adding this category to the proposed definition of ''health plan''; we seek public comment on its application. The Secretary would determine which plans that meet the criteria in the preceding paragraph are health plans for purposes of title II of HIPAA.

Consistent with the other parts of HIPAA, the provisions of this rule generally would not apply to certain types of insurance entities, such as workers' compensation and automobile insurance carriers, other property and casualty insurers, and certain forms of limited benefits coverage, even when such arrangements provide coverage for health care services. 29 U.S.C. 1186(c). We note that health care providers would be subject to the provisions of this rule with respect to the health care they provide to individuals, even if such providers seek or receive reimbursement from an insurance entity that is not a covered entity under these rules. However, nothing in this rule would be intended to prevent a health care provider from disclosing protected health information to a non-covered insurance entity for the purpose of obtaining payment for services. Further, under proposed § 164.510(n), this rule would permit disclosures by health care providers of protected health information to such insurance entities and to other persons when mandated by applicable law for the purposes of determining eligibility for coverage or benefits under such insurance arrangements. For example, a State workers' compensation law that requires disclosure of protected health information to an insurer or employer for the purposes of determining an individual's eligibility for medical or other benefits, or for the purpose of determining fitness for duty, would not be disturbed by this rule.

8. *Secretary*. This term means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated. It is provided for ease of reference.

9. *Small health plan*. The HIPAA does not define a ''small health plan,'' but instead explicitly leaves the definition to be determined by the Secretary. We propose to adopt the size classification used by the Small Business Administration. We would therefore define a ''small health plan'' as a health plan with annual receipts of $5 million or less. 31 CFR 121.201. This differs from the definition of ''small health plan'' in prior proposed Administrative Simplification rules. We will conform the definitions in the final Administrative Simplification rules.

10. *Standard*. The term ''standard'' would mean a prescribed set of rules, conditions, or requirements concerning classification of components, specification of materials, performance or operations, or delineation of procedures in describing products, systems, services, or practices. This definition is a general one, to accommodate the varying functions of the specific standards proposed in the other HIPAA regulations, as well as the rules proposed below.

11. *State*. This term would include the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, and Guam. This definition follows the statutory definition of ''State'' in section 1101(a) of the Act.

12. *Transaction*. We would define ''transaction,'' as we have done in other Administrative Simplification regulations, to mean the exchange of information between two parties to carry out financial or administrative activities related to health care. A transaction would be (1) any of the transactions listed in section 1173(a)(2) of the Act, and (2) any transaction determined appropriate by the Secretary in accordance with Section 1173(a)(1) of the Act.

A ''transaction'' would mean any of the following:

a. *Health claims or equivalent encounter information*. This transaction could be used to submit health care claim billing information, encounter information, or both, from health care providers to payers, either directly or via intermediary billers and claims clearinghouses.

b. *Health care payment and remittance advice*. This transaction could be used by a health plan to make a payment to a financial institution for a health care provider (sending payment only), to send an explanation of benefits remittance advice directly to a health care provider (sending data only), or to make payment and send an explanation of benefits remittance advice to a health car provider via a financial institution (sending both payment and data).

c. *Coordination of benefits*. This transaction could be used to transmit health care claims and billing payment information between payers with different payment responsibilities where coordination of benefits is required or between payers and regulatory agencies to monitor the furnishing, billing, and/or payment of health care services within a specific health care/insurance industry segment.

d. *Health claims status*. This transaction could be used by health care providers and recipients of health care products or services (or their authorized agents) to request the status of a health care claim or encounter from a health plan.

e. *Enrollment and disenrollment in a health plan*. This transaction could be used to establish communication

between the sponsor of a health benefit and the payer. It provides enrollment data, such as subscriber and dependents, employer information, and primary care health care provider information. A sponsor would be the backer of the coverage, benefit, or product. A sponsor could be an employer, union, government agency, association, or insurance company. The health plan would refer to an entity that pays claims, administers the insurance product or benefit, or both.

f. *Eligibility for a health plan.* This transaction could be used to inquire about the eligibility, coverage, or benefits associated with a benefit plan, employer, plan sponsor, subscriber, or a dependent under the subscriber's policy. It also could be used to communicate information about or changes to eligibility, coverage, or benefits from information sources (such as insurers, sponsors, and payers) to information receivers (such as physicians, hospitals, third party administrators, and government agencies).

g. *Health plan premium payments.* This transaction could be used by, for example, employers, employees, unions, and associations to make and keep track of payments of health plan premiums to their health insurers. This transaction could also be used by a health care provider, acting as liaison for the beneficiary, to make payment to a health insurer for coinsurance, copayments, and deductibles.

h. *Referral certification and authorization.* This transaction could be used to transmit health care service referral information between health care providers, health care providers furnishing services, and payers. It could also be used to obtain authorization for certain health care services from a health plan.

i. *First report of injury.* This transaction could be used to report information pertaining to an injury, illness, or incident to entities interested in the information for statistical, legal, claims, and risk management processing requirements.

j. *Health claims attachments.* This transaction could be used to transmit health care service information, such as subscriber, patient, demographic, diagnosis, or treatment data for the purpose of a request for review, certification, notification, or reporting the outcome of a health care services review.

k. *Other transactions as the Secretary may prescribe by regulation.* Under section 1173(a)(1)(B) of the Act, the Secretary may adopt standards, and data elements for those standards, for other financial and administrative transactions deemed appropriate by the Secretary. These transactions would be consistent with the goals of improving the operation of the health care system and reducing administrative costs.

In addition to the above terms, a number of terms are defined in proposed § 164.504, and are specific to the proposed privacy rules. They are as follows:

13. *Business partner.* This term would mean a person to whom a covered entity discloses protected health information so that the person can carry out, assist with the performance of, or perform on behalf of, a function or activity for the covered entity. Such term includes any agent, contractor or other person who receives protected health information from the covered entity (or from another business partner of the covered entity) for the purposes described in the previous sentence. It would not include a person who is an employee, a volunteer or other person associated with the covered entity on a paid or unpaid basis.

14. *Designated record set.* This term would be defined as a group of records under the control of a covered entity from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual, and which is used by the covered entity to make decisions about the individual. The concept of a ''designated record set'' is derived from the Privacy Act's concept of a ''system of records.'' Under the Privacy Act, federal agencies must provide an individual with access to ''information pertaining to him which is contained in [a system of records].'' 5 U.S.C. 552a(d)(1). A ''system of records'' is defined as ''a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.'' 5 U.S.C. 552a(a)(5). Under this rule, we would substitute the term ''covered entity'' for ''agency'' and limit the information to that used by the covered entity to make decisions about the individual.

We would define a ''record'' as ''any item, collection, or grouping of protected health information maintained, collected, used, or disseminated by a covered entity.'' Under the Privacy Act, ''the term 'record' means any item, collection, or grouping of information about an individual that is maintained by an agency, including, but not limited to, his education, financial transactions, medical history, and criminal or employment history and that contains his name, or the identifying number, symbol, or other identifying particular assigned to the individual, such as a finger or voice print or a photograph.'' 5 U.S.C. 552a(a)(4). For purposes of this rule we propose to limit the information to protected health information, as defined in this rule. ''Protected health information'' already incorporates the concept of identifiability, and therefore our definition of ''record'' is much simpler.

For health plans, designated record sets would include, at a minimum, the claims adjudication, enrollment, and patient accounting systems. For health care providers, designated record sets would include, at a minimum, the medical records and billing records. Designated record set would also include a correspondence system, a complaint system, or an event tracking system if decisions about individuals are made based, in whole or in part, on information in those systems. Files used to backup a primary data system or the sequential files created to transmit a batch of claims to a clearinghouse are clear examples of data files which would not fall under this definition.

We note that a designated record set would only exist for types of records that a covered entity actually ''retrieves'' by an identifier, and not records that are only ''retrievable'' by an identifier. In many cases, technology will permit sorting and retrieving by a variety of fields and therefore the ''retrievable'' standard would be relatively meaningless.

15. *Disclosure.* This term would be defined as the release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information.

16. *Health care operations.* We propose the term ''health care operations'' to clarify the activities we consider to be ''compatible with and directly related to'' treatment and payment and therefore would not require authorization from the individual for use or disclosure of protected health information.

Under our proposal, ''health care operations'' means the following services or activities if provided by or on behalf of a covered health plan or health care provider for the purposes of carrying out the management functions of such plan or provider necessary for the support of treatment or payment:

- Conducting quality assessment and improvement activities, including evaluating outcomes, and developing clinical guidelines;

• Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which undergraduate and graduate students and trainees in all areas of health care learn under supervision to practice as health care providers (e.g., residency programs, grand rounds, nursing practicums), accreditation, certification, licensing or credentialing activities;

• Insurance rating and other insurance activities relating to the renewal of a contract for insurance, including underwriting, experience rating, and reinsurance, but only when the individuals are already enrolled in the health plan conducting such activities and only when the use or disclosure of such protected health information relates to an existing contract of insurance (including the renewal of such a contract);

• Conducting or arranging for auditing services, including fraud and abuse detection and compliance programs; and

• Compiling and analyzing information in anticipation of, or for use in, civil or criminal legal proceedings.

Our definition proposes to limit health care operations to functions and activities performed by a health plan or provider or by a business partner on behalf of a health plan or a provider. Our definition anticipates that in order for treatment and payment to occur, protected health information would be used within entities, would be shared with business partners, and in some cases would be shared between covered entities (or their business partners). However, a health care operation should not result in protected health information being disclosed to an entity that is not the covered entity (or a business partner of such entity) on whose behalf the operation is being performed. For example, a health plan may request a health care provider to provide protected health information to the health plan, or to a business partner of the health plan, as part of an outcomes evaluation effort relating to providers affiliated with that plan. This would be a health care operation.

We are aware that the health care industry is changing and that these categories, though broad, may need to be modified to reflect different conditions in the future.

17. *Health oversight agency.* We would define the term ''health oversight agency'' as it is defined in the Secretary's Recommendations. See section II.E. below for further discussion.

18. *Individual.* We would define ''individual'' to mean the person who is the subject of protected health information. We would define the term to include, with respect to the signing of authorizations and other rights (such as access, copying, and correction), various types of legal representatives. The term would include court-appointed guardians or persons with a power of attorney, including persons making health care decisions for incapacitated persons, persons acting on behalf of a decedent's estate, where State or other applicable law authorizes such legal representatives to exercise the person's rights in such contexts, and parents subject to certain restrictions explained below. We would define this term to exclude foreign military and foreign diplomatic personnel and their dependents who receive health care provided or paid for by the DOD or other federal agency or entity acting on its behalf, and overseas foreign national beneficiaries of health care provided by the DOD or other federal agency, or non-governmental organization acting on its behalf.

a. *Disclosures pursuant to a power of attorney.* The definition of an individual would include legal representatives, to the extent permitted under State or other applicable law. We considered several issues in making this determination.

A ''power of attorney'' is a legal agreement through which a person formally grants authority to another person to make decisions on the person's behalf about financial, health care, legal, and/or other matters. In granting power of attorney, a person does not give up his or her own right to make decisions regarding the health care, financial, legal, or other issues involved in the legal agreement. Rather, he or she authorizes the other person to make these decisions as well.

In some cases, an individual gives another person power of attorney over issues not directly related to health care (e.g., financial matters) while informally relying on a third person (either implicitly or through verbal agreement) to make health care decisions on his or her behalf. In such situations, the person with power of attorney could seek health information from a health plan or provider in order to complete a task related to his or her power of attorney. For example, a person with financial power of attorney may request health information from a health plan or provider in order to apply for disability benefits on the individual's behalf.

In developing proposed rules to address these situations, we considered two options: (1) Allowing health plans and health care providers to disclose health information without authorization directly to the person with power of attorney over issues not directly related to health care; and (2) prohibiting health plans or health care providers from disclosing health information without authorization directly to such persons and stating that disclosure without authorization is permitted only to persons designated formally (through power of attorney for health care) or informally as the patient's health care decision-maker. We believe that both options have merit.

The first option recognizes that the responsibilities of persons with power of attorney often are broad, and that even when the power of attorney agreement does not relate directly to health care, the person with power of attorney at times has a legitimate need for health information in order to carry out his or her legal responsibility. The second option recognizes that when an individual is competent to make health care decisions, it is appropriate for him or her (or, if the individual wishes, for the informally designated health care decision maker) to decide whether the covered entity should disclose health information to someone with power of attorney over issues not directly related to health care.

In light of the fact that laws vary by State regarding power of attorney and that implementation of either option could be in the individual's interest, we would allow health plans and health care providers to disclose protected health information without authorization directly to persons with power of attorney to handle any issue on the individual's behalf, in accordance with State or other applicable laws regarding this issue.

This definition also accounts for situations in which a competent individual has granted one person power of attorney over health care issues yet, in practice, relies on another person to make health care decisions. We recognize that, by giving power of attorney for health care issues to one person and involving another person informally in making treatment decisions, the individual is, in the first instance, formally granting consent to release his or her health information and, in practice, granting consent to release medical information to the second person. Therefore, we would allow a health plan or provider, pursuant to State or other applicable law, to disclose protected health information without authorization to a person with power of attorney for the patient's health care and to a person

informally designated as the patient's health care decision maker.

b. *Disclosures pertaining to incapacitated individuals.* Covered entities would be permitted to disclose protected health information to any person making health care decisions for an incapacitated person under State or other applicable law. This definition defers to current laws regarding health care decision-making when a patient is not a minor and is incapable of making his or her own decisions. We propose to permit information to follow such decision-making authority. It is our intent not to disturb existing practices regarding incapacitated patients.

Applicable laws vary significantly regarding the categories of persons who can make health care decisions when a patient is incapable of making them. For example, some State laws establish a hierarchy of persons who may make medical decisions for the incapacitated person (e.g., first a person with power of attorney, if not then next-of-kin, if none then close friend, etc.). In other States, health care providers may exercise professional judgment about which person would make health care decisions in the patient's best interest. We also recognize that federal agencies have, in some cases, established rules regarding such patients. For example, the DOD has established requirements regarding military personnel who are based overseas and who have become incapable of making their own decisions.

Because laws vary regarding patients unable to make their own decisions and because these patients' interests could be served through a variety of arrangements, we would allow health plans and health care providers to disclose information in accordance with applicable laws regarding incapacitated patients.

c. *Disclosures pertaining to minors.* In general, because the definition of individual would include parents, a parent, guardian, or person acting *in loco parentis* could exercise the rights established under this regulation on behalf of their minor (as established by applicable law) children. However, in cases where a minor lawfully obtains a health care service without the consent of or notification to a parent, the minor would be treated as the individual for purposes of exercising any rights established under this regulation with respect to protected health information relating to such health services. Laws regarding access to health care for minors and confidentiality of their medical records vary widely; this proposed regulation recognizes and respects the current diversity of the law in this area. It would not affect applicable regulation of the delivery of health care services to minors, and would not preempt any law authorizing or prohibiting disclosure of individually identifiable health information of minor individuals to their parents. The disclosure of individually identifiable health information from substance abuse records is also addressed by additional requirements established under 42 CFR part 2.

d. *Foreign recipients of defense related health care.* We would define the term ''individual'' to exclude foreign military and foreign diplomatic personnel and their dependents who receive health care provided by or paid for by the DOD or other federal agency, or by an entity acting on its behalf, pursuant to a country-to-country agreement or federal statute. We would also exclude from this term overseas foreign national beneficiaries of health care provided by the DOD or other federal agency or by a non-governmental organization acting on behalf of DOD or such agency. This exclusion is discussed in section II.E.l3.

e. *Disclosures pertaining to deceased persons.* This provision is discussed in Section II.C.6.

19. *Individually identifiable health information.* We would define ''individually identifiable health information'' as it is defined in section 1171(6) of the Act. While the definition of individually identifiable health information does not expand on the statutory definition, we recognize that the issue of how the identifying characteristics can be removed from such information (referred to in this rule as de-identification) presents difficult operational issues. Accordingly, we propose in § 164.506(d) an approach for de-identifying identifiable information, along with restrictions designed to ensure that de-identified information is not used inappropriately.

The privacy standards would apply to ''individually identifiable health information,'' and not to information that does not identify the individual. We are aware that, even after removing obvious identifiers, there is always some probability or risk, however remote, that any information about an individual can be attributed. A 1997 MIT study showed that, because of the public availability of the Cambridge, Massachusetts voting list, 97 percent of the individuals in Cambridge whose data appeared in a data base which contained only their nine digit zip code and birth date could be identified with certainty.[1] Their information had been ''de-identified'' (some obvious identifiers had been removed) but it was not anonymous (it was still possible to identify the individual).

It is not always obvious when information identifies the subject. If the name and identifying numbers (e.g., SSN, insurance number, etc.) are removed, a person could still be identified by the address. With the address removed, the subject of a medical record could be identified based on health and demographic characteristics (e.g., age, race, diagnosis). ''Identifiability'' varies with the location of the subject; there could be hundreds of people in Manhattan who have the same age, race, gender, and diagnosis, but only one such person in a small town or rural county. Gauging the risk of identification of information requires statistical experience and expertise that most covered entities will not possess.

Obvious identifiers on health information could be replaced with random numbers or encrypted codes, which can prevent the person using the record from identifying the subject, but which allow the person holding the code to re-identify the information. Information with coded or encrypted identifiers would be considered ''de-identified'' but not ''anonymous,'' because it is still possible for someone to identify the subject.

We considered defining ''individually identifiable health information'' as any information that is not anonymous, that is, for which there is any possibility of identifying the subject. We rejected this option, for several reasons. First, the statute suggests a different approach. The term ''individually identifiable health information'' is defined in HIPAA as health information that ''* * * identifies the individual, or with respect to which there is a reasonable basis to believe that the information can be used to identify the individual.'' By including the modifier ''reasonable basis,'' Congress appears to reject the absolute approach to defining ''identifiable.''

Second, covered entities may not have the statistical sophistication to know with certainty when sufficient identifying information has been removed so that the record is no longer identifiable. We believe that covered entities need more concrete guidance as to when information will and will not be ''identifiable'' for purposes of this regulation.

[1] Sweeney, L. Guaranteeing Anonymity when Sharing Medical Data, the Datafly System. Masys, D., Ed. Proceedings, American Medical Informatics Association, Nashville, TN: Hanley & Belfus, Inc., 1997:51–55.

Finally, defining non-identifiable to mean anonymous would require covered entities to comply with the terms of this regulation with respect to information for which the probability of identification of the subject is very low. We want to encourage covered entities and others to remove obvious identifiers or encrypt them whenever possible; use of the absolute definition of ''identifiable'' would not promote this salutary result.

For these reasons, we propose at § 164.506(d)(2)(ii) that there be a presumption that, if specified identifying information is removed and if the holder has no reason to believe that the remaining information can be used by the reasonably anticipated recipients alone or in combination with other information to identify an individual, then the covered entity is presumed to have created de-identified information.

At the same time, in proposed § 164.506(d)(2)(iii), we would leave leeway for more sophisticated data users to take a different approach. We would include a ''reasonableness'' standard so that entities with sufficient statistical experience and expertise could remove or code a different combination of information, so long as the result is still a low probability of identification. With this approach, our intent is to provide certainty for most covered entities, while not limiting the options of more sophisticated data users.

In § 164.504, we propose to define ''individually identifiable health information'' to mean health information created or received by a health care provider, health plan, employer or health care clearinghouse, that could be used directly or indirectly to identify the individual who is the subject of the information. Under proposed § 164.506(d)(2)(ii), information would be presumed not to be ''identifiable'' if:

- All of the following data elements have been removed or otherwise concealed: Name; address, including street address, city, county, zip code, or equivalent geocodes; names of relatives and employers; birth date; telephone and fax numbers; e-mail addresses; social security number; medical record number; health plan beneficiary number; account number; certificate/license number; any vehicle or other device serial number; web URL; Internet Protocol (IP) address; finger or voice prints; photographic images; and any other unique identifying number, characteristic, or code (whether generally available in the public realm or not) that the covered entity has reason to believe may be available to an anticipated recipient of the information, and
- The covered entity has no reason to believe that any reasonably anticipated recipient of such information could use the information alone, or in combination with other information, to identify an individual. Thus, to create de-identified information, entities that had removed the listed identifiers would still have to remove additional data elements if they had reason to believe that a recipient could use the remaining information, alone or in combination with other information, to identify an individual. For example, if the ''occupation'' field is left intact and the entity knows that a person's occupation is sufficiently unique to allow identification, that field would have to be removed from the relevant record. The presumption does not allow use or disclosure if the covered entity has reason to believe the subject of the information can be re-identified. Our concern with the potential for re-identification is heightened by our limited jurisdiction under HIPAA. Because we can only regulate health care providers, health plans and health care clearinghouses, we cannot prohibit other recipients of de-identified information from attempting to re-identify it.

To assist covered entities in ascertaining whether their attempts to create de-identified information would be successful, the Secretary would from time to time issue guidance establishing methods that covered entities could use to determine the identifiability of information. This guidance would include information on statistical and other tests that could be performed by covered entities in assessing whether they have created de-identified information. The manner in which such guidance would be published and distributed will be addressed in the final regulation. We solicit comment on the best ways in which to inform covered entities of appropriate and useful information on methods that they can use to determine whether information is de-identified.

In enforcing this regulation, the Secretary would consider the sophistication of covered entities when determining whether a covered entity had reason to believe that information that it had attempted to de-identify continued to identify the subject. Covered entities that routinely create and distribute de-identified data would be expected to be aware of and to use advanced statistical techniques, including the guidance issued by the Secretary, to ensure that they are not improperly disclosing individually identifiable health information. Covered entities that rarely create de-identified information would not be expected to have the same level of knowledge of these statistical methods, and generally could rely on the presumption that information from which they have removed the listed identifiers (and provided that they do not know that the information remains identifiable) is de-identified. We solicit comment on whether the enforcement approach that we are suggesting here and our overall approach relating to the creation of de-identified information would provide sufficient guidance to covered entities to permit them to create, use and disclose de-identified information.

In addition, we propose to permit entities with appropriate statistical experience and expertise (obtained through a statistical consultant or staff with statistical expertise) to decide that some of the above named data elements could be retained in the de-identified data set if: (1) The entity determines that the probability of identifying an individual with the remaining information is very low, or (2) the entity has converted the ''identifiable'' data elements into data elements that, in combination with the remaining information, have a very low probability of being used to identify an individual. An example of such a conversion would be the translation of birth date into age expressed in years or, if still determined to convey ''identifiability,'' age expressed in categories of years (e.g., age 18 to 24). In making these determinations, the entity must consider the data elements taken together as well as any additional information that might reasonably be available to a recipient. Examples of the types of entities that would have the statistical experience and expertise to make this type of judgment include large health research institutions such as medical schools with epidemiologists and statisticians on the faculty; federal agencies such as the National Center for Health Statistics, the Agency for Health Care Policy and Research, FDA, the Bureau of the Census, and NIH; and large corporations that do health research such as pharmaceutical manufacturers with epidemiologists and statisticians on staff.

An important component of this approach to defining ''identifiable'' would be the prohibition on re-identification of health information. We propose that a covered entity that is a recipient of de-identified information who attempts to re-identify such de-identified information for a purpose for which protected health information could not be used or disclosed under

this rule be deemed to be in violation of the law. See proposed § 164.506(d) and section II.C. below. There may be circumstances, however, when recipients of de-identified information will have a legitimate reason to request that the de-identified information be re-identified by the originating covered entity. For example, if a researcher received de-identified information from a covered entity and the research revealed that a particular patient was misdiagnosed, the covered entity should be permitted to re-identify the patient's health information so that the patient could be informed of the error and seek appropriate care. One of the principal reasons entities retain information in coded form, rather than rendering it anonymous, is to enable re-identification of the information for appropriate reasons. Although we would anticipate that the need for re-identification would be rare, entities that expect to have to perform this function should establish a process for determining when re-identification is appropriate. Once covered entities re-identify information, it becomes protected information and may, therefore, be used and disclosed only as permitted by this regulation.

The phrase ''individually identifiable'' information is already in use by many HHS agencies and others. In particular, the Common Rule regulation includes ''identifiable private information'' in its definition of ''human subject.'' Because of this, medical records research on ''identifiable private information'' is subject to Common Rule consent and IRB review requirements. It would not be our intent to suggest changes to this practice. Researchers and others can and are encouraged to continue to use more stringent approaches to protecting information.

We invite comment on the approach that we are proposing and on alternative approaches to standards for covered entities to determine when health information can reasonably be considered no longer individually identifiable.

20. *Law enforcement official.* We propose a new definition of ''law enforcement official,'' to mean an officer of the United States or a political subdivision thereof, who is empowered by law to conduct an investigation or official proceeding inquiring into a violation of, or failure to comply with, any law; or a criminal, civil, or administrative proceeding arising from a violation of, or failure to comply with, any law.

21. *Payment.* We offer a new definition of payment. The term ''payment'' would mean activities undertaken by a health plan (or by a business partner on behalf of a health plan) to determine its responsibilities for coverage under the health plan policy or contract including the actual payment under the policy or contract, or by a health care provider (or by a business partner on behalf of a provider) to obtain reimbursement for the provision of health care, including:

- Determinations of coverage, improving payment methodologies or coverage policies, or adjudication or subrogation of claims;
- Risk adjusting payments based on enrollee health status and demographic characteristics;
- Billing, claims management, medical review, medical data processing;
- Review of health care services with respect to medical necessity, coverage under a health plan policy or contract, appropriateness of care, or justification of charges; and,
- Utilization review activities, including pre-certification and preauthorization of services.

Our proposed definition is intended to capture the necessary sharing of protected health information among health care providers who provide care, health plans and other insurers who pay for care, their business partners, as well as sponsors of group health plans, such as employers, who pay for care and sometimes provide administrative services in conjunction with health plan payment activities. For example, employers sometimes maintain the eligibility file with respect to a group health plan.

Our proposed definition anticipates that protected health information would be used for payment purposes within entities, would be shared with business partners, and in most cases would be shared between health care providers and health plans (and their business partners). In some cases, a payment activity could result in the disclosure of protected health information by a plan to an employer or to another payer of health care, or to an insurer that is not a covered entity, such as for coordination of benefits or to a workers compensation carrier. For example, a health plan could disclose protected health information to an employer in connection with determining the experience rate for group coverage.

We are concerned that disclosures for payments may routinely result in disclosures of protected health information to non-covered entities, such as employers, which are not subject to the use and disclosure requirements of this rule. We considered prohibiting disclosures to employers without individual authorization, or alternatively, requiring a contractual relationship, similar to the contracts required for business partners, before such disclosures could occur. We note that the National Committee on Quality Assurance has adopted a standard for the year 2000 that would require health plans to ''have policies that prohibit sending identifiable personal health information to fully insured or self-insured employers and provide safeguards against the use of information in any action relating to an individual'' (Standard R.R.6, National Committee for Quality Assurance 2000 Standards).

We did not adopt either of these approaches, however, because we were concerned that we might disrupt some beneficial activities if we were to prohibit or place significant conditions on disclosures by health plans to employers. We also recognize that employers are paying for health care in many cases, and it has been suggested to us that they may need access to claims and other information for the purposes of negotiating rates, quality improvement and auditing their plans and claims administrators. We invite comment on the extent to which employers currently receive protected health information about their employees, for what types of activities protected health information is received, and whether any or all of these activities could be accomplished with de-identified health information. We also invite other comments on how disclosures to employers should be treated under this rule.

22. *Protected health information.* We would create a new definition of ''protected health information'' to mean individually identifiable health information that is or has been electronically maintained or electronically transmitted by a covered entity, as well as such information when it takes any other form. For example, protected health information would remain protected after it is read from a computer screen and discussed orally, printed onto paper or other media, photographed, or otherwise duplicated. We note that individually identifiable health information created or received by an employer as such would not be considered protected health information, although such information created or received by an employer in its role as a health plan or provider would be protected health information.

Under this definition, information that is ''electronically transmitted'' would include information exchanged with a computer using electronic media, even when the information is physically

moved from one location to another using magnetic or optical media (e.g., copying information from one computer to another using a floppy disc). Transmissions over the Internet (i.e., open network), Extranet (i.e., using Internet technology to link a business with information only accessible to collaborating parties), leased lines, dial-up lines, and private networks would all be included. Telephone voice response and ''faxback'' (i.e., a request for information from a computer made via voice or telephone keypad input with the requested information returned as a fax) systems would be included because these are computer output devices similar in function to a printer or video screen. This definition would not include ''paper-to-paper'' faxes, or person-to-person telephone calls, video teleconferencing, or messages left on voice-mail. The key concept that determines if a transmission meets the definition is whether the source or target of the transmission is a computer. The medium or the machine through which the information is transmitted or rendered is irrelevant.

Also, information that is ''electronically maintained'' would be information stored by a computer or on any electronic medium from which the information may be retrieved by a computer. These media include, but are not limited to, electronic memory chips, magnetic tape, magnetic disk, or compact disc (CD) optical media.

Individually identifiable health information that is part of an ''education record'' governed by the Family Educational Rights and Privacy Act (FERPA), 20 U.S.C. 1232g, would not be considered protected health information. Congress specifically addressed such information when it enacted FERPA to protect the privacy rights of students and parents in educational settings. FERPA applies to educational records that are maintained by educational agencies and institutions that are recipients of federal funds from the Department of Education. FERPA requires written consent of the parent or student prior to disclosure of education records except in statutorily specified circumstances. We do not believe that Congress intended to amend or preempt FERPA in enacting HIPAA.

Individually identifiable health information of inmates of correctional facilities and detainees in detention facilities would be excluded from this definition because unimpeded sharing of inmate identifiable health information is crucial for correctional and detention facility operations. In a correctional or detention setting, prison officials are required by law to safely house and provide health care to inmates. These activities require the use and disclosure of identifiable health information. Therefore, correctional and detention facilities must routinely share inmate health information among their health care and other components, as well as with community health care facilities. In order to maintain good order and protect the well-being of prisoners, the relationship between such facilities and inmates or detainees involves a highly regulated, specialized area of the law which has evolved as a carefully balanced compromise with due deference to institutional needs and obligations.

Federal and other prison facilities routinely share health information with community health care facilities in order to provide medical treatment to persons in their custody. It is not uncommon for inmates and detainees to be transported from one facility to another, for example, for the purpose of making a court appearance in another jurisdiction, or to obtain specialized medical care. In these and other circumstances, law enforcement agencies such as the Federal Bureau of Prisons (the Bureau), the United States Marshals Service (USMS), the Immigration and Naturalization Service, State prisons, county jails, and U.S. Probation Offices, share identifiable health information about inmates and detainees to ensure that appropriate health care and supervision of the inmate or detainee is maintained. Likewise, these agencies must, in turn, share health information with the facility that resumes custody of the inmate or detainee.

Requiring an inmate's or detainee's authorization for disclosure of identifiable health information for day-to-day operations would represent a significant shift in correctional and detention management philosophy. If correctional and detention facilities were covered by this rule, the proposed provisions for individual authorizations could potentially be used by an inmate or detainee to override the safety and security concerns of the correctional/custodial authority; for example, an inmate being sent out on a federal writ could refuse to permit the Bureau to disclose a suicide history to the USMS. Additionally, by seeking an authorization to disclose the information, staff may give the inmate or detainee advance notice of an impending transfer, which in turn may create security risks.

Therefore we propose to exclude the individually identifiable health information of inmates of correctional facilities and detainees in detention facilities from the definition of protected health information. We note that existing federal laws limiting the disclosure and release of information (e.g., FOIA/Privacy Act) protect the privacy of identifiable federal inmate health information. Subject to certain limitations, these laws permit inmates and detainees to obtain and review a copy of their medical records and to correct inaccurate information.

Under this approach, the identifiable health information held by correctional and detention facilities of persons who have been released would not be protected. The facilities require continued access to such information for security, protection and health care purposes because inmates and detainees are frequently readmitted to correctional and detention facilities. However, concern has been expressed about the possibility that absent coverage by this proposed rule, correctional and detention facilities may disclose information about former inmates and detainees without restriction. We therefore request comments on whether identifiable health information held by correctional and detention facilities about former inmates and detainees should be subject to this rule, and the potential security concerns and burden such a requirement might place on these facilities.

23. *Psychotherapy notes.* We would define ''psychotherapy notes'' to mean detailed notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session. Such notes are used only by the therapist who wrote them, maintained separately from the medical record, and not involved in the documentation necessary for health care treatment, payment, or operations. Such term would not include medication prescription and monitoring, counseling session start and stop times or the modalities and frequencies of treatment furnished, results of clinical tests, or a brief summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis and progress to date.

24. *Public health authority.* We would define ''public health authority'' as an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe that is responsible for public health matters as part of its official mandate.

25. *Research.* We would define ''research'' as a systematic investigation,

including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. We further explain that ''generalizable knowledge'' is knowledge related to health that can be applied to populations outside of the population served by the covered entity.

This is the definition of ''research'' in the federal regulation that protects human subjects, entitled The Federal Policy for the Protection of Human Subjects (often referred to as the ''Common Rule,'' at 45 CFR part 46). This definition is well understood in the research community and elsewhere, and we propose to use it here to maintain consistency with other federal regulations that affect research.

26. *Research information unrelated to treatment.* We would define ''research information unrelated to treatment'' as information that is received or created by a covered entity in the course of conducting research for which there is insufficient scientific and medical evidence regarding the validity or utility of the information such that it should not be used for the purpose of providing health care,[2] and with respect to which the covered entity has not requested payment from a health plan.

27. *Treatment.* We would define ''treatment'' to mean the provision of health care by, or the coordination of health care (including health care management of the individual through risk assessment, case management, and disease management) among, health care providers, or the referral of an individual from one provider to another, or coordination of health care or other services among health care providers and third parties authorized by the health plan or the individual. Our definition is intended to relate only to services provided to an individual and not to an entire enrolled population.

28. *Use.* We would propose a new definition of the term ''use'' to mean the employment, application, utilization, examination or analysis of health information within an entity that holds the information.

29. *Workforce.* We would define ''workforce'' to mean employees, volunteers, trainees and other persons under the direct control of a covered entity, including persons providing labor on an unpaid basis.

[2] For example, *validity* is an indicator of how well a test measures the property or characteristic it is intended to measure and the reliability of a test, *i.e.*, whether the same result is obtained each time the test is used. Validity is also a measurement of the accuracy with which a test predicts a clinical condition. *Utility* refers to the degree to which the results of test can be used to make decisions about the subsequent delivery of health care.

C. General Rules. (§ 164.506)

[*Please label comments about this section with the subject: ''Introduction to general rules''*]

The purpose of our proposal is to define and limit the circumstances in which an individual's protected health information could be used or disclosed by covered entities. As discussed above, we are proposing to make the use and exchange of protected health information relatively easy for health care purposes and more difficult for purposes other than health care.

As a general rule, we are proposing that protected health information not be used or disclosed by covered entities except as authorized by the individual who is the subject of such information or as explicitly provided by this rule. Under this proposal, most uses and disclosures of an individual's protected health information would not require explicit authorization by the individual, but would be restricted by the provisions of the rule. Covered entities would be able to use or disclose an individual's protected health information without authorization for treatment, payment and health care operations. See proposed § 164.506(a)(1)(i). Covered entities also would be permitted to use or disclose an individual's protected health information for specified public and public policy-related purposes, including public health, research, health oversight, law enforcement, and use by coroners. Covered entities would be *permitted* by this rule to use and disclose protected health information when required to do so by other law, such as a mandatory reporting requirement under State law or pursuant to a search warrant. See proposed § 164.510. Covered entities would be *required* by this rule to disclose protected health information for only two purposes: To permit individuals to inspect and copy protected health information about them (see proposed § 164.514) and for enforcement of this rule (see proposed § 164.522(e)).

The proposed rule generally would not require covered entities to vary the level of protection of protected health information based on the sensitivity of such information. We believe that all protected health information should have effective protection from inappropriate use and disclosure by covered entities, and except for limited classes of information that are not needed for treatment and payment purposes, we have not provided additional protection to protected health information that might be considered particularly sensitive. We would note that the proposed rule would not preempt provisions of other applicable laws that provide additional privacy protection to certain classes of protected health information. We understand, however, that there are medical conditions and treatments that individuals may believe are particularly sensitive, or which could be the basis of stigma or discrimination. We invite comment on whether this rule should provide for additional protection for such information. We would appreciate comment that discusses how such information should be identified and the types of steps that covered entities could take to provide such additional protection. We also invite comment on how such provisions could be enforced.

Covered entities of all types and sizes would be required to comply with the proposed privacy standards outlined below. The proposed standards would not impose particular mechanisms or procedures that covered entities must adopt to implement the standards. Instead, we would require that each affected entity assess its own needs and devise, implement, and maintain appropriate privacy policies, procedures, and documentation to address its business requirements. How each privacy standard would be satisfied would be business decisions that each entity would have to make. This allows the privacy standards to establish a stable baseline, yet remain flexible enough to take advantage of developments and methods for protecting privacy that will evolve over time.

Because the privacy standards would need to be implemented by all covered entities, from the smallest provider to the largest, multi-state health plan, a single approach to implementing these standards would be neither economically feasible nor effective in safeguarding health information privacy. For example, in a small physician practice, the office manager might be designated to serve as the privacy official as one of many duties (see proposed § 164.518(a)) whereas at a large health plan, the privacy official may constitute a full time position and have the regular support and advice of a privacy staff or board.

Similarly, a large enterprise may make frequent electronic disclosures of similar data. In such a case, the enterprise would be expected to remove identifiers or to limit the data fields that are disclosed to fit the purpose of the disclosure. The process would be documented and perhaps even automated. A solo physician's office, however, would not be expected to have

the same capabilities to limit the amount of information disclosed, although, in the cases of disclosures involving a small number of records, such an office could be expected to hide identifiers or to limit disclosures to certain pages of the medical record that are relevant to the purpose of the disclosure.

In taking this approach, we intend to strike a balance between the need to maintain the confidentiality of protected health information and the economic cost of doing so. Health care entities must consider both aspects in devising their solutions. This approach is similar to the approach we proposed in the Notice of Proposed Rulemaking for the administrative simplification security and electronic signature standards.

1. Use and Disclosure for Treatment, Payment, and Health Care Operations. (§ 164.506(a))

[*Please label comments about this section with the subject: ''Treatment, payment, and health care operations''*]

We are proposing that, subject to limited exceptions for psychotherapy notes and research information unrelated to treatment discussed below, a covered entity be permitted to use or disclose protected health information without individual authorization for treatment, payment or health care operations.

The Secretary's Recommendations proposed that covered entities be able to use individually identifiable health information without authorization of the identified individual for treatment and payment and for purposes that are ''compatible with and directly related to'' treatment and payment. The Recommendations further explained that the terms ''treatment'' and ''payment'' were to be construed broadly, encompassing treatment and payment for all patients. They also noted that the test of ''compatible with and directly related to'' is meant to be more restrictive than the test currently used in the Privacy Act, 5. U.S.C. 552a, for determining whether a proposed ''routine use'' is sufficiently related to the primary purpose for which the information would be collected to permit its release under the proposed ''routine use.'' The Privacy Act permits release of such information if the proposed routine use is ''compatible with'' the purpose for which the information is collected. Our proposal is intended to be consistent with this discussion from the Secretary's Recommendations.

a. *General rule for treatment, payment, and health care operations.* We are not proposing to require individual authorizations of uses and disclosures for health care and related purposes, although such authorizations are routinely gathered today as a condition of obtaining health care or enrolling in a health plan. Although many current disclosures of health information are made pursuant to individual authorizations, these authorizations provide individuals with little actual control over their health information. When an individual is required to sign a blanket authorization at the point of receiving care or enrolling for coverage, that consent is often not voluntary because the individual must sign the form as a condition of treatment or payment for treatment. Individuals are also often asked to sign broad authorizations but are provided little or no information about how their health information may be or will in fact be used. Individuals cannot make a truly informed decision without knowing all the possible uses, disclosures and re-disclosures to which their information will be subject. In addition, since the authorization usually precedes creation of the record, the individual cannot predict all the information the record may contain and therefore cannot make an informed decision as to what would be released.

Our proposal is intended to make the exchange of protected health information relatively easy for health care purposes and more difficult for purposes other than health care. For individuals, health care treatment and payment are the core functions of the health care system. This is what they expect their health information will be used for when they seek medical care and present their proof of insurance to the provider. Consistent with this expectation, we considered requiring a separate individual authorization for every use or disclosure of information but rejected such an approach because it would not be realistic in an increasingly integrated health care system. For example, a requirement for separate patient authorization for each routine referral could impair care, by delaying consultation and referral, as well as payment.

We therefore propose that covered entities be permitted to use and disclose protected health information without individual authorization for treatment and payment purposes, and for related purposes that we have defined as health care operations. For example, health care providers could maintain and refer to a medical record, disclose information to other providers or persons as necessary for consultation about diagnosis or treatment, and disclose information as part of referrals to other providers. Health care providers also could use a patient's protected health information for payment purposes such as submitting a claim to a payer. In addition, they could use a patient's protected health information for health care operations, such as use for an internal quality oversight review. We would note that, in the case of an individual where the provider has agreed to restrictions on use or disclosure of the patient's protected health information, the provider is bound by such restrictions as provided in § 164.506(c).

Similarly, health plans could use an enrollee's protected health information for payment purposes, such as reviewing and paying health claims that have been submitted to it, pre-admission screening of a request for hospitalization, or post-claim audits of health care providers. Health plans also could use an enrollee's protected health information for health care operations, such as reviewing the utilization patterns or outcome performance of providers participating in their network.

Further, as described in more detail below, health care providers and health plans would not need individual authorization to provide protected health information to a business partner for treatment, payment or health care operations functions if the other requirements for disclosing to business partners are met. See proposed § 164.506(e).

We intend that the right to use and disclose protected health information be interpreted to apply for treatment and payment of all individuals. For example, in the course of providing care to a patient, a physician could wish to examine the records of other patients with similar conditions. Likewise, a physician could consult the records of several people in the same family or living in the same household to assist in diagnosis of conditions that could be contagious or that could arise from a common environmental factor. A health plan or a provider could use the protected health information of a number of enrollees to develop treatment protocols, practice guidelines, or to assess quality of care. All of these uses would be permitted under this proposed rule.

Our proposal would not restrict to whom disclosures could be made for treatment, payment or operations. For example, covered entities could make disclosures to non-covered entities for payment purposes, such as a disclosure to a workers compensation carrier for coordination of benefits purposes. We note, however, that when disclosures are made to non-covered entities, the

ability of this proposed rule to protect the confidentiality of the information ends. This points to the need for passage of more comprehensive privacy legislation that would permit the restrictions on use and disclosure to follow the information beyond covered entities.

We also propose to prohibit covered entities from seeking individual authorization for uses and disclosures for treatment, payment and health care operations unless required by State or other applicable law. As discussed above in this section, such authorizations could not provide meaningful privacy protections or individual control and could in fact cultivate in individuals erroneous understandings of their rights and protections.

The general approach that we are proposing is not new. Some existing State health confidentiality laws permit disclosures without individual authorization to other health care providers treating the individual, and the Uniform Health-Care Information Act permits disclosure ''to a person who is providing health-care to the patient'' (9 part I, U.L.A. 475, 2–104 (1988 and Supp. 1998)). We believe that this approach would be the most realistic way to protect individual confidentiality in an increasingly data-driven, electronic and integrated health care system. We recognize, however, that particularly given the limited scope of the authority that we have under this proposed rule to reach some significant actors in the health care system, that other approaches could be of interest. We invite comments on whether other approaches to protecting individuals' health information would be more effective.

b. *Health care operations.* We considered the extent to which the covered entities might benefit from further guidance on the types of activities that appropriately would be considered health care operations. The term is defined in proposed § 164.504. In the debates that have surrounded privacy legislation before the Congress, there has been substantial discussion of the definition of health care operations, with some parties advocating for a very broad definition and others advocating a more restrictive approach.

Given the lack of consensus over the extent of the activities that could be encompassed within the term health care operations, we determined that it would be helpful to identify activities that, in our opinion, are sufficiently unrelated to the treatment and payment functions to require a individual to authorize use of his or her information. We want to make clear that these activities would not be prohibited, and do not dispute that many of these activities are indeed beneficial to both individuals and the institutions involved. Nonetheless, they are not necessary for the key functions of treatment and payment and therefore would require the authorization of the individual before his/her information could be used. These activities would include but would not be limited to:

- The use of protected health information for marketing of health and non-health items and services;
- The disclosure of protected health information for sale, rent or barter;
- The use of protected health information by a non-health related division of the same corporation, e.g., for use in marketing or underwriting life or casualty insurance, or in banking services;
- The disclosure, by sale or otherwise, of protected health information to a plan or provider for making eligibility or enrollment determinations, or for underwriting or risk rating determinations, prior to the individual's enrollment in the plan;
- The disclosure of information to an employer for use in employment determinations; and
- The use or disclosure of information for fund raising purposes.

We invite comments on the activities within the proposed definitions of ''treatment,'' ''payment,'' and ''health care operations,'' as well as the activities proposed to be excluded from these definitions.

c. *Exception for psychotherapy notes.* We propose that a covered health care provider not be permitted to disclose psychotherapy notes, as defined by this proposed rule, for treatment, payment, or health care operations unless a specific authorization is obtained from the individual. In addition, a covered entity would not be permitted to condition treatment of an individual, enrollment of an individual in a health plan, or payment of a claim for benefits made by or on behalf of an individual on a requirement that the individual provide a specific authorization for the disclosure of psychotherapy notes.

We would define ''psychotherapy notes'' to mean detailed notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session. Such notes could be used only by the therapist who wrote them, would have to be maintained separately from the medical record, and could not be involved in the documentation necessary for health care treatment, payment, or operations (as defined in § 164.504). Such term would not include medication prescription and monitoring, counseling session start and stop times or the modalities and frequencies of treatment furnished, results of clinical tests, or summaries of the following items: diagnoses, functional status, the treatment plan, symptoms, prognosis and progress to date.

Psychotherapy notes are of primary value to the specific provider and the promise of strict confidentiality helps to ensure that the patient will feel comfortable freely and completely disclosing very personal information essential to successful treatment. Unlike information shared with other health care providers for the purposes of treatment, psychotherapy notes are more detailed and subjective and are subject to unique rules of disclosure. In *Jaffee* v. *Redmond,* 518 U. S. 1 (1996), the Supreme Court ruled that conversations and notes between a patient and psychotherapist are confidential and protected from compulsory disclosure. The language in the Supreme Court opinion makes the rationale clear:

> Like the spousal and attorney-client privileges, the psychotherapist-patient privilege is ''rooted in the imperative need for confidence and trust.'' * * * Treatment by a physician for physical ailments can often proceed successfully on the basis of a physical examination, objective information supplied by the patient, and the results of diagnostic tests. Effective psychotherapy, by contrast, depends upon an atmosphere of confidence and trust in which the patient is willing to make a frank and complete disclosure of facts, emotions, memories, and fears. Because of the sensitive nature of the problems for which individuals consult psychotherapists, disclosure of confidential communications made during counseling sessions may cause embarrassment or disgrace. For this reason, the mere possibility of disclosure may impede development of the confidential relationship necessary for successful treatment. As the Judicial Conference Advisory Committee observed in 1972 when it recommended that Congress recognize a psychotherapist privilege as part of the Proposed Federal Rules of Evidence, a psychiatrist's ability to help her patients ''is completely dependent upon (the patients') willingness and ability to talk freely. This makes it difficult if not impossible for (a psychiatrist) to function without being able to assure * * * patients of confidentiality and, indeed, privileged communication. Where there may be exceptions to this general rule * * *, there is wide agreement that confidentiality is a *sine qua non* for successful psychiatric treatment. * * *''
>
> By protecting confidential communications between a psychotherapist and her patient

from involuntary disclosure, the proposed privilege thus serves important private interests. * * * The psychotherapist privilege serves the public interest by facilitating the provision of appropriate treatment for individuals suffering the effects of a mental or emotional problem. The mental health of our citizenry, no less than its physical health, is a public good of transcendent importance.

That it is appropriate for the federal courts to recognize a psychotherapist privilege under Rule 501 is confirmed by the fact that all 50 States and the District of Columbia have enacted into law some form of psychotherapist privilege. * * * Because state legislatures are fully aware of the need to protect the integrity of the fact finding functions of their courts, the existence of a consensus among the States indicates that ''reason and experience'' support recognition of the privilege. In addition, given the importance of the patient's understanding that her communications with her therapist will not be publicly disclosed, any State's promise of confidentiality would have little value if the patient were aware that the privilege would not be honored in a federal court. * * * *Jaffee,* 518 U.S. 7–9.

The special status of the psychotherapist privilege in our society as well as the physical and conceptual segregation of the psychotherapy notes makes this prohibition on disclosures for treatment, payment and health care operations without a specific authorization from the individual reasonable and practical.

We note that the policy being applied to psychotherapy notes differs from the policy being applied to most other types of protected health information. For most protected health information, a covered entity would be prohibited from soliciting an authorization from an individual for treatment, payment and health operations unless such an authorization is required by other applicable law. In this case, because of the special status of psychotherapy notes as described above, we propose that a specific authorization be required before such notes can be disclosed within the treatment and payment systems. We propose this special treatment because there are few reasons why other health care entities should need the psychotherapy notes about an individual, and in those cases, the individual is in the best position to determine if the notes should be disclosed. For example, an individual could authorize disclosure if they are changing health care providers. Since we have defined psychotherapy notes in such a way that they do not include information that health plans would need to process a claim for services, special authorizations for payment purposes should be rare. We would note that the provisions governing authorizations under § 164.508 would apply to the special authorizations under this provision.

We also propose that covered entities not be permitted to condition treatment or payment decisions on a requirement that an individual provide a specific authorization for the use or disclosure of psychotherapy notes. The special protections that are being proposed would not be meaningful if covered entities could coerce individuals by conditioning treatment or payment decisions on a requirement that the individual authorize use or disclosures of such notes. This requirement would not prohibit the provider that creates the psychotherapy notes information from using the notes for treatment of the individual. The provider could not, however, condition the provision of treatment on a requirement that the individual authorize the use of the psychotherapy notes by the covered entity for other purposes or the disclosure of the notes by the provider to others.

We considered including other disclosures permitted under proposed § 164.510 within the prohibition described in this provision, but were unsure if psychotherapy notes were ever relevant to the public policy purposes underlying those disclosures. For example, we would assume that such notes are rarely disclosed for public health purposes or to next of kin. We solicit comment on whether there are additional categories of disclosures permitted under proposed § 164.510 for which the disclosure of psychotherapy notes by covered entities without specific individual authorization would be appropriate.

d. *Exception for research information unrelated to treatment.* Given the voluntary, often altruistic, nature of research participation, and the experimental character of data generated from many research studies, research participants should have assurances that the confidentiality of their individually identifiable information will be maintained in a manner that respects these unique characteristics. In the process of conducting health research, some information that is collected could be related to the delivery of health care to the individual and some could be unrelated to the care of the individual. Some information that is generated in the course of a research study could have unknown analytic validity, clinical validity, or clinical utility. In general, unknown analytic or clinical validity means that the sensitivity, specificity, and predictive value of the research information is not known. Specifically, analytic validity refers to how well a test performs in measuring the property or characteristic it is intended to measure. Another element of the test's analytical validity is its reliability—that is, it must give the same result each time. Clinical validity is the accuracy with which a test predicts a clinical condition. Unknown clinical utility means that there is an absence of scientific and medical agreement regarding the applicability of the information for the diagnosis, prevention, or treatment of any malady, or the assessment of the health of the individual.

We would define ''research information unrelated to treatment'' as information that is received or created by a covered entity in the course of conducting research for which there is insufficient scientific and medical evidence regarding the validity or utility of the information such that it should not be used for the purpose of providing health care, and with respect to which the covered entity has not requested payment from a health plan.

Such information should never be used in a clinical treatment protocol but could result as a byproduct of such a protocol. For example, consider a study which involves the evaluation of a new drug, as well as an assessment of a genetic marker. The drug trial includes physical and radiographic examinations, as well as blood tests to monitor potential toxicity of the new drug on the liver; all of these procedures are part of the provision of health care, and therefore, would constitute ''protected health information,'' but not ''research information unrelated to treatment.'' In the same study, the investigators are searching for a genetic marker for this particular disease. To date, no marker has been identified and it is uncertain whether or not the preliminary results from this research study would prove to be a marker for this disease. The genetic information generated from this study would constitute ''research information unrelated to treatment''.

We solicit comment on this definition of ''research information unrelated to treatment'' and how it would work in practice.

Because the meaning of this information is currently unknown, we would prohibit its use and disclosure for treatment, payment and health care operations unless a specific authorization is obtained from the subject of the information. Failing to limit the uses and disclosures of this information within the health payment system would place research participants at increased risk of discrimination, which could result in

individuals refusing to volunteer to participate in this type of research. Without the special protections that we are proposing, we are concerned that much potentially life-saving research could be halted. Moreover, because this information that lacks analytical or clinical validity and clinical utility, and because we have defined it in terms that preclude researchers from seeking third-party reimbursement for its creation, there would not be a reason for this information to be further used or disclosed within the treatment and payment system without individual authorization.

We also propose that covered entities not be permitted to condition treatment or payment decisions on a requirement that an individual provide a specific authorization for the use or disclosure of research information unrelated to treatment. The special protections that are being proposed would not be meaningful if covered entities could coerce individuals into authorizing disclosure by conditioning treatment or payment decisions on a requirement that the individual authorize disclosures of such information. This requirement would not prohibit the covered entity that creates the information from using the information for the research purposes for which it was collected. The entity could not, however, condition the provision of treatment on a requirement that the individual authorize use of research information unrelated to treatment by the covered entity for other purposes or the disclosure of the information by the covered entity to others.

We considered including other of the uses and disclosures that would be permitted under § 164.510 within the prohibition described in this provision, but were unsure if research information unrelated to treatment would ever be relevant to the public policy purposes underlying those disclosures. We solicit comment on whether there are additional categories of uses or disclosures that would be permitted under proposed § 164.510 for which the use or disclosure of such information by covered entities without specific individual authorization would be appropriate.

2. Minimum Necessary Use and Disclosure. (§ 164.506(b))

[*Please label comments about this section with the subject: ''Minimum necessary''*]

We propose that, except as discussed below, a covered entity must make all reasonable efforts not to use or disclose more than the minimum amount of protected health information necessary to accomplish the intended purpose of the use or disclosure, taking into consideration practical and technological limitations.

In certain circumstances, the assessment of what is minimally necessary is appropriately made by a person other than the covered entity; in those cases, discussed in this paragraph, and reflected in proposed § 164.506(b)(1)(i), the requirements of this section would not apply. First, the covered entity would not be required to make a ''minimum necessary'' analysis for the standardized content of the various HIPAA transactions, since that content has been determined through regulation. Second, with one exception, when an individual authorizes a use or disclosure the covered entity would not be required to make a ''minimum necessary'' determination. In such cases, the covered entity would be unlikely to know enough about the information needs of the third party to make a ''minimum necessary'' determination. The exception, when the ''minimum necessary'' principle would apply to an authorization, is for authorizations for use of protected health information by the covered entity itself. See proposed § 164.508(a)(2). Third, with respect to disclosures that are mandatory under this or other law, and which would be permitted under the rules proposed below, public officials, rather than the covered entity, would determine what information is required (e.g., coroners and medical examiners, State reporting requirements, judicial warrants). See proposed §§ 164.510 and 164.506(b)(1)(ii). Fourth, disclosure made pursuant to a request by the individual for access to his or her protected health information presents no possible privacy threat and therefore lies outside this requirement. See proposed § 164.506(b)(1)(i).

Under this proposal, covered entities generally would be required to establish policies and procedures to limit the amount of protected health care information used or disclosed to the minimum amount necessary to meet the purpose of the use or disclosure, and to limit access to protected health information only to those people who need access to the information to accomplish the use or disclosure. With respect to use, if an entity consists of several different components, the entity would be required to create barriers between components so that information is not used inappropriately. For example, a health plan that offers other insurance products would have policies and procedures to prevent protected health information from crossing over from one product line to another. The same principle applies to disclosures. For example, if a covered entity opts to disclose protected health information to a researcher pursuant to proposed § 164.510(j), it would need to ensure that only the information necessary for the particular research protocol is disclosed.

It should be noted that, under section 1173(d) of the Act, covered entities would also be required to satisfy the requirements of the Security standards, by establishing policies and procedures to provide access to health information systems only to persons who require access, and implement procedures to eliminate all other access. Thus, the privacy and security requirements would work together to minimize the amount of information shared, thereby lessening the possibility of misuse or inadvertent release.

A ''minimum necessary'' determination would need to be consistent with and directly related to the purpose of the use or disclosure and take into consideration the ability of a covered entity to delimit the amount of information used or disclosed and the relative burden imposed on the entity. The proposed minimum necessary requirement is based on a reasonableness standard: covered entities would be required to make reasonable efforts and to incur reasonable expense to limit the use and disclosure of protected health information as provided in this section.

In determining what a reasonable effort is under this section, covered entities should take into consideration the amount of information that would be used or disclosed, the extent to which the use or disclosure would extend the number of individuals or entities with access to the protected health information, the importance of the use or disclosure, the likelihood that further uses or disclosures of the protected health information could occur, the potential to achieve substantially the same purpose with de-identified information, the technology available to limit the amount of protected health information that is used or disclosed, the cost of limiting the use or disclosure, and any other factors that the covered entity believes are relevant to the determination. We would expect that in most cases where covered entities have more information than is necessary to accomplish the purpose of a use or disclosure, some method of limiting the information that is used or disclosed could be found.

We note that all of the uses and disclosures subject to the requirements of this provision are permissive; the minimum necessary provision does not

apply to uses or disclosures mandated by law. Covered entities should not make uses or disclosures of protected health information where they are unable to make any efforts to reasonably limit the amount of protected health information used or disclosed for a permissive purpose. Where there is ambiguity regarding the particular information to be used or disclosed, this provision should be interpreted to require the covered entity or make some effort to limit the amount of information used or disclosed.

We note that procedures for implementing the minimum necessary requirement for uses would often focus on limiting the physical access that employees, business partners and others would have to the protected health information. Procedures which limit the specific employees or business partners, or the types of employees or business partners, who would be qualified to gain access to particular records would often be appropriate. Covered entities with advanced technological capabilities should also consider limiting access to appropriate portions of protected health information when it would be practical to do so.

The ''minimum necessary'' determination would include a determination that the purpose of the use or disclosure could not be reasonably accomplished with information that is not identifiable. Each covered entity would be required to have policies for determining when information must be stripped of identifiers before disclosure. If identifiers are not removed simply because of inconvenience to the covered entity, the ''minimum necessary'' rule would be violated.

Similarly, disclosure of an entire medical record, in response to a request for something other than the entire medical record, would presumptively violate the ''minimum necessary'' rule. Except where the individual has specifically authorized use or disclosure of the full medical record, when a covered entity receives a request for an entire medical record, the covered entity could not, under these proposed rules, disclose the entire record unless the request included an explanation of why the purpose of the disclosure could not reasonably be accomplished without the entire medical record.

The decisions called for in determining what would be the minimum necessary information to accomplish an allowable purpose should include both a respect for the privacy rights of the subjects of the medical record and the reasonable ability of covered entities to delimit the amount of individually identifiable health information in otherwise permitted uses and disclosures. For example, a large enterprise that makes frequent electronic disclosures of similar data would be expected to remove identifiers or to limit the data fields that are disclosed to fit the purpose of the disclosure. An individual physician's office would not be expected to have the same capabilities to limit the amount of information disclosed, although, in the cases of disclosures involving a small number of records, such an office could be expected to hide identifiers or to limit disclosures to certain pages of the medical record that are relevant to the purpose of the disclosure.

Even where it might not be reasonable for a covered entity to limit the amount of information disclosed, there could be opportunities, when the use or disclosure does not require authorization by the individual, to reduce the scope of the disclosure in ways that substantially protect the privacy interests of the subject. For example, if a health researcher wants access to relatively discrete parts of medical records that are presently maintained in paper form for a large number of patients with a certain condition, it could be financially prohibitive for the covered entity to isolate the desired information. However, it could be reasonable for the covered entity to allow the researcher to review the records on-site and to abstract only the information relevant to the research. Much records research is done today through such abstracting, and this could be a good way to meet the ''minimum necessary'' principle. By limiting the physical distribution of the record, the covered entity would have effectively limited the scope of the disclosure to the information necessary for the purpose.

Proposed § 164.506(b) generally would place the responsibility for determining what disclosure is the ''minimum necessary'' on the covered entity making the disclosure. The exception would be for health plan requests for information from health care providers for auditing and related purposes. In this instance, since the provider is not in a position to negotiate with the payer, the duty would be shifted to the payer to request the ''minimum necessary'' information for the purpose. See proposed § 164.506(b)(1)(iv). Whenever a health plan requests a disclosure, it would be required to limit its requests to the information to achieve the purpose of the request. For example, a health plan seeking protected health information from a provider or other health plan to process a payment should not request the entire health record unless it is actually necessary.

In addition, the proposal would permit covered entities to reasonably rely on requests by certain public agencies in determining the minimum necessary information for certain disclosures. For example, a covered entity that reasonably relies on the requests of public health agencies, oversight agencies, law enforcement agencies, coroners or medical examiners would be in compliance with this requirement. See proposed § 164.506(b)(3).

As discussed in prior HIPAA proposed rulemakings, it is likely to be easier to limit disclosure when disclosing computerized records than when providing access to paper records. Technological mechanisms to limit the amount of information available for a particular purpose, and make information available without identifiers, are an important contribution of technology to personal privacy. For example, the fields of information that are disclosed can be limited, identifiers (including names, addresses and other data) can be removed, and encryption can restrict to authorized personnel the ability to link identifiers back to the record.

For electronic information covered by the proposed rules, the ''minimum necessary'' requirement would mean reviewing, forwarding, or printing out only those fields and records relevant to the user's need for information. Where reasonable (based on the size, sophistication and volume of the covered entity's electronic information systems), covered entities would configure their record systems to allow selective access to different portions of the record, so that, for example, administrative personnel get access to only certain fields, and medical personnel get access to other fields. This selective access to information would be implemented using the access control technology discussed in the electronic security regulation.

For non-electronic information covered by the proposed rules, ''minimum necessary'' would mean the selective copying of relevant parts of protected health information or the use of ''order forms'' to convey the relevant information. These techniques are already in use in the health care environment today, not because of privacy considerations, but because of the risk of losing access to the full medical record when needed for clinic or emergency visits.

This rule would require, in proposed § 164.520, that each covered entity document the administrative policies and procedures that it will use to meet the requirements of this section. With respect to the ''minimum necessary'' compliance standard, such procedures would have to describe the process or processes by which the covered entity will make minimum necessary determinations, the person or persons who will be responsible for making such determinations, and the process in place to periodically review routine uses and disclosures in light of new technologies or other relevant changes. Proposed uses or disclosures would have to be reviewed by persons who have an understanding of the entity's privacy policies and practices, and who have sufficient expertise to understand and weigh the factors described above. See proposed § 164.506(b)(2). The policies that would be reasonable would vary depending on the nature and size of the covered entity. For large enterprises, the documentation of policies and procedures might identify the general job descriptions of the people that would make such decisions throughout the organization.

In addition, the procedures would provide that the covered entity will review each request for disclosure individually on its own merits (and, for research, the documentation of required IRB or other approval). Covered entities should not have general policies of approving all requests (or all requests of a particular type) for disclosures or uses without carefully considering the factors identified above as well as other information specific to the request that the entity finds important to the decision.

We understand that the requirements outlined in this section do not create a bright line test for determining the minimum necessary amount of protected health information appropriate for most uses or disclosures. Because of this lack of precision, we considered eliminating the requirement altogether. We also considered merely requiring covered entities to address the concept within their internal privacy procedures, with no further guidance as to how each covered entity would address the issue. These approaches were rejected because minimizing both the amount of protected health information used and disclosed within the health care system and the number of persons who have access to such information is vital if we are to successfully enhance the confidentiality of people's personal health information. We invite comments on the approach that we have adopted and on alternative methods of implementing the minimum necessary principle.

3. Right to Restrict Uses and Disclosures. (§ 164.506(c))

[*Please label comments about this section with the subject: ''Right to restrict''*]

We propose to permit in § 164.506(c) that individuals be able to request that a covered entity restrict further uses and disclosures of protected health information for treatment, payment, or health care operations, and if the covered entity agrees to the requested restrictions, the covered entity could not make uses or disclosures for treatment, payment or health care operations that are inconsistent with such restrictions, unless such uses or disclosures are mandated by law. This provision would not apply to health care provided to an individual on an emergency basis.

This proposal would not restrict the right of a provider to make an otherwise permissible disclosure under § 164.510, such as a disclosure for public health or emergency purposes. While there is nothing in this proposed rule that would prohibit a provider and an individual from agreeing in advance not to make such disclosures, such an agreement would not be enforceable through this proposed rule.

We should note that there is nothing in this proposed rule that requires a covered entity to agree to a request to restrict, or to treat or provide coverage to an individual requesting a restriction under this provision. Covered entities who do not wish to, or due to contractual obligations cannot, restrict further use or disclosure would not be obligated to treat an individual making a request under this provision. For example, some health care providers could feel that it is medically inappropriate to honor patient requests under this provision. The medical history and records of a patient, particularly information about current medications and other therapies, are often very much relevant when new treatment is sought, and the patient cannot seek to withhold this information from subsequent providers without risk.

Under this proposal, individuals could request broad restrictions on further uses and disclosures for treatment, payment or health care operations, or could request more limited restrictions relating to further uses or disclosures of particular portions of the protected health information or to further disclosures to particular persons. Covered entities could choose to honor the individual's request, could decline to treat or provide coverage to the individual, or could propose an alternative restriction of further use or disclosure. The covered entity would not be bound by an individual's request for restriction until its scope has been agreed to by the individual and the provider. Once an agreement has been reached, however, a covered entity that uses or discloses the protected health information resulting from the encounter in any manner that violates such agreement would be in violation of this provision.

We are not proposing to extend this right to individuals receiving emergency medical care, because emergency situations may not afford sufficient opportunity for the provider and patient to discuss the potential implications of restricting further use and disclosure of the resulting medical information. Additionally, a health care provider may not be free to refuse treatment to an emergency patient if the provider does not wish to honor a request to restrict further use or disclosure of health information, leaving the provider in an unfair position where she or he must choose between permitting medical harm to come to the patient or honoring a request that she or he feels may be inappropriate or which may violate the provider's business practices or contractual obligations. Some health care providers are legally required to treat emergency patients (e.g., hospital emergency rooms), and would have no opportunity to refuse treatment as a result of a request to restrict further use and disclosure under this provision. Under the pressure of an emergency, a provider should not be expected to adhere to the restrictions associated with a particular individual's information.

Under this proposal, covered entities would not be responsible for ensuring that agreed-upon restrictions are honored when the protected health information leaves the control of the covered entity or its business partners. For example, a provider would not be out of compliance if information she or he disclosed to another provider (consistent with the agreed upon restrictions and with notice of the applicable restrictions on uses and disclosures) is subsequently used or disclosed in violation of the restrictions.

The agreement to restrict use and disclosure under this provision would have to be documented to be binding on the covered entity. In proposed § 164.520, we would require covered entities to develop and document policies and procedures reasonably designed to ensure that the requests are followed, i.e., that unauthorized uses and disclosures are not made.

We note that this proposed rule would not permit covered entities to require individuals to invoke their right to restrict uses and disclosures; only the patient could make a request and invoke this right to restrict.

We considered providing individuals substantially more control over their protected health information by requiring all covered entities to attempt to accommodate any restrictions on use and disclosure requested by patients. We rejected this option as unworkable. While industry groups have developed principles for requiring patient authorizations, we have not found widely accepted standards for implementing patient restrictions on uses or disclosures. Restrictions on information use or disclosure contained in patient consent forms are sometimes ignored because they may not be read or are lost in files. Thus, it seems unlikely that a requested restriction could successfully follow a patient's information through the health care system—from treatment to payment, through numerous operations, and potentially through certain permissible disclosures. Instead we would limit the provision to restrictions that have been agreed to by the covered entity.

We recognize that the approach that we are proposing could be difficult because of the systems limitations described above. However, we believe that the limited right for patients included in this proposed rule can be implemented because it only applies in instances in which the covered entity agrees to the restrictions. We assume that covered entities would not agree to restrictions that they are unable to implement.

We considered limiting the rights under this provision to patients who pay for their own health care (or for whom no payment was made by a health plan). Individuals and health care providers that engage in self-pay transactions have minimal effect on the rights or responsibilities of payers or other providers, and so there would be few instances when a restriction agreed to in such a situation would have negative implications for the interests of other health care actors. Limiting the right to restrict to self-pay patients also would reduce the number of requests that would be made under this provision. We rejected this approach however, because the desire to restrict further uses and disclosures arises in many instances other than self-pay situations. For example, a patient could request that his or her records not be shared with a particular physician because that physician is a family friend. Or an individual could be seeking a second opinion and might not want his or her treating physician consulted. Individuals have a legitimate interest in restricting disclosures in these situations. We solicit comment on the appropriateness of limiting this provision to instances in which no health plan payment is made on behalf of the individual.

In making this proposal, we recognize that it could be difficult in some instances for patients to have a real opportunity to make agreements with covered entities, because it would not be clear in all cases which representatives of a covered entity could make an agreement on behalf of the covered entity. There also are concerns about the extent to which covered entities could ensure that agreed-upon restrictions would be followed. As mentioned above, current restrictions contained in patient consent forms are sometimes ignored because the person handling the information is unaware of the restrictions. We solicit comments on the administrative burdens this provision creates for covered entities, such as the burdens of administering a system in which some information is protected by federal law and other information is not.

We would note that we expect that systems for handling patient requests to restrict use and disclosure of information will become more responsive as technology develops. Therefore, we will revisit this provision as what is practicable changes over time. Proposed requirements for documenting internal procedures to implement this proposed provision are included in proposed § 164.520. We request comments on whether the final rule should provide examples of appropriate, scalable systems that would be in compliance with this standard.

4. Creation of De-identified Information (164.506(d))

[*Please label comments about this section with the subject: ''Creation of de-identified information''*]

In this rule we are proposing that covered entities and their business partners be permitted to use protected health information to create de-identified health information. Covered entities would be permitted to further use and disclose such de-identified information in any way, provided that they do not disclose the key or other mechanism that would enable the information to be re-identified, and provided that they reasonably believe that such use or disclosure of de-identified information will not result in the use or disclosure of protected health information. See proposed § 164.506(d)(1). This means that a covered entity could not disclose de-identified information to a person if the covered entity reasonably believes that the person would be able to re-identify some or all of that information, unless disclosure of protected health information to such person would be permitted under this proposed rule. In addition, a covered entity could not use or disclose the key to coded identifiers if this rule would not permit the use or disclosure of the identified information to which the key pertains. If a covered entity re-identifies the de-identified information, it may only use or disclose the re-identified information consistent with these proposed rules, as if it were the original protected health information.

In some instances, covered entities creating de-identified health information could want to use codes or identifiers to permit data attributable to the same person to be accumulated over time or across different sources of data. For example, a covered entity could automatically code all billing information as it enters the system, substituting personal identifiers with anonymous codes that permit tracking and matching of data but do not permit people handling the data to create protected health information. Such a mechanism would be permissible as long as the key to unlocking the codes is not available to the people working with the de-identified information, and the entity otherwise makes no attempt to create protected health information from the de-identified information.

There are many instances in which such individually identifiable health information is stripped of the information that could identify individual subjects and is used for analytical, statistical and other related purposes. Large data sets of de-identified information can be used for innumerable purposes that are vital to improving the efficiency and effectiveness of health care delivery, such as epidemiological studies, comparisons of cost, quality or specific outcomes across providers or payers, studies of incidence or prevalence of disease across populations, areas or time, and studies of access to care or differing use patterns across populations, areas or time. Researchers and others often obtain large data sets with de-identified information from providers and payers (including from public payers) to engage in these types of studies. This information is valuable for public health activities (e.g., to identify cost-effective interventions for a particular disease) as well as for

commercial purposes (e.g., to identify areas for marketing new health care services).

We intend that this proposed provision will permit the important health care research that is being conducted today to continue under this rule. Indeed, it would be our hope that covered entities, their business partners, and others would make greater use of de-identified health information than they do today, when it is sufficient for the research purpose. Such practice would reduce the confidentiality concerns that result from the use of individually identifiable health information for some of these purposes. The selective transfer of health information without identifiers into an analytic database would significantly reduce the potential for privacy violations while allowing broader access to information for analytic purposes, without the overhead of audit trails and IRB review. For example, providing de-identified information to a pharmaceutical manufacturer to use in determining patterns of use of a particular pharmaceutical by general geographic location would be appropriate, even if the information were sold to the manufacturer. Such analysis using protected health information would be research and therefore would require individual authorization or approval by an IRB or similar board. We note that data that includes an individual's address is ''identifiable'' by definition and could not be used in such databases.

We invite comment on the approach that we are proposing and on whether alternative approaches to standards for entities determining when health information can reasonably be considered no longer individually identifiable.

5. Application to business partners. (§ 164.506(e))

[*Please label comments about this section with the subject: ''Business partners''*]

In § 164.506(e), we propose to require covered entities to take specific steps to ensure that protected health information disclosed to a business partner remains protected. We intend these provisions to allow customary business relationships in the health care industry to continue while providing privacy protections to the information shared in these relationships. Business partners would not be permitted to use or disclose protected health information in ways that would not be permitted of the covered entity itself under these rules.

Other than for purposes of consultation or referral for treatment, we would allow covered entities to disclose protected health information to business partners only pursuant to a written contract that would, among other specified provisions, limit the business partner's uses and disclosures of protected health information to those permitted by the contract, and would impose certain security, inspection and reporting requirements on the business partner. We would hold the covered entity responsible for certain violations of this proposed rule made by their business partners, and require assignment of responsibilities when a covered entity acts as a business partner of another covered entity.

a. *Who is a business partner?* Under this proposed rule, a business partner would be a person to whom the covered entity discloses protected health information so that the person can carry out, assist with the performance of, or perform on behalf of, a function or activity for the covered entity. This would include contractors or other persons who receive protected health information from the covered entity (or from another business partner of the covered entity) for the purposes described in the previous sentence, including lawyers, auditors, consultants, third-party administrators, health care clearinghouses, data processing firms, billing firms, and other covered entities. This would not include persons who would be members of the covered entity's workforce. The key features of the relationship would be that the business partner is performing an activity or function for or on behalf of the covered entity and that the business partner receives protected health information from the covered entity as part of providing such activity or function.

Many critical functions are performed every day by individuals and organizations that we would define as business partners. Under the proposal, billing agents, auditors, third-party administrators, attorneys, private accreditation organizations, clearinghouses, accountants, data warehouses, consultants and many other actors would be considered business partners of a covered entity. Most covered entities will use one or more business partners, to assist with functions such as claims filing, claims administration, utilization review, data storage, or analysis. For example, if a covered entity seeks accreditation from a private accreditation organization and provides such organization with protected health information as part of the accreditation process, the private accreditation organization would be a business partner of the covered entity. This would be true even if a third party, such as an employer or a public agency, required accreditation as a condition of doing business with it. The accreditation is being performed for the covered entity, not the third party, in such cases.

The covered entity may have business relationships with organizations that would not be considered to be business partners because protected health information is not shared or because services are not provided to the covered entity. For example, a covered entity could contract with another organization for facility management or food services; if these organizations do not receive protected health information for these functions or activities, they would not be considered business partners. In the case where a covered entity provides management services to another organization, the other organization would not be a business partner because it would be receiving, not providing, a service or function.

Under the proposal, a covered entity could become a business partner of another covered entity, such as when a health plan acts as a third-party administrator to an insurance arrangement or a self-funded employee benefit plan. In such cases, we propose that the authority of the covered entity acting as a business partner to use and disclose protected health information be constrained to the authority that any business partner in the same situation would have. Thus, the authority of a covered entity acting as a business partner to use and disclose protected health information obtained as a business partner would be limited by the contract or arrangement that created the business partner relationship.

In most cases, health care clearinghouses would fall under our definition of ''business partner'' because they receive protected health information in order to provide payment processing and other services to health plans, health care providers and their business partners, a case that would fall under our definition of ''business partner.'' Therefore, although health care clearinghouses would be covered entities, in many instances under this proposed rule they would also be treated as business partners of the health care providers or health plans for whom they are performing a service. We would note that because health care clearinghouses would generally be operating as business partners, we are proposing not to apply several requirements to health care clearinghouses that we otherwise would apply to covered plans and providers, such as requiring a notice of information

practices, access for inspection and copying, and accommodation of requests for amendment or correction. See proposed §§ 164.512, 164.514 and 164.516.

b. *Limitations on use or disclosure.*

i. *Scope of the covered entity's authority.*

Under this proposed rule, a business partner would be acting on behalf of a covered entity, and we propose that its use or disclosure of protected health information be limited to the same extent that the covered entity for whom they are acting would be limited. Thus, a business partner could have no more authority to use or disclose protected health information than that possessed by the covered entity from which the business partner received the information. For example, a business partner could not sell protected health information to a financial services firm without individual authorization because the covered entity would not be permitted to do so under these proposed rules. We would note that a business partner's authority to use and disclose protected health information could be further restricted by its contract with a covered entity, as described below.

We are not proposing to require the business partners of covered entities to develop and distribute a notice of information practices, as provided in proposed § 164.512. A business partner would, however, be bound by the terms of the notice of the covered entity from which it obtains protected health information. For example, if a covered entity provided notice to its subscribers that it would not engage in certain permissible disclosures of protected health information, we are proposing that such a limitation would apply to all of the business partners of the covered entity that made the commitment. See proposed § 164.506(e). We are proposing this approach so that individuals could rely on the notices that they receive from the covered entities to which they disclose protected health information. If the business partners of a covered entity were able to make wider use or make more disclosures than the covered entity, the patients or enrollees of the covered entity would have difficulty knowing how their information was being used and to whom it was being disclosed.

ii. *Scope of the contractual agreement.*

We are also proposing that a business partner's use and disclosure of protected health information be limited by the terms of the business partner's contractual agreement with the covered entity. We propose that a contract between a covered entity and a business partner could not grant the business partner authority to make uses or disclosures of protected health information that the covered entity itself would not have the authority to make. The contract between a covered entity and a business partner could further limit the business partner's authority to use or disclose protected health information as agreed to by the parties. Further, the business partner would have to apply the same limitations to its subcontractors (or persons with similar arrangements) who assist with or carry out the business partner's activities.

To help ensure that the uses and disclosures of business partners would be limited to those recognized as appropriate by the covered entities from whom they receive protected health information, subject to the exception discussed below, we are proposing that covered entities be prohibited from disclosing protected health information to a business partner unless the covered entity has entered into a written contract with the business partner that meets the requirements of this subsection. See proposed § 164.506(e)(2)(i). The written contract between a covered entity and a business partner would be required to:

- Prohibit the business partner from further using or disclosing the protected health information for any purpose other than the purpose stated in the contract.
- Prohibit the business partner from further using or disclosing the protected health information in a manner that would violate the requirements of this proposed rule if it were done by the covered entity. As discussed above, the covered entity could not permit the business partner to make uses or disclosures that the covered entity could not make.
- Require the business partner to maintain safeguards as necessary to ensure that the protected health information is not used or disclosed except as provided by the contract. We are only proposing a general requirement; the details can be negotiated to meet the particular needs of each arrangement. For example, if the business partner is a two-person firm the contractual provisions regarding safeguards may focus on controlling physical access to a computer or file drawers, while a contract with a business partner with 500 employees would address use of electronic technologies to provide security of electronic and paper records.
- Require the business partner to report to the covered entity any use or disclosure of the protected health information of which the business partner becomes aware that is not provided for in the contract.
- Require the business partner to ensure that any subcontractors or agents to whom it provides protected health information received from the covered entity will agree to the same restrictions and conditions that apply to the business partner with respect to such information.
- Establish how the covered entity would provide access to protected health information to the subject of that information, as would be required under § 164.514, when the business partner has made any material alteration in the information. The covered entity and the business partner would determine in advance how the covered entity would know or could readily ascertain, when a particular individual's protected health information has been materially altered by the business partner, and how the covered entity could provide access to such information.
- Require the business partner to make available its internal practices, books and records relating to the use and disclosure of protected health information received from the covered entity to HHS or its agents for the purposes of enforcing the provisions of this rule.
- Establish how the covered entity would provide access to protected health information to the subject of that information, as would be required under § 164.514, in circumstances where the business partner will hold the protected health information and the covered entity will not.
- Require the business partner to incorporate any amendments or corrections to protected health information when notified by the covered entity that the information is inaccurate or incomplete.
- At termination of the contract, require the business partner to return or destroy all protected health information received from the covered entity that the business partner still maintains in any form to the covered entity and prohibit the business partner from retaining such protected health information in any form.
- State that individuals who are the subject of the protected health information disclosed are intended to be third party beneficiaries of the contract.
- Authorize the covered entity to terminate the contract, if the covered entity determines that the business partner has repeatedly violated a term of the contract required by this paragraph.

Each specified contract term above would be considered a separate implementation specification under this proposal for situations in which a

contract is required, and, as discussed below, a covered entity would be responsible for assuring that each such implementation standard is met by the business partner. See proposed § 164.506(e)(2). The contract could include any additional arrangements that do not violate the provisions of this regulation.

The contract requirement that we are proposing would permit covered entities to exercise control over their business partners' activities and provide documentation of the relationship between the parties, particularly the scope of the uses and disclosures of protected health information that business partners could make. The presence of a contract also would formalize the relationship, better ensuring that key questions such as security, scope of use and disclosure, and access by individuals are adequately addressed and that the roles of the respective parties are clarified. Finally, a contract can bind the business partner to return any protected health information from the covered entity when the relationship is terminated.

In lieu of a contracting requirement, we considered imposing only affirmative duties on covered entities to ensure that their relationships with business partners conformed to the standards discussed in the previous paragraph. Such an approach could be considered less burdensome and restrictive, because we would be leaving it to the parties to determine how to make the standards effective. We rejected this approach primarily because we believe that in the vast majority of cases, the only way that the parties could establish a relationship with these terms would be through contract. We also determined that the value of making the terms explicit through a written contract would better enable the parties to know their roles and responsibilities, as well as better enable the Secretary to exercise her oversight role. In addition, we understand that most covered entities already enter into contracts in these situations and therefore this proposal would not disturb general business practice. We invite comment on whether there are other contractual or non-contractual approaches that would afford an adequate level of protection to individuals' protected health information. We also invite comment on the specific provisions and terms of the proposed approach.

We are proposing one exception to the contracting requirement: when a covered entity consults with or makes a referral to another covered entity for the treatment of an individual, we would propose that the sharing of protected health information pursuant to that consultation or referral not be subject to the contracting requirement described above. See proposed § 164.506(e)(1)(i). Unlike most business partner relationships, which involve the systematic sharing of protected health information under a business relationship, consultation and referrals for treatment occur on a more informal basis among peers, and are specific to a particular individual. Such exchanges of information for treatment also appear to be less likely to raise concerns about further impermissible use or disclosure, because health care providers receiving such information are unlikely to have a commercial or other interest in using or disclosing the information. We invite comment on the appropriateness of this exception, and whether there are additional exceptions that should be included in the final regulation.

We note that covered health care providers receiving protected health information for consultation or referral purposes would still be subject to this rule, and could not use or disclose such protected health information for a purpose other than the purpose for which it was received (i.e., the consultation or referral). Further, we note that providers making disclosures for consultations or referrals should be careful to inform the receiving provider of any special limitations or conditions to which the disclosing provider has agreed to impose (e.g., the disclosing provider has provided notice to its patients that it will not make disclosures for research).

Under the system that we are proposing, business partners (including business partners that are covered entities) that have contracts with more than one covered entity would have no authority to combine, aggregate or otherwise use for a single purpose protected health information obtained from more than one covered entity unless doing so would have been a lawful use or disclosure for each of the covered entities that supplied the protected health information that is being combined, aggregated or used. In addition, the business partner must be authorized through the contract or arrangement with each covered entity that supplied the protected health information to combine or aggregate the information. For example, a business partner of a health plan would be permitted to disclose information to another health plan for coordination of benefits purposes, if such a disclosure were authorized by the business partner's contract with the covered entity that provided the protected health information. However, a business partner that is performing an audit of a group medical practice on behalf of several health plans could not combine protected health information that it had received from each of the plans, even if the business partner's contracts with the plans attempted to allow such activity, because the plans themselves would not be permitted to exchange protected health information for such a purpose. A covered entity would not be permitted to obtain protected health information through a business partner that it could not otherwise obtain itself.

We further note that, as discussed above in section II.C.4, under our proposal a business partner generally could create a database of de-identified health information drawn from the protected health information of more than one covered entity with which it does business, and could use and disclose information and analyses from the database as they see fit, as long as there was no attempt to re-identify the data to create protected health information. In the example from the preceding paragraph, the business partner could review the utilization patterns of a group medical practice on behalf of several groups of plans by establishing a data base of de-identified health information drawn from all of its contracts with covered entities and review the use patterns of all of the individuals in the data base who had been treated by the medical group. The results of the analyses could be used by or distributed to any person, subject to the limitation that the data could not be identified. We would caution that business partners releasing such information and analyses would need to ensure that they do not inadvertently disclose protected health information by releasing examples or discussing specific cases in such a way that the information could be identified by people receiving the analysis or report.

c. *Accountability.* We are proposing that covered entities be accountable for the uses and disclosures of protected health information by their business partners. A covered entity would be in violation of this rule if the covered entity knew or reasonably should have known of a material breach of the contract by a business partner and it failed to take reasonable steps to cure the breach or terminate the contract. See proposed § 164.506(e)(2)(iii). A covered entity that is aware of impermissible uses and disclosures by a business partner would be responsible for taking such steps as are necessary to prevent further improper use or disclosures and, to the extent practicable, for mitigating any harm caused by such violations.

This could include, for example, requiring the business partner to retrieve inappropriately disclosed information (even if the business partner must pay for it) as a condition of continuing to do business with the covered entity. A covered entity that knows or should know of impermissible use of protected health information by its business partner and fails to take reasonable steps to end the breach would be in violation of this rule.

Where a covered entity acts as a business partner to another covered entity, the covered entity that is acting as business partner would also be responsible for any violations of the regulation.

We considered requiring covered entities to terminate relationships with business partners if the business partner committed a serious breach of contact terms required by this subsection or if the business partner exhibited a pattern or practice of behavior that resulted in repeated breaches of such terms. We rejected that approach because of the substantial disruptions in business relationships and customer service when terminations occur. We instead require the covered entity to take reasonable steps to end the breach and mitigate its effects. We would expect covered entities to terminate the arrangement if it becomes clear that a business partner cannot be relied upon to maintain the privacy of protected health information provided to it. We invite comments on our approach here and whether requiring automatic termination of business partner contracts would be warranted in any circumstances.

We also considered imposing more strict liability on covered entities for the actions of their business partners, just as principals are strictly liable for the actions of their agents under common law. We decided, however, that this could impose too great a burden on covered entities, particularly small providers. We are aware that, in some cases, the business partner will be larger and more sophisticated with respect to information handling than the covered entity. Therefore we instead opted to propose that covered entities monitor use of protected health information by business partners, and be held responsible only when they knew or reasonably should have known of improper use of protected health information.

Our intention in this subsection is to recognize the myriad business relationships that currently exist and to ensure that when they involve the exchange of protected health information, the roles and responsibilities of the different parties with respect to the protected health information are clear. We do not propose to fundamentally alter the types of business relationships that exist in the health care industry or the manner in which they function. We request comments on the extent to which our proposal would disturb existing contractual or other arrangements among covered entities and business partners.

6. Application to Information About Deceased Persons (§ 164.506(f))

[Please label comments about this section with the subject: ''Deceased persons'']

We are proposing that information otherwise protected by these regulations retain that protection for two years after the death of the subject of the information. The only exception that we are proposing is for uses and disclosures for research purposes.

HIPAA includes no temporal limitations on the application of the privacy protections. Although we have the authority to protect individually identifiable health information maintained by a covered entity indefinitely, we are proposing that the requirements of this rule generally apply for only a limited period, as discussed below. In traditional privacy law, privacy interests, in the sense of the right to control use or disclosure of information about oneself, cease at death. However, good arguments exist in favor both of protecting and not protecting information about the deceased. Considering that one of the underlying purposes of health information confidentiality is to encourage a person seeking treatment to be frank in the interest of obtaining care, there is good reason for protecting information even after death. Federal agencies and others sometimes withhold sensitive information, such as health information, to protect the privacy of surviving family members. At the same time, perpetual confidentiality has serious drawbacks. If information is needed for legitimate purposes, the consent of a living person legally authorized to grant such consent must be obtained, and the further from the date of death, the more difficult it may be to identify the person. The administrative burden of perpetual protection may eventually outweigh the privacy interests served.

The proposed two-year period of confidentiality, with an exception for uses and disclosures for research purposes, would preserve dignity and respect by preventing uncontrolled disclosure of information immediately after death while allowing access to the information for proper purposes during this period and for any purpose thereafter. We would not subject the use or disclosure of protected health information of deceased individuals to the requirements in proposed § 164.510(j) governing most uses and disclosures for research because we believe that it is important to remain as consistent as possible with the Common Rule. The Common Rule does not consider deceased persons to be ''human subjects'' and therefore they have never been covered in the standard research protocol assessments conducted under the Common Rule. The Department of Health and Human Services will examine this issue in the context of an overall assessment of the Common Rule. Pending the outcome of this examination, we concluded that this exception was warranted so as not to interfere with standard research practice. We invite comments on whether the exception that we are proposing is necessary, or whether existing research using the protected health information of deceased individuals could proceed under the requirements of proposed § 164.510(j).

Under our proposal, and subject to the exceptions discussed above, the right to control the individual's health information within that two-year time period would be held by an executor or administrator, or in the absence of such an officer, by next-of-kin, as determined under applicable law, or in absence of both, by the holder of the health information. This is reflected in the proposed definition of ''individual'' discussed above. The legally authorized representative would make decisions for the individual with regard to uses or disclosures of the information for purposes not related to treatment, payment or health care operations. Likewise, an authorized representative could exercise the individual rights of inspection, copying, amendment or correction under proposed §§ 164.514 and 164.516.

Under our proposal, information holders could choose to keep information confidential for a longer period. These proposed rules also would not override any legally required prohibitions on disclosure for longer periods.

One area of concern regarding the proposed two-year period of protection relates to information on individual genetic make-up or individual diseases and conditions that may be hereditary. Under the proposed rules, covered entities would be legally allowed to use such information or to disclose records to others, such as commercial collectors

of information, two years after the death of the individual. Since genetic information about one family member may reveal health information about other members of that family, the health data confidentiality of living relatives could be compromised by such uses or disclosures. Likewise, information regarding the hereditary diseases or conditions of the deceased person may reveal health information about living relatives. In the past, information that may not have been legally protected was *de facto* protected for most people because of the difficulty of its collection and aggregation. With the dramatic proliferation of large electronic databases of information about individuals, growing software-based intelligence, and the declining cost of linking information from disparate sources, such information could now be more readily and cost-effectively accessed.

While various State laws have been passed specifically addressing privacy of genetic information, there is currently no federal legislation that deals with these issues. We considered extending the two-year period for genetic and hereditary information, but were unable to construct criteria for protecting the possible privacy interests of living children without creating extensive burden for information holders and hampering health research. We invite comments on whether further action is needed in this area and what types of practical provisions may be appropriate to protect genetic and hereditary health information.

7. Adherence to the Notice of Information Practices (§ 164.506(g))

[Please label comments about this section with the subject: ''Adherence to notice'']

In § 164.506(g), we are proposing that covered plans and providers be required to adhere to the statements reflected in the notice of information practices that would be required under proposed § 164.512. In binding covered plans and providers to their notices, we intend to create a system where open and accurate communication between entities and individuals would become necessary and routine. The corollary to this general rule is that the covered plan or provider would be permitted to modify its notice at any time.

The information practices reflected in the most recent notice would apply to all protected health information regardless of when the information was collected. For example, if information was collected during a period when the notice stated that no disclosures would be made to researchers, and the covered plan or provider later decided that it wanted to disclose information to researchers, the entity would then need to revise its notice. The entity would be permitted to disclose all of the information in its custody to researchers as long as the notice is revised and re-distributed as provided below in § 164.512. We considered permitting a covered entity to change its information practices only with respect to protected health information obtained after it revised its notice. Such a requirement would ensure individuals that the notice they received when they disclosed information to the covered entity would continue to apply to that information. We rejected that approach because compliance with such a standard would require covered entities to segregate or otherwise mark information to be based on the information practices that were in effect at different times. Such an approach would make covered entities extremely reluctant to revise the information practices, and otherwise would be extremely burdensome to administer.

We are concerned that by requiring covered plans and providers to adhere to the practices reflected in their notice, we would encourage entities to create broad, general notices so that all possible uses, disclosures and other practices would be included. Such broad notices would not achieve the goals of open and accurate communication between entities and individuals. We welcome comments on this requirement and alternative proposals to achieve the same goals.

8. Application to Covered Entities That Are Components of Organizations That Are Not Covered Entities

[Please label comments about this section with the subject: ''Component entities'']

In this section we describe how the provisions of this proposed rule apply to persons or organizations that provide health care or have created health plans but are primarily engaged in other unrelated activities. Examples of such organizations include schools that operate on-site clinics, employers who operate self-funded health plans, and information processing companies that include a health care services component. The health care component (whether or not separately incorporated) of the organization would be the covered entity. Therefore, any movement of protected health information into another component of the organization would be a ''disclosure,'' and would be lawful only if such disclosure would be authorized by this regulation. In addition, we propose to require such entities to create barriers to prevent protected health information from being used or disclosed for other activities not authorized or permitted under these proposed rules.

For example, schools frequently employ school nurses or operate on-site clinics. In doing so, the nurse or clinic component of the school would be acting as a provider, and must conform to this proposed rule. School clinics would be able to use protected health information obtained in an on-site clinic for treatment and payment purposes, but could not disclose it to the school for disciplinary purposes except as permitted by this rule. Similarly, an employee assistance program of an employer could meet the definition of ''provider,'' particularly if health care services are offered directly by the program. Protected health information obtained by the employee assistance program could be used for treatment and payment purposes, but not for other purposes such as hiring and firing, placement and promotions, except as may be permitted by this rule.

D. Uses and Disclosures With Individual Authorization (§ 164.508)

[Please label comments about this section With the subject: ''Individual authorization'']

This section addresses the requirements that we are proposing when protected health information is disclosed pursuant to the individual's explicit authorization. The regulation would require that covered entities have authorization from individuals before using or disclosing their protected health information for any purpose not otherwise recognized by this regulation. Circumstances where an individual's protected health information may be used or disclosed without authorization are discussed in connection with proposed §§ 164.510 and 164.522 below.

This section proposes different conditions governing such authorizations in two situations in which individuals commonly authorize covered entities to disclose information:

- Where the individual initiates the authorization because he or she wants a covered entity to disclose his or her record, and
- Where a covered entity asks an individual to authorize it to disclose or use information for purposes other than treatment, payment or health care operations.

In addition, this section proposes conditions where a covered entity or the individual initiates an authorization for use or disclosure of psychotherapy notes or research information unrelated

to treatment. See discussion above in section II.C.1.c.

Individually identifiable health information is used for a vast array of purposes not directly related to providing or paying for an individual's health care. Examples of such uses include targeted marketing of new products and assessing the eligibility of an individual for certain public benefits or for commercial products based on their health status. Under these rules, these types of uses and disclosures could only be made by a covered entity with the specific authorization of the subject of the information. The requirements proposed in this section are not intended to interfere with normal uses and disclosures of information in the health care delivery or payment process, but only to permit control of uses extraneous to health care. The restrictions on disclosure that the regulation would apply to covered entities may mean that some existing uses and disclosures of information could take place only if the individual explicitly authorized them under this section.

Authorization would be required for these uses and disclosures because individuals probably do not envision that the information they provide when getting health care would be disclosed for such unrelated purposes. Further, once a patient's protected health information is disclosed outside of the treatment and payment arena, it could be very difficult for the individual to determine what additional entities have seen, used and further disclosed the information. Requiring an authorization from the patient for such uses and disclosures would enhance individuals' control over their protected health information.

We considered requiring a uniform set of requirements for all authorizations, but concluded that it would be appropriate to treat authorizations initiated by the individual differently from authorizations sought by covered entities. There are fundamental differences in the uses of information and in the relationships and understandings among the parties in these two situations. When individuals initiate authorizations, they are more likely to understand the purpose of the release and to benefit themselves from the use or disclosure. When a covered entity asks the individual to authorize disclosure, we believe the entity should make clear what the information will be used for, what the individual's rights are, and how the covered entity would benefit from the requested disclosure.

Individuals seek disclosure of their health information to others in many circumstances, such as when applying for life or disability insurance, when government agencies conduct suitability investigations, and in seeking certain job assignments where health is relevant. Another common instance is tort litigation, where an individual's attorney needs individually identifiable health information to evaluate an injury claim and asks the individual to authorize disclosure of records relating to the injury to the attorney.

There could also be circumstances where the covered entity asks an individual to authorize use or disclosure of information, for example to disclose it to a subsidiary to market life insurance to the individual. Similarly, the covered entity might ask that the individual authorize it to send information to a person outside that covered entity—possibly another covered entity or class of covered entity—for purposes outside of treatment, payment, or health care operations. See proposed § 164.508(a)(2)(ii).

1. Requirements When the Individual Has Initiated the Authorization

We are proposing several requirements that would have to be met in the authorization process when the individual has initiated the authorization.

The authorization would have to include a description of the information to be used or disclosed with sufficient specificity to allow the covered entity to know to which information the authorization references. For example, the authorization could include a description of ''laboratory results from July 1998'' or ''all laboratory results'' or ''results of MRI performed in July 1998.'' The covered entity would then use or disclose that information and only that information. If the covered entity does not understand what information is covered by the authorization, the use or disclosure would not be permitted unless the covered entity were able to clarify the request.

We are proposing no limitations on the information to be disclosed. If an individual wishes to authorize a covered entity to disclose his or her entire medical record, the authorization could so specify. But in order for the covered entity to disclose the entire medical record, the authorization would have be specific enough to ensure that individuals have a clear understanding of what information is to be disclosed under the circumstances. For example, if the Social Security Administration seeks authorization for release of all health information to facilitate the processing of benefit applications, then the description would need to specify ''all health information.''

We would note that our proposal does not require a covered entity to disclose information pursuant to an individual's authorization. Therefore individuals may face reluctance on the part of covered entities that receive authorizations requiring them to classify and selectively disclose information when they do not benefit from the activity. Individuals would need to consider this when specifying the information in the authorization. Covered entities may respond to requests to analyze and separate information for selective disclosure by providing the entire record to the individual, who may then redact and release the information to others.

We do not propose to require an authorization initiated by an individual to state a purpose. When the individual has initiated the authorization, the entity would not need to know why he or she wants the information disclosed. Ideally, anyone asking an individual to authorize release of individually identifiable health information would indicate the purpose and the intended uses. We are unable to impose requirements on the many entities that make such requests, and it would not be feasible to ask covered entities to make judgments about intended uses of records that are disclosed. In the absence of legal controls in this situation, the prudent individual would obtain a clear understanding of why the requester needs the information and how it would be used.

We are proposing that the authorization would be required to identify sufficiently the covered entity or covered entities that would be authorized to use or disclose the protected health information by the authorization. Additionally, the authorization would be required to identify the person or persons that would be authorized to use or receive the protected health information with sufficient specificity to reasonably permit a covered entity responding to the authorization to identify the authorized user or recipient. When an authorization permits a class of covered entities to disclose information to an authorized person, each covered entity would need to know with reasonable certainty that the individual intended for it to release protected health information under the authorization.

Often, individuals provide authorizations to third parties, who present them to one or more covered entities. For example, an authorization could be completed by an individual

and provided to a government agency, authorizing the agency to receive medical information from any health care provider that has treated the individual within a defined period. Such an authorization would be permissible (subject to the other requirements of this part) if it sufficiently identifies the government entity as the recipient of the disclosures and it sufficiently identifies the health care providers who would be authorized to release the individual's protected health information under the authorization.

We are proposing that the authorization must state a specific expiration date. We considered providing an alternative way of describing the termination of the authorization, such as ''the conclusion of the clinical trial,'' or ''upon acceptance or denial of this application for life insurance'' (an ''event''), but we are concerned that covered entities could have difficulty implementing such an approach. We also considered proposing that if an expiration date were indicated on the authorization, it be no more than two or three years after the date of the signature. We are soliciting comment on whether an event can be a termination specification, and whether this proposed rule should permit covered entities to honor authorizations with ''unlimited'' or extremely lengthy expiration dates or limit it to a set term of years, such as two or three years.

We are proposing that the authorization include a signature or other authentication (e.g., electronic signature) and the date of the signature. If the authorization is signed by an individual other than the subject of the information to be disclosed, that individual would have to indicate his or her authority or relationship with the subject.

The authorization would also be required to include a statement that the individual understands that he or she may revoke an authorization except to the extent that action has been taken in reliance on the authorization.

When an individual authorizes disclosure of health information to other than a covered entity, the information would no longer be protected under this regulation once it leaves the covered entity. Therefore, we propose that the authorization must clearly state that the individual understands that when the information is disclosed to anyone except a covered entity, it would no longer be protected under this regulation.

We understand that the requirements that we are imposing here would make it quite unlikely that an individual could actually initiate a completed authorization, because few individuals would know to include all of these elements in a request for information. We understand that in most instances, individuals accomplish authorizations for release of health records by completing a form provided by another party, either the ultimate recipient of the records (who may have a form authorizing them to request the records from the record holders) or a health care provider or health plan holding the records (who may have a form that documents a request for the release of records to a third party). For this reason, we do not believe that our proposal would create substantial new burdens on individuals or covered entities in cases when an individual is initiating an authorized release of information. We invite comment on whether we are placing new burdens on individuals or covered entities. We also invite comment on whether the approach that we have proposed provides sufficient protection to individuals who seek to have their protected health information used or disclosed.

2. Requirements When the Covered Entity Initiates the Authorization

We are proposing that when covered entities initiate the authorization by asking individuals to authorize disclosure, the authorization be required to include all of the items required above as well as several additional items. We are proposing additional requirements when covered entities initiate the request for authorization because in many cases it could be the covered entity, and not the individual, that achieves the primary benefit of the disclosure. We considered permitting covered entities to request authorizations with only the basic features proposed for authorizations initiated by the individual, for the sake of simplicity and consistency. However, we believe that additional protections would be merited when the entity that provides or pays for health care requests an authorizations to avert possible coercion.

When a covered entity asks an individual to sign an authorization, we propose to require that it provide on the authorization a statement that identifies the purposes for which the information is sought as well as the proposed uses and disclosures of that information. The required statements of purpose would provide individuals with the facts they need to make an informed decision as to whether to allow release of the information. Covered entities and their business partners would be bound by the statements provided on the authorization, and use or disclosure by the covered entity inconsistent with the statement would constitute a violation of this regulation. We recognize that the covered entities cannot know or control uses and disclosures that will be made by persons who are not business partners to whom the information is properly disclosed. As discussed above, authorizations would need to notify individuals that when the information is disclosed to anyone except a covered entity, it would no longer be protected under this regulation.

We propose to require that authorizations requested by covered entities be narrowly tailored to authorize use or disclosure of only the protected health information necessary to accomplish the purpose specified in the authorization. The request would be subject to the minimum necessary requirement as discussed in section II.C.2. We would prohibit the use of broad or blanket authorizations requesting the use or disclosure of protected health information for a wide range of purposes. Both the information that would be used or disclosed and the specific purposes for such uses or disclosures would need to be specified in the notice.

We are proposing that when covered entities ask individuals to authorize use or disclosure for purposes other than for treatment, payment, or health care operations, they be required to advise individuals that they may inspect or copy the information to be used or disclosed as provided in proposed § 164.514, that they may refuse to sign the authorization, and that treatment and payment could not be conditioned on the patient's authorization. For example, a request for authorization to use or disclose protected health information for marketing purposes would need to clearly state that the individual's decision would have no influence on his or her health care treatment or payment. In addition, we are proposing that when a covered entity requests an authorization, it must provide the individual with a copy of the signed authorization form.

Finally, we are proposing that when the covered entity initiates the authorization and the covered entity would be receiving financial or in-kind compensation in exchange for using or disclosing the health information, the authorization would include a statement that the disclosure would result in commercial gain to the covered entity. For example, a health plan may wish to sell or rent its enrollee mailing list. A pharmaceutical company may offer a provider a discount on its products if

the provider can obtain authorization to disclose the demographic information of patients with certain diagnoses so that the company can market new drugs to them directly. A pharmaceutical company could pay a pharmacy to send marketing information to individuals on its behalf. Each such case would require a statement that the requesting entity will gain financially from the disclosure.

We considered requiring a contract between the provider and the pharmaceutical company in this type of arrangement, because such a contract could enhance protections and enforcement options against entities who violate these rules. A contract also would provide covered entities a basis to enforce any limits on further use or disclosures by authorized recipients. Although we are not proposing this approach now, we are soliciting comment on how best to protect the interests of the patient when the authorization for use or disclosure would result in commercial gain to the covered entity.

3. Model Forms

Covered entities and third parties that wish to have information disclosed to them would need to prepare forms for individuals to use to authorize use or disclosure. A model authorization form is displayed in Appendix to this proposed rule. We considered presenting separate model forms for the two different types of authorizations (initiated by the individual and not initiated by the individual). However, this approach could be subject to misuse and be confusing to covered entities and individuals, who may be unclear as to which form is appropriate in specific situations. The model in the appendix accordingly is a unitary model, which includes all of the requirements for both types of authorization.

4. Plain Language Requirement

We are proposing that all authorizations must be written in plain language. If individuals cannot understand the authorization they may not understand the results of signing the authorization or their right to refuse to sign. See section II.F.1 for more discussion of the plain language requirement.

5. Prohibition on Conditioning Treatment or Payment

We propose that covered entities be prohibited, except in the case of clinical trial as described below, from conditioning treatment or payment for health care on obtaining an authorization for purposes other than treatment, payment or health care operations. This is intended to prevent covered plans and providers from coercing individuals into signing an authorization for a disclosure that is not necessary for treatment, payment or health care operations. For example, a provider could not refuse to treat an individual because the individual refused to authorize a disclosure to a pharmaceutical manufacturer for the purpose of marketing a new product.

We propose one exception to this provision: health care providers would be permitted to condition treatment provided as part of a clinical trial on obtaining an authorization from the individual that his or her protected health information could be used or disclosed for research associated with such clinical trial. Permitting use of protected health information is part of the decision to receive care through a clinical trial, and health care providers conducting such trials should be able to condition participation in the trial on the individual's willingness to authorize that his or her protected health information be used or disclosed for research associated with the trial. We note that the uses and disclosures would be subject to the requirements of § 164.510(j) below.

Under the proposal, a covered entity would not be permitted to obtain an authorization for use or disclosure of information for treatment, payment or health care operations unless required by applicable law. Where such an authorization is required by law, however, it could not be combined in the same document with an individual authorization to use or disclosure of protected health information for any purpose other than treatment, payment or health care operations (e.g., research). We would require that a separate document be used to obtain any other individual authorizations to make it clear to the individual that providing an authorization for such other purpose is not a condition of receiving treatment or payment.

6. Inclusion in the Accounting and Disclosures

As discussed in section II.H.6, we propose that covered entities be required to keep a record of all disclosures for purposes other than treatment, payment or health care operations, including those made pursuant to authorization. In addition, we propose that when an individual requests such an accounting or requests a copy of a signed authorization form, the covered entity must give a copy to the individual. See proposed § 164.515.

7. Revocation of an Authorization by the Individual

We are proposing that an individual be permitted to revoke an authorization at any time except to the extent that action has been taken in reliance on the authorization. See proposed § 164.508(e). That is, an individual could change her or his mind about an authorization and cancel it, except that she or he could not thereby prevent the use or disclosure of information if the recipient has already acted in reliance on the authorization. For example, an individual might cancel her or his authorization to receive future advertisements, but the entity may be unable to prevent mailing of the advertisements that the covered entity or third party has already prepared but not yet mailed.

An individual would revoke the old authorization and sign a new authorization when she or he wishes to change any of the information in the original authorization. Upon receipt of the revocation, the covered entity would need to stop processing the information for use or disclosure to the greatest extent practicable.

8. Expired, Deficient, or False Authorization

The model authorization form or a document that includes the elements set out at proposed § 164.508 would meet the requirements of this proposed rule and would have to be accepted by the covered entity. Under § 164.508(b), there would be no ''authorization'' within the meaning of the rules proposed below if the submitted document has any of the following defects:

- The date has expired;
- On its face it substantially fails to conform to any of the requirements set out in proposed § 164.508, because it lacks an element;
- It has not been filled out completely. Covered entities may not rely on a blank or incomplete authorization;
- The authorization is known to have been revoked; or
- The information on the form is known by the person holding the records to be materially false.

We understand that it would be difficult for a covered entity to confirm the identity of the person who signed the authorization. We invite comment on reasonable steps that a covered entity could take to be assured that the individual who requests the disclosure is whom she or he purports to be.

E. Uses and Disclosures Permitted Without Individual Authorization (§ 164.510)

[Please label comments about this section with the subject: ''Introduction to uses and disclosures without individual authorization'']

This section describes uses and disclosures of protected health information that covered entities could make for purposes other than treatment, payment, and health care operations without individual authorization, and the conditions under which such uses and disclosures could be made. We propose to allow covered entities to use or disclose protected health information without individual authorization for such purposes if the use or disclosure would comply with the applicable requirements of this section.

These categories of allowable uses and disclosures are designed to permit and promote key national health care priorities, and to ensure that the health care system operates smoothly. For each of these categories, this rule would permit—but not require—the covered entity to use or disclose protected health information without the individual's authorization. Some covered entities could conclude that the records they hold, or portions of them, should not be used or disclosed for one or more of these permitted purposes without individuals' authorization (absent a law mandating such disclosure), even under the conditions imposed here. The proposed regulation is intended to reflect the importance of safeguarding individuals' confidentiality, while also enabling important national priority activities that require protected health information.

We considered permitting uses and disclosures only where law affirmatively requires the covered entity to use or disclose protected health information. However, because the activities described below are so important to the population as a whole, we decided to permit a covered entity to use or disclose information to promote those activities even when such activities are not legally mandated. In some cases, however, we would permit a use or disclosure only when such use or disclosure is authorized by other law. The requirements for verification of legal authority are discussed in each relevant section.

Where another law forbids the use or disclosure of protected health information without the individual's authorization, nothing in this section would permit such use or disclosure.

Other law may require use or disclosure of protected health information. If such a use or disclosure is not otherwise addressed in proposed § 164.510(b) through (m), we would in proposed § 164.510(n) permit covered entities to use or disclose protected health information without individual authorization pursuant to any law that mandates such use or disclosure. To be in compliance with this rule, the covered entity must meet the requirements of such other law requiring the use or disclosure. Similarly, nothing in this rule would provide authority for a covered entity to restrict or refuse to make a use or disclosure mandated by other law.

The HIPAA legislative authority generally does not bring the entities that receive disclosures pursuant to this section, including public health authorities, oversight and law enforcement agencies, researchers, and attorneys, under the jurisdiction of this proposed rule. We therefore generally cannot propose restrictions on the further use and disclosure of protected health information obtained by the recipients of these disclosures (unless the recipient is also a covered entity). We believe, however, that in most instances it is sound policy to restrict further uses and disclosures of such protected health information. For example, the Secretary's Recommendations proposed that protected health information obtained by researchers not be further disclosed except for emergency circumstances, for a research project that meets certain conditions, and for oversight of research. We believe that federal legislation should include appropriate restrictions on further use and disclosure of protected health information received by entities for purposes such as those described in this section. We note that, under S.578 (introduced by Senator Jeffords), protected health information disclosed for oversight could not be used against the subject of the protected health information unless the action arises out of and is directly related to a health care fraud or a fraudulent claim for benefits, unless such use is judicially authorized. We believe such safeguards strike the right balance between encouraging national priority oversight activities and protecting individuals' privacy.

The provisions of this section contain requirements related to use and requirements related to disclosure, as appropriate to each of the purposes discussed. For many of these purposes, only requirements relating to disclosure are proposed because there are no appropriate internal uses for such a purpose. Examples include disclosures for next-of-kin and disclosures for banking and financial purposes.

For many of these permitted disclosures, we would require the covered entity to verify the identity of the requestor and his or her legal authority to make the request. Requirements for verifying the identity and authority of requests for information are further discussed in II.G, ''Administrative Requirements.'' As discussed in more detail in section II.G.3. of this preamble, the verification requirement would apply where the identity of the person making the request is not already known to the covered entity (e.g., where the disclosure is not part of a routine business transaction). We would ask health plans and health care providers to take reasonable steps to verify the identity of persons requesting protected health information, such as asking to see a badge or other proof of the identity of government officials, and would allow covered entities to rely on the statement of government officials and others regarding the legal authority for the activity. We would not require covered entities to make an independent inquiry into the legal authority behind requests for protected health information.

The provisions below would permit covered entities to use or disclose protected health information without individual authorization, pursuant to certain requirements. Although health care clearinghouses would be defined as covered entities under this rule, in most instances clearinghouses will be receiving and maintaining protected health information as the business partner of a covered health plan or provider. In such cases, proposed § 164.510(a)(2) provides that the clearinghouses that hold protected health information as business partners would not be permitted to make uses or disclosures otherwise permitted by this section unless such uses or disclosures also were permitted under the terms of the contract between the clearinghouse and the business partner.

1. Uses and Disclosures for Public Health Activities (§ 164.510(b))

[Please label comments about this section with the subject: ''Public health'']

We propose to permit covered entities to disclose protected health information without individual authorization to public health authorities carrying out public health activities authorized by law, to non-governmental entities authorized by law to carry out public health activities, and to persons who may be at risk of contracting or spreading a disease (when other law

authorizes notification). Where the covered entity also is a public health agency, such as a public hospital or local health department, it would be permitted to use protected health information in all cases in which it would be permitted to disclose such information for public health activities under this section.

a. *Importance of public health and need for protected health information.* Public health authorities are responsible for promoting health and quality of life by preventing and controlling disease, injury, and disability. Inherent in the collection of information for public health activities is a balancing of individual versus communal interests. While the individual has an interest in maintaining the privacy of his or her health information, public health authorities have an interest in the overall health and well-being of the entire population of their jurisdictions. To accomplish this, public health authorities engage in a number of activities, including: traditional public health surveillance; investigations and interventions with respect to communicable diseases; registries (such as immunization or cancer registries); programs to combat diseases that involve contacting infected persons and providing treatment; and actions to prevent transmission of serious communicable diseases.

Public health activities also include regulatory investigations and interventions such as pre-market review of medical products, and evaluations of the risk-benefit profile of a drug or medical product before and after approval (relying on critical epidemiological techniques and resources such as HMO claims databases and medical records). Public health agencies use the results of analyses to make important labeling changes and take other actions, such as the removal of non-compliant products from the market.

We considered requiring individual authorization for certain public health disclosures, but rejected this approach because many important public health activities would not be possible if individual authorization were required. In the case of contagious diseases, for example, if individual authorization were required before individually identifiable information could be provided to public health workers, many other people who may be harboring contagious diseases may be missed by efforts to halt the spread of disease because they failed to provide the appropriate individual authorization. Their failure to authorize could place the general population at risk for contracting an infectious disease. Furthermore, always requiring individual authorization to disclose protected health information to public health authorities would be impractical due to the number of reports and the variety of sources from which they are made. If individuals were permitted to opt out from having their information included in these public health systems, the number of persons with a particular condition would be undercounted. Furthermore, the persons who did authorize the inclusion of their information in the system might not be representative of all persons with the disease or condition.

We also considered limiting certain public health disclosures to de-identified health information. However, identifiable information could be required in order to track trends in a disease over time, and to assess the safety of medical treatments. While de-identified information could be appropriate for many public health activities, there are also many public health activities that require individual identifiers. We decided not to attempt to define specific public health activities for which only de-identified information could be disclosed, in part because public health data collection requirements would be better addressed in public health laws, and in part to reflect the variation in information technologies available to public health authorities. Instead, we rely on the judgment of public health authorities as to what information would be necessary for a public health activity. See discussion in section II.C.2.

b. *Public health activities.* We intend a broad reading of the term ''public health activities'' to include the prevention or control of disease, injury, or disability. We considered whether to propose a narrow or broad scope of public health activities for which disclosure without individual authorization would be permitted. For the reasons described above, we believe that both the general public and individual interests are best served by a broad approach to public health disclosures.

We therefore propose that covered entities be permitted to disclose protected health information to public health authorities for the full range of public health activities described above, including reporting of diseases, injuries, and conditions, reporting of vital events such as birth and death to vital statistics agencies, and a variety of activities broadly covered by the terms public health surveillance, public health investigation, and public health intervention. These would include public health activities undertaken by the FDA to evaluate and monitor the safety of food, drugs, medical devices, and other products. These terms would be intended to cover the spectrum of public health activities carried out by federal, State, and local public health authorities. The actual authorities and terminology used for public health activities will vary under different jurisdictions. We do not intend to disturb or limit current public health activities.

c. *Permitted recipients of disclosures for public health activities.* Disclosures without individual authorization for public health activities would be permitted to be made to only three types of persons: public health authorities, non-governmental entities authorized by law to carry out public health activities, and persons who may be at risk of contracting or spreading a disease, if other law authorizes notification.

i. *Public health authorities.*

We propose to define ''public health authority'' broadly, based on the function being carried out, not the title of the public entity. Therefore, disclosures under this proposed rule would not be limited to traditional public health entities such as State health departments. Other government agencies and entities carry out public health activities in the course of their missions. For example, the Occupational Safety and Health Administration, the Mine Safety and Health Administration, and the National Institute for Occupational Safety and Health conduct public health investigations related to occupational health and safety. The National Transportation Safety Board investigates airplane and train crashes in an effort to reduce mortality and injury by making recommendations for safety improvements. Similar inquiries are conducted by the military services. The Food and Drug Administration reviews product performance prior to marketing, and investigates adverse events reported after marketing by industries, health professionals, consumers, and others. The Environmental Protection Agency investigates the effects of environmental factors on health. The definition of public health authority reflects the need for access to data and information including protected health information by these other agencies and authorities consistent with their official mandates under applicable law.

ii. *Non-governmental entities carrying out public health activities.*

The proposed rule would further provide that disclosures may be made not only to government agencies, but also to other public and private entities

as otherwise required or authorized by law. For example, this would include tracking medical devices, where the initial disclosure is not to a government agency, but to a device manufacturer that collects information under explicit legal authority, or at the direction of the Food and Drug Administration. Also, the cancer registries mentioned above could be operated by non-profit organizations such as universities funded by public health authorities which receive reports from physicians and laboratories pursuant to State statutory requirements to report.

We considered limiting public health disclosures to only government entities, but the reality of current public health practice is that a variety of activities are conducted by public health authorities in collaboration with non-governmental entities. Federal agencies also use a variety of mechanisms including contracts, grants, cooperative agreements, and other agreements such as memoranda of understanding to carry out and support public health activities. These relationships could be based on specific or general legal authorities. It is not our intent to disturb these relationships. Limiting the ability to collaborate with other entities and designate them to receive protected health information, could potentially have an adverse impact on public health practice.

iii. *Persons who may be at risk of contracting or spreading a disease.*

The proposed rule would allow disclosure to a person who could have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition and is authorized by law to be notified as necessary in the conduct of a public health intervention or investigation. Physicians, in carrying out public health interventions authorized by law, can notify persons who have been exposed to a communicable disease, or who otherwise may be at risk of contracting or spreading a disease or condition. That notification may implicitly or explicitly reveal the identity of the individual with the disease to which the person could have been exposed, but should be permitted as a disclosure in the course of a legally authorized public health intervention or investigation. The proposed rule would not (and, under the HIPAA legislative authority, cannot) impose a confidentiality obligation on the person notified.

d. *Additional requirements.* Under proposed § 164.518(c), covered entities would have to verify the identity of the person requesting protected health information and the legal authority supporting that request, before the disclosure would be permitted under this subsection. Preamble section II.G.3 describes these requirements in more detail.

We note that to the extent that the public health authority is providing treatment as defined in proposed § 164.504, the public health authority would be a covered health care provider for purposes of that treatment, and would be required to comply with this regulation.

We also note that the preemption provision of the HIPAA statute creates a special rule for a subset of public health disclosures: this regulation cannot preempt State law regarding ''public health surveillance, or public health investigation or intervention * * *''.

2. Use and Disclosure for Health Oversight Activities. (§ 164.510(c))

[*Please label comments about this section with the subject: ''Health oversight''*]

In section § 164.510(c), we propose to allow covered entities to disclose protected health information to public oversight agencies (and to private entities acting on behalf of such agencies) without individual authorization, for health oversight activities authorized by law. In cases in which a covered entity is also an oversight agency, it would be permitted to use protected health information in all cases in which it would be permitted to disclose such information for health oversight activities under this section.

a. *Importance of oversight and need for protected health information.* Oversight activities are critical to support national priorities, including combating fraud in the health care industry, ensuring nondiscrimination, and improving the quality of care. The goals of public agencies' oversight activities are: to monitor the fiscal and programmatic integrity of health programs and of government benefit programs; to ensure that payments or other benefits of these programs are being provided properly; to safeguard health care quality; to monitor the safety and efficacy of medical products; and to ensure compliance with statutes, regulations, and other administrative requirements applicable to public programs and to health care delivery.

Oversight activities are a national priority in part because of the losses in the healthcare system due to error and abuse. For example, the HHS Office of Inspector General recently estimated losses due to improper Medicare benefit payments to be about seven percent. See ''Improper Fiscal Year 1998 Medicare Fee-For Service-Payments,'' transmittal from Inspector General June Gibbs Brown to HCFA Administrator Nancy-Ann Min DeParle (February 9, 1999). Similarly, the final report of the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry concluded that ''employing the extensive knowledge and expertise of organizations that oversee health care quality * * * is essential to quality improvement.'' (http://www.hcqualitycommission.gov/final/chap09.html)

There are certain oversight activities done as statistical inquiries that can be conducted without direct access to individually identifiable health information. However, many instances exist in which government oversight agencies, and private entities under contracting to act on their behalf, need to examine individually identifiable health information to conduct their investigations effectively. For example, to determine whether a hospital has engaged in fraudulent billing practices, it could be necessary to examine billing records for a set of individual cases. Billing abuses are detected by cross-checking the records of specific patients to see the medical documentation in support of a service. To determine whether a health plan is complying with federal or State health care quality standards, it may be necessary to examine individually identifiable health information. Other inquiries require review of individually identifiable health information to identify specific instances of the anomalies in treatment or billing patterns detected in statistical analysis. Even in most statistical inquiries of the type just described, in a paper environment particular patient charts must be examined, and the patient's name would be disclosed because it would be on each page of the chart.

b. *Proposed requirements.* Specifically, we would permit covered entities to disclose protected health information without individual authorization to a health oversight agency to conduct oversight activities authorized by law. Disclosures also could be made to private entities working under a contract with or grant of authority from one or more of the government oversight agencies described above. As discussed below, oversight activities by private entities operating pursuant to contracts with covered entities, such as accreditation organizations, would not be permitted to receive information under this provision, even if accreditation by such an organization is recognized by law as fulfilling a government requirement or

condition of participation in a government program (often referred to as ''deemed status'').

Under our rule, oversight activities would include conducting or supervising the following activities: Audits; investigations; inspections; civil, criminal or administrative proceedings or actions; and other activities necessary for appropriate oversight of the health care system, of government benefit programs for which health information is relevant to beneficiary eligibility, and of government regulatory programs for which health information is necessary for determining compliance with program standards. This regulation does not create any new right of access to health records by oversight agencies, and could not be used as authority to obtain records not otherwise legally available to the oversight agency.

Under our rule, a health oversight agency would be defined as a public agency authorized by law to conduct oversight activities relating to the health care system, a government program for which health information is relevant to determining beneficiary eligibility or a government regulatory program for which health information is necessary for determining compliance with program standards. Examples of agencies in the first category would include State insurance commissions, State health professional licensure agencies, Offices of Inspectors General of federal agencies, the Department of Justice, State Medicaid fraud control units, Defense Criminal Investigative Services, the Pension and Welfare Benefit Administration, the HHS Office for Civil Rights, and the FDA. Examples of agencies in the second category include the Social Security Administration and the Department of Education. Examples of agencies in the third category include the workplace safety programs such as the Occupational Health and Safety Administration and the Environmental Protection Agency. Agencies that conduct both oversight and law enforcement activities would be subject to this provision when conducting oversight activities.

In cases where health oversight agencies are working in tandem with other agencies overseeing public benefit programs to address compliance, fraud, or other integrity issues that could span across programs, the oversight activities of the team would be considered health oversight and disclosure to and among team members would be permitted under the proposed rule to the extent permitted under other law. For example, a fraud investigation could attempt to find a pattern of abuse across related programs, such as Medicaid and the supplemental security income program. Protected health information could be disclosed to the team of oversight agencies and could be shared among such agencies for oversight activities.

Public oversight agencies sometimes contract with private entities to conduct program integrity activities on a public agency's behalf. Such audits or investigations may include, for example, program integrity reviews of fraud and abuse in billing Federal and State health care programs; investigations conducted in response to consumer complaints regarding the quality or accessibility of a particular provider, health plan, or facility; and investigations related to disciplinary action against a health care provider, health plan, or health care facility. Covered entities may disclose protected health information to these agents to the extent such disclosure would be permitted to the public oversight body.

In many cases today, public agencies' contracts with private entities conducting investigations on their behalf require the private oversight organization to implement safeguards to protect individual privacy. HIPAA does not provide statutory authority to regulate the contracts between public oversight entities and their agents. However, we encourage public oversight entities to include privacy safeguards in all such contracts, and believe it would be appropriate for federal legislation to impose such safeguards.

In developing our proposal, we considered but rejected the option of providing an exemption from the general rules for situations in which a covered entity has a contract with a private accreditation organization to conduct an accreditation inspection. In such instances, the accreditation organization is performing a service for the covered entity much like any other contractor. The situation is not materially different in instances where accreditation from a private organization would have the effect of ''deeming'' the covered entity to be in compliance with a government standard or condition of participation in a government program. In both cases, the accreditation organization is performing a service for the covered entity, not for the government. In our considerations, we were unable to identify a reason that covered entities should hold these contractors to lesser standards than their other contractors. Individuals' privacy interests would not be diminished in this situation, nor is there any reason why such accreditation organizations should not be held to the requirements described above for business partners. Proposed rules for disclosure to these entities are discussed in section II.C.5., ''Application to business partners.'' We invite comment on our proposed approach.

c. *Additional considerations.* We do not propose any new administrative or judicial process prior to disclosure. This regulation would permit disclosure of protected health information without compulsory process where such disclosure is otherwise allowed. However, this regulation also would not abrogate or modify other statutory requirements for administrative or judicial determinations or for other procedural safeguards, nor would it permit disclosures forbidden by other law.

Under this § 164.518(c), covered entities would have an obligation to verify the identity of the person requesting protected health information and the legal authority behind the request before the disclosure would be permitted under this subsection. Preamble section II.G.3. describes these requirements in more detail.

3. Use and Disclosure for Judicial and Administrative Proceedings (§ 164.510(d))

[*Please label comments about this section with the subject: ''Judicial and administrative proceedings''*]

In § 164.510(d), we propose to permit covered entities to disclose protected health information in a judicial or administrative proceeding if the request for such protected health information is made through or pursuant to an order by a court or administrative tribunal. A court order would not be required if the protected health information being requested relates to a party to the proceeding whose health condition is at issue, or if the disclosure would otherwise be permitted under this rule. A covered entity that also is a government entity would be permitted to use protected health information in a judicial or administrative proceeding under the same conditions that it could make a disclosure of protected health information under this paragraph.

a. *Importance of judicial and administrative process and the need for protected health information.* Protected health information is often needed as part of an administrative or judicial proceeding. Examples of such proceedings would include personal injury or medical malpractice cases or other lawsuits in which the medical condition of a person is at issue, and judicial or administrative proceedings to determine whether an illness or injury was caused by workplace conditions or

exposure to environmental toxins. The information may be sought well before a trial or hearing, to permit the party to discover the existence or nature of testimony or physical evidence, or in conjunction with the trial or hearing, in order to obtain the presentation of testimony or other evidence. These uses of health information are clearly necessary to allow the smooth functioning of the legal system. Requiring the authorization of the subject prior to disclosure could mean that crucial information would not be available, and could be unfair to persons who have been wronged.

b. *Proposed requirements.* We propose to permit covered entities to disclose protected health information in a judicial or administrative proceeding if the request for such protected health information is made through or pursuant to a court order or an order by an administrative law judge specifically authorizing the disclosure of protected health information. The exception to this requirement is where the protected health information being requested relates to a party to the proceeding whose health condition is at issue, and where the disclosure is made pursuant to lawful process (e.g., a discover order) or is otherwise authorized by law. We note that this would not apply where the disclosure would otherwise be permitted under this rule.

The proposed provisions of this section are intended to apply to the broad spectrum of judicial and administrative procedures by which litigants, government agencies, and others request information for judicial or administrative proceedings, including judicial subpoenas, subpoenas duces tecum, notices of deposition, interrogatories, administrative subpoenas, and any disclosure pursuant to the Federal Rules of Civil Procedures, the Federal Rules of Criminal Procedures, comparable rules of other courts (including State, tribunal, or territorial courts) and comparable rules of administrative agencies. Under the rule, a covered entity could not respond to such requests unless they determined that the request is pursuant to a court order authorizing disclosure of protected health information or if the individual who is the subject of the protected health information is a party to the proceeding and his or her medical condition or history is at issue.

Covered entities generally would not be required to conduct any independent investigation of the legality of the process under which the protected health information is being sought, but would need to review the request protected health information to ensure that the disclosure would meet the terms of this provision. Where the request is accompanied by an order from a court, the covered entity could rely on a statement in the order authorizing disclosure of protected health information. The statement could be a general one, indicating that protected health information is relevant to the matter, or it could identify specifically what protected health information may be disclosed. The covered entity could rely on either type of statement, but it could not disclose more information than was authorized by the court where the scope of the authorized disclosure is clear.

Where the request is not accompanied by a court order or order from an administrative law judge, the covered entity would be required to determine whether the request relates to the protected health information of a litigant whose health is at issue, a written statement from the requester certifying that the protected health information being requested is about a litigant to the proceeding and that the health condition of such litigant is at issue at such proceeding. Such a certification could be from the agency requesting the information (e.g., in an administrative proceeding) or from legal counsel representing a party to litigation. We invite comments on whether this requirement is overly burdensome and on whether it is sufficient to protect protected health information from unwarranted disclosures.

We are not proposing to preclude a covered entity from contesting the nature or scope of the process when the procedural rules governing the proceeding so allow and covered entities could well choose to assert privileges against disclosure on behalf of individuals.

In developing our proposal, we considered permitting covered entities to disclose protected health information pursuant to any request made in conjunction with a judicial or administrative proceeding. We rejected this option because we believe that current procedures for document production could result in unwarranted disclosure of protected health information. Under current practice, requests for documents are developed by the parties to a proceeding, with little review or oversight unless the request is challenged by the opposing party. In many instances, the parties make very broad discovery requests that result in the production of large numbers of documents for review. Recipients of broad motions for document production often provide the requester with a substantial quantity of material, expecting the requester to page through the documents to identify the ones that are relevant to the proceeding. While such a process may be appropriate for many types of records, we are concerned that it could lead to substantial breaches of privacy where the material being requested is protected health information. We are unsure if it is appropriate for private attorneys, government officials and others who develop such requests to be able to circumvent the protections provided by this rule with simple motions for document production that have not been subject to third-party review.

Under our proposal, therefore, a party to a proceeding that wishes production of information that includes protected health information would generally need to seek judicial review of the request. If a court determines that a request for protected health information is appropriate to the proceeding, a covered entity can produce the protected health information pursuant to an otherwise lawful request.

We propose an exception to the general requirement for judicial review for protected health information for instances in which the protected health information of a party to the proceeding is relevant to the proceeding. In such instances, the party will have counsel who can object to an overly broad or unwarranted discovery of the party's protected health information or will receive the discovery request directly and, again, will have an opportunity to object prior to disclosure.

We note that there are other existing legal requirements governing the disclosure of protected health information, and which govern the procedures in federal, State and other judicial and administrative proceedings. For example, 42 U.S.C. 290dd–2 and the implementing regulations, 42 CFR part 2, will continue to govern the disclosure of substance abuse patient records. There may also be provisions of a particular State's law governing State judicial or administrative proceedings, including State medical record privacy statutes, as well as precedential court opinions, which apply to the circumstances described in the section, that will not be preempted by this part. Also, the discovery of psychiatric counseling records in federal proceedings governed by section 501 of the Federal Rules of Evidence, has been restricted in certain circumstances, by *Jaffee* v. *Redmond,* 116 S. Ct. 1923 (1996). These more stringent rules would remain in place.

4. Disclosure to Coroners and Medical Examiners (§ 164.510(e))

[*Please label comments about this section with the subject: ''Coroners and medical examiners''*]

In § 164.510(e), we propose to allow covered entities to disclose protected health information without individual authorization to coroners and medical examiners, as authorized by law, for identification of a deceased person or to determine cause of death.

a. Importance of disclosure to coroners and medical examiners and the need for protected health information. Coroners and medical examiners, who under State or other law typically are public officials, have a legitimate need to obtain protected health information in an expeditious manner in order to carry out their legal responsibility to identify deceased persons and determine cause of death. Such disclosure would be clearly in the public interest, and should be included among the types of disclosures for which the public interest in efficient sharing of medical information outweighs any individual privacy interests that may be compromised.

b. *Proposed requirements.* Proposed § 164.510(e) would allow covered entities to disclose protected health information about a deceased person without individual authorization to coroners and medical examiners, consistent with other law, for the purpose of a post-mortem investigation.

We recognize that a deceased person's medical record could include information that potentially could reveal health information about others, for example, relatives who have the same genetically linked disease as the deceased individual. In developing this section of the proposed rule, we considered requiring covered entities to redact any protected health information about persons other than the deceased before giving the record to coroners or medical examiners.

We rejected this option for two reasons. First, coroners and medical examiners typically need significant portions of a deceased person's medical record, and, in some cases, all medical records that are available, to conduct a post-mortem investigation, which may also include an autopsy. Second, they need to obtain the record quickly, because there is a limited time period after death within which an autopsy can be conducted. Requiring covered entities to take the time to review and redact portions of the health information before providing it to a coroner or medical examiner would create delays that could make it impossible to conduct an autopsy appropriately. Nothing in this rule would prohibit a covered entity from undertaking such redaction on its own initiative so long as the information provided would meet the needs of the coroner or medical examiner.

In addition to these two reasons, it is our understanding that health care providers, as a standard record keeping practice, rarely identify specific persons other than the patient in the record. We are soliciting comment on whether health care providers routinely identify other persons specifically in a individual's record and if so, whether we should require the provider to redact the information about the other person before providing it to a coroner or medical examiner.

Under § 164.518(c), covered entities would have an obligation to verify the identity of the coroner or medical examiner making the request for protected health information and the legal authority supporting the request, before the disclosure would be permitted under this subsection. Preamble section II.G.3. describes these requirements in more detail.

We intend to allow only those disclosures that are authorized by other applicable law. Laws vary widely regarding release of health information to coroners and medical examiners for the purposes of identifying deceased persons or determining cause of death, and we do not intend to disturb those practices.

5. Disclosure for Law Enforcement (§ 164.510(f))

[*Please label comments about this section with the subject: ''Law enforcement''*]

In § 164.510(f), we propose to permit covered entities to disclose protected health information without individual authorization to a law enforcement official conducting a law enforcement inquiry authorized by law if the request for protected health information is made pursuant to a judicial or administrative process, as described below. Similarly, we propose to permit covered entities to disclose protected health information to a law enforcement official without individual authorization for the conduct of lawful intelligence activities. We also propose to permit covered entities to disclose protected health information to a law enforcement official about the victim of a crime, abuse or other harm, if the information is needed to determine both whether a violation of law by a person other than the victim has occurred and whether an immediate law enforcement activity might be necessary. We would further permit such disclosure for the purpose of identifying a suspect, fugitive, material witness, or missing person, if the covered entity discloses only limited identifying information. Finally, we would permit disclosure of protected health information by a health plan or a health care provider without individual authorization to law enforcement officials if the plan or provider believed in good faith that the disclosed protected health information would constitute evidence of criminal conduct that constitutes health care fraud, occurred on the premises of the covered entity, or was witnessed by an employee of the covered entity.

i. *Law enforcement need for protected health information.* Law enforcement officials need protected health information for their investigations in a variety of circumstances. Health information about a victim of a crime may be needed to investigate the crime, or to allow prosecutors to determine the proper charge. For some crimes, the severity of the victim's injuries will determine what charge should be brought against a suspect. The medical condition of a defendant could also be relevant to whether a crime was committed, or to the seriousness of a crime. The medical condition of a witness could be relevant to the reliability of that witness. Medical, billing, accounting or other documentary records in the possession of a covered entity can be important evidence relevant to criminal fraud or conspiracy investigations. Nor is this list of important uses by law enforcement exhaustive.

In many cases, the law enforcement official will obtain such evidence through legal process, such as judicially executed warrant, an administrative subpoena, or a grand jury subpoena. In other circumstances, time constraints preclude use of such process. For example, health information may be needed when a law enforcement official is attempting to apprehend an armed suspect who is rapidly fleeing. Health information may be needed from emergency rooms to locate a fleeing prison escapee or criminal suspect who was injured and is believed to have stopped to seek medical care.

Protected health information could be sought as part of a law enforcement investigation, to determine whether and who committed a crime, or it could be sought in conjunction with the trial to be presented as evidence. These uses of medical information are clearly in the public interest. Requiring the authorization of the subject prior to disclosure could impede important law enforcement activities by making

apprehension and conviction of some criminals difficult or impossible.

As described above, this proposed rule seeks to respond appropriately to new risks to privacy that could emerge as the form of medical records changes in coming years. The administrative simplification mandated by HIPAA will lead to far greater exchanges of individually identifiable health information among covered entities in the future, increasingly in electronic form. If a misperception were to develop that law enforcement had instant and pervasive access to medical records, the goals of this proposed regulation could be undermined. For instance, individuals might become reluctant to seek needed care or might report inaccurately to providers to avoid revealing potentially embarrassing or incriminating information. In addition, popular concerns about government access to sensitive medical records might impede otherwise achievable progress toward administrative simplification. We believe that the proposed prophylactic and administrative rules governing disclosure to law enforcement officials, as described below, are justified in order to avoid these harms in the future.

ii. *Proposed requirements.* In § 164.510(f), we propose to permit covered entities to disclose protected health information to law enforcement officials conducting or supervising a law enforcement inquiry or proceeding authorized by law if the request for protected health information is made:

- Pursuant to a warrant, subpoena, or order issued by a judicial officer;
- Pursuant to a grand jury subpoena;
- Pursuant to an administrative subpoena or summons, civil investigative demand, or similar certification or written order issued pursuant to federal or state law where (i) the records sought are relevant and material to a legitimate law enforcement inquiry; (ii) the request is as specific and narrowly drawn as is reasonably practicable to meet the purposes of the inquiry; and (iii) de-identified information could not reasonably be used to meet the purposes of the inquiry;
- For limited identifying information where necessary to identify a suspect, fugitive, witness, or missing person;
- By a law enforcement official requesting protected health information about an individual who is, or who is suspected to be, the victim of a crime, abuse or other harm, if such law enforcement official represents that (i) such information is needed to determine whether a violation of law by a person other than the victim has occurred and (ii) immediate law enforcement activity which depends on the official obtaining such information may be necessary;
- For the conduct of lawful intelligence activities conducted pursuant to the National Security Act of 1947 (50 U.S.C. 401 *et seq.*) or in connection with providing protective services to the President or other individuals pursuant to section 3056 of title 18, United States Code, and the disclosure is otherwise authorized under Federal or state law; or
- To law enforcement officials when a covered entity believes in good faith that the disclosed protected health information constitutes evidence of criminal conduct that: (i) Arises out of and is directly related to the receipt of health care or payment for health care (including a fraudulent claim for health care) or qualification for or receipt of benefits, payments or services based on a fraudulent statement or material misrepresentation of the health of a patient; (ii) occurred on the premises of the covered entity; or (iii) was witnessed by an employee or other workforce member of the covered entity.

In drafting the proposed rule, we have attempted to match the level of procedural protection for privacy with the nature of the law enforcement need for access. Therefore, access for law enforcement under this rule would be easier where other rules would impose procedural protections, such as where access is granted after review by an independent judicial officer. Access would also be easier in an emergency situation or where only limited identifying information would be provided. By contrast, this rule proposes stricter standards for administrative requests, where other rules could not impose appropriate procedural protections.

Under the first part of this proposal, we would authorize disclosure of protected health information pursuant to a request that has been reviewed by a judicial officer. Examples of such requests include State or federal warrants, subpoenas, or other orders signed by a judicial officer. Review by a judicial officer is significant procedural protection for the proper handling of individually identifiable health information. Where such review exists, we believe that it would be appropriate for covered entities to disclose individually identifiable health information pursuant to the order.

Under the second part of this proposal, we would authorize disclosure of protected health information pursuant to a State or federal grand jury subpoena. Information disclosed to a grand jury is covered by significant secrecy protections, such as under Federal Rule of Criminal Procedure 6(e) and similar State laws. Our understanding is that State grand juries have secrecy protections substantially as protective as the federal rule. We solicit comment on whether there are any State grand jury secrecy provisions that are not substantially as protective.

Under the third part of this proposal, we would set somewhat stricter standards than exist today for disclosure pursuant to administrative requests, such as an administrative subpoena or summons, civil investigative demand, or similar process authorized under law. These administrative actions do not have the same procedural protections as review by an independent judicial officer. They also do not have the grand jury secrecy protections that exist under federal and State law. For administrative requests, an individual law enforcement official can define the scope of the request, sometimes without any review by a superior, and present it to the covered entity. We propose, therefore, that a greater showing should be made for an administrative request before the covered entity would be permitted to release protected health information. We also believe that the somewhat stricter test for administrative requests would provide some reason for officials to choose to obtain protected health information through process that includes the protections offered by judicial review or grand jury secrecy.

We therefore propose that a covered entity could disclose protected health information pursuant to an administrative request, issued pursuant to a determination that: (i) The records sought are relevant and material to a legitimate law enforcement inquiry; (ii) the request is as specific and narrowly drawn as is reasonably practicable; and (iii) de-identified information could not reasonably be used to meet the purpose of the request.

Because our regulatory authority does not extend to law enforcement officials, we are seeking comment on how to create an administrable system for implementing this three-part test. We do not intend that this provision require a covered entity to second guess representations by an appropriate law enforcement official that the three part test has been met.

To verify that the three-part test has been met, we propose that a covered entity be permitted to disclose protected health information to an appropriate law enforcement official pursuant to a subpoena or other covered administrative request that on its face indicates that the three-part test has

been met. In the alternative, where the face of the request does not indicate that the test has been met, a covered entity could disclose the information upon production of a separate document, signed by a law enforcement official, indicating that the three-part test has been met. Under either of these alternatives, disclosure of the information can also be made if the document applies any other standard that is as strict or stricter than the three-part test.

This approach would parallel the research provisions of proposed § 164.510(j). Under that section, disclosure would be authorized by a covered entity where the party seeking the records produces a document that states it has met the standards for the institutional review board process. We solicit comments on additional, administrable ways that a law enforcement official could demonstrate that the appropriate issuing authority has determined that the three-part test has been met.

We solicit comment on the burdens and benefits of the proposed three-part test for administrative requests. For covered entities, we are interested in comments on how burdensome it would be to determine whether the three-part test has been met, and we would explore suggestions for approaches that would be more easily administered. For law enforcement, we are interested in the potential impact that this approach might have on current law enforcement practices, and the extent to which law enforcement officials believe that their access to information critical to law enforcement investigations could be impaired. We solicit comment on the burden on law enforcement officials, compared to current practice, of writing the administrative requests. We would also like comments on whether there are any federal, State, or local laws that would create an impediment to application of this section, including the proposed three-part test. If there are such impediments, we would solicit comment on whether extending the effective date of this section could help to prevent difficulties. On the benefit side, we are interested in comments on the specific gains for privacy that would result from requiring law enforcement to comply with greater procedures than currently exist for gaining access to protected health information.

As the fourth part of this proposal, we address limited circumstances where the disclosure of health information by covered entities would not be made pursuant to lawful process such as judicial order, grand jury subpoena, or administrative request. In some cases law enforcement officials could seek limited but focused information needed to obtain a warrant. For example, a witness to a shooting may know the time of the incident and the fact that the perpetrator was shot in the left arm, but not the identity of the perpetrator. Law enforcement would then have a legitimate need to ask local emergency rooms whether anyone had presented with a bullet wound to the left arm near the time of the incident. Law enforcement may not have sufficient information to obtain a warrant, but instead would be seeking such information. In such cases, when only limited identifying information is disclosed and the purpose is solely to ascertain the identity of a person, the invasion of privacy would be outweighed by the public interest.

In such instances, we propose to permit covered entities to disclose ''limited identifying information'' for purposes of identifying a suspect, fugitive, material witness, or missing person. We would define ''limited identifying information'' as the name, address, social security number, date of birth, place of birth, type of injury, date and time of treatment, and date of death. Disclosure of any additional information would cause the covered entity to be out of compliance with this provision, and subject to sanction. The request for such information could be made orally or in writing. Requiring the request to be in writing could defeat the purposes of this provision. We solicit comment on whether the list of ''limited identifying information'' is appropriate, or whether additional identifiers, such as blood type, also should be permitted disclosures under this section. Alternatively, we solicit comment on whether any of the proposed items on the list are sufficiently sensitive to warrant a legal process requirement before they should be disclosed.

Under the fifth part of the proposal, we would clarify that the protected health information of the victim of a crime, abuse or other harm could be disclosed to a law enforcement official if the information is needed to determine both whether a violation of law by a person other than the victim has occurred and whether an immediate law enforcement activity might be necessary. There could be important public safety reasons for obtaining medical records or other protected health information quickly, perhaps before there would be time to get a judicial order, grand jury subpoena, or administrative order. In particular, where the crime was violent, information about the victim's condition could be needed to present to a judge in a bond hearing in order to keep the suspect in custody while further evidence is sought. Information about the victim also could be important in making an appropriate charging decision. Rapid access to victims' medical records could reduce the risk of additional violent crimes, such as in cases of spousal or child abuse or in situations where the protected health information could reveal evidence of the identity of someone who is engaged in ongoing criminal activities.

In some of these instances, release of protected health information would be authorized under other sections of this proposed regulation, pursuant to provisions for patient consent, health oversight, circumstances, or disclosure pursuant to mandatory reporting laws for gunshot wounds or abuse cases. (As discussed later in section II.I, our rule would not be construed to invalidate or limit the authority, powers or procedures established under any law that provides for reporting of injury, child abuse or death.) In addition, § 164.510(k) addressing emergency circumstances would permit covered entities to disclose protected health information in instances where the disclosure could prevent imminent harm to the individuals or to the public. However, we propose to include this fifth provision for law enforcement access to ensure that immediate need for law enforcement access to information about a victim would be permitted under this rule.

Under the sixth part of this proposal, we seek to assure that this rule would not interfere with the conduct of lawful security functions in protection of the public interest, as defined by the Congress. Therefore, we would allow disclosure of protected health information for the conduct of lawful intelligence activities conducted pursuant to the National Security Act of 1947. Similarly, we would allow disclosure of protected health information for providing protective services to the President or other individuals pursuant to section 3056 of title 18, United States Code. Where such disclosures are authorized by Federal or state law, we would not interfere with these important national security activities.

Under the final part of this proposal, we would permit covered entities that uncover evidence of health care fraud to disclose the protected health information that evidences such fraud to law enforcement officials without receiving a request from such officials. This provision would permit covered entities to make certain disclosures to law enforcement officials on their own

initiative if the information disclosed constitutes evidence of criminal conduct that arises out of and is directly related to (i) the receipt of health care or payment for health care (including a fraudulent claim for health care) or (ii) qualification for or receipt of benefits, payments or services based on a fraudulent statement or material misrepresentation of the health of a patient. Similarly, we would permit covered entities on their own initiative to disclose to law enforcement officials protected health information that the covered entity believes in good faith constitutes evidence of criminal conduct that either occurred on the covered entity's premises or was witnessed by an employee (or other workforce member) of the covered entity. In such situations, covered entities should be permitted to take appropriate steps to protect the integrity and safety of their operations or to assure that the such criminal conduct is properly prosecuted.

To be protected by this provision, the covered entity would have to have good faith belief that the disclosed protected health information was evidence of such conduct. If the covered entity disclosed protected health information in good faith but was wrong in its belief that the information evidenced a legal violation, the covered entity would not be subject to sanction under this regulation. We would not require the covered entity to accurately predict the outcome of a criminal investigation.

There also are situations where law enforcement officials would need access to information for emergency circumstances. In those cases, the disclosure could be made under § 164.510(k), ''Disclosure in emergency circumstances.''

Pursuant to § 164.518(c), covered entities would have an obligation to verify the identity of the person seeking disclosure of protected health information and the legal authority behind the request. As described in section II.H.3. of this preamble, we would permit covered entities to rely on a badge or similar identification to confirm that the request for protected health information is being made by a law enforcement official. If the request is not made in person, we would permit the covered entity to rely on official letter head or similar proof.

Where the covered entity must verify that lawful process has been obtained, § 164.518(c) would require the covered entity to review the document evidencing the order. The covered entity could not disclose more information than was authorized in the document.

Because the regulation applies to covered entities, and not to the law enforcement officials seeking the protected health information, the covered entity would not be in a position to determine with any certainty whether the underlying requirements for the process have been met. For instance, it may be difficult for the covered entity to determine whether the three-part test has been met for an administrative request. In light of this difficulty facing covered entities, the proposed rule would include a good faith provision. Under that provision, covered entities would not be liable under the rule for disclosure of protected health information to a law enforcement official where the covered entity or its business partners acted in a good faith belief that the disclosure was permitted under this title. We solicit comment on the extent to which this good faith provision would make the proposed rule less burdensome on covered entities and law enforcement officials. We also solicit comment on the extent to which the provision could undermine the effectiveness of the provision.

For requests for the conduct of intelligence activities or for protective services, covered entities would be required to verify the identity of the person or entity requesting the information, through a badge or other identification, or official letter head, as just described. If such verification of identity is obtained, covered entities would be permitted to reasonably rely on the representations of such persons that the request is for lawful national security or protective service activities and is authorized by law. Similarly, to disclose limited identifying information, covered entities would be required to obtain verification that the request comes from a law enforcement official, and would be permitted to reasonably rely on such official's representation that the information is needed for the purpose of identifying a suspect, fugitive, material witness, or missing person and is authorized by law.

iii. *Additional considerations.* This section is not intended to limit or preclude a covered entity from asserting any lawful defense or otherwise contesting the nature or scope of the process when the procedural rules governing the proceeding so allow, although it is not intended to create a basis for appealing to federal court concerning a request by state law enforcement officials. Each covered entity would continue to have available legal procedures applicable in the appropriate jurisdiction to contest such requests where warranted. This proposed rule would not create any new affirmative requirement for disclosure of protected health information. Similarly, this section is not intended to limit a covered entity from disclosing protected health information for law enforcement purposes where other sections of the rule permit such disclosure, e.g., as permitted by § 164.510 under emergency circumstances, for oversight or public health activities, to coroners or medical examiners, and in other circumstances permitted by the rule.

In obtaining protected health information, law enforcement officials would have to comply with whatever other law was applicable. In certain circumstances, while this subsection could authorize a covered entity to disclose protected health information to law enforcement officials, there could be additional applicable statutes that further govern the specific disclosure. If the preemption provisions of this regulation do not apply, the covered entity must comply with the requirements or limitations established by such other law, regulation or judicial precedent. See proposed §§ 160.201 through 160.204. For example, if State law would permit disclosure only after compulsory process with court review, a provider or payer would not be allowed to disclose information to state law enforcement officials unless the officials had complied with that requirement. Similarly, disclosure of substance abuse patient records subject to, 42 U.S.C. 290dd–2, and the implementing regulations, 42 CFR part 2, would continue to be governed by those provisions.

In some instances, disclosure of protected health information to law enforcement officials would be compelled by other law, for example, by compulsory judicial process or compulsory reporting laws (such as laws requiring reporting of wounds from violent crimes, suspected child abuse, or suspected theft of prescription controlled substances). Disclosure of protected health information under such other mandatory law would be permitted under proposed § 164.510(n).

In developing our proposal, we considered permitting covered entities to disclose protected health information pursuant to any request made by a law enforcement official, rather than requiring some form of legal process or narrowly defined other circumstances. We rejected this option because we believe that in most instances some form of review should be required. Individuals' expectation of privacy with respect to their health information is sufficiently strong to require some form of process prior to disclosure to the

government. At the same time, we recognize that the public interest would not be served by requiring such formal process in every instance. Under our proposal, therefore, law enforcement could obtain certain identifying information in order to identify suspects and witnesses, and could obtain information for national security or protective services activities or in emergency circumstances. Similarly, we would not require process before a law enforcement official could obtain information about the victim of a crime, where the information is necessary as the basis for immediate action. In addition, in seeking an appropriate balance between public safety and individuals' expectation of privacy, we are proposing that covered entities not be subject to enforcement under this regulation if they disclose protected health information to law enforcement officials in a good faith belief that the disclosure was permitted under this title.

We solicit comment on what additional steps, if any, are appropriate for allowing law enforcement access to protected health information. We are interested in comments concerning situations where needed access to protected health information would not be available under these or other provisions of this proposed rule. We also seek comment on specific privacy or other concerns that would apply if the final regulation included provision for law enforcement access to protected health information without requiring a judicial order, grand jury subpoena, or administrative request, under such additional defined circumstances.

In some of these instances, release of protected health information would be authorized under the proposed regulation pursuant to provisions for patient consent, health oversight, emergency circumstances, or under mandatory reporting laws for gunshot wounds or abuse cases. We are interested in comments concerning situations where needed access to protected health information would not be available under these or other provisions of this proposed rule. We also seek comment on specific privacy or other concerns that would apply if the final regulation included provision for law enforcement access to protected health information without requiring a judicial order, grand jury subpoena, or administrative request, under such additional defined circumstances.

Our proposal with respect to law enforcement has been shaped by the limited scope of our regulatory authority under HIPAA, which applies only to the covered entities and not to law enforcement officials. We believe the proposed rule sets the correct standards for when an exception to the rule of non-disclosure is appropriate for law enforcement purposes. There may be advantages, however, to legislation that applies the appropriate standards directly to judicial officers, prosecutors in grand juries, and to those making administrative or other requests for protected health information, rather than to covered entities as in the proposed regulation. These advantages could include measures to hold officials accountable if they seek or receive protected health information contrary to the legal standard. In Congressional consideration of law enforcement access, there have also been useful discussions of other topics, such as limits on re-use of protected health information gathered in the court of oversight activities. These limitations on our regulatory authority provide additional reason to support comprehensive medical privacy legislation.

6. Uses and Disclosures for Governmental Health Data Systems (§ 164.510(g))

[*Please label comments about this section with the subject: ''Governmental health data systems''*]

In § 164.510(g), we propose to permit covered entities to disclose protected health information for inclusion in State or other governmental health data systems without individual authorization when such disclosures are authorized by State or other law in support of policy, planning, regulatory or management functions.

a. *Importance of Governmental health data systems and the need for protected health information.* Governmental agencies collect and analyze individually identifiable health information as part of their efforts to improve public policies and program management, improve health care and reduce costs, and improve information available for consumer choices. Governments use the information to analyze health care outcomes, quality, costs and patterns of utilization, effects of public policies, changes in the health care delivery system, and related trends. These important purposes are related to public health, research and oversight (although the information in State or other governmental data systems usually is not collected specifically to audit or evaluate health care providers or for public health surveillance). The data are an important resource that can be used for multiple public policy evaluations.

The collection of health information by governmental health data systems often occurs without specification of the particular analyses that could be conducted with the information. These governmental data collection programs frequently call for reporting of information for all individuals treated or released by specified classes of providers. For example, many States request and receive from hospitals records containing individual diagnosis and treatment data for all discharges from their facilities. State hospital discharge data have been used to compare treatment practices and costs between hospitals, to evaluate implications for funding of health care, as well as to provide hospital ''report cards'' to consumers. As part of its general evaluation activities, the DOD maintains a very large database, called the Comprehensive Clinical Evaluation Program, involving military personnel who have reported illnesses possibly arising from service during the Gulf War.

b. *Proposed requirements.* We propose to permit covered entities to disclose protected health information for inclusion in State or other governmental health data systems when such disclosure is authorized by law for analysis in support of policy, planning, regulatory, and management functions. The recipient of the information must be a government agency (or privacy entity acting on behalf of a government agency). Where the covered entity is itself a government agency that collects health data for analysis in support of policy, planning, regulatory, or management functions, it would be permitted to use protected health information in all cases in which it is permitted to disclose such information for government health data systems under this section.

We believe that Congress intended to permit States, Tribes, territories, and other governmental agencies to operate health data collection systems for analyzing and improving the health care system. In section 1178(c), ''State regulatory reporting,'' HIPAA provides that it is not limiting the ability of a State to require a health plan to report, or to provide access to, information for a variety of oversight activities, as well as for ''program monitoring and evaluation.'' We also believe that the considerations Congress applied to State capacities to collect data would apply to similar data collection efforts by other levels of government, such as those undertaken by Tribes, territories and federal agencies. Therefore, we considered two questions regarding governmental health data systems; first,

which entities could make such disclosures; and second, what type of legal authority would be necessary for the disclosure to be permitted.

We considered whether to allow disclosure by all covered entities to governmental data collection systems or to limit permitted disclosures to those made by health plans, as specified in the regulatory reporting provision of HIPAA. While this provision only mentions data collected from health plans, the conference agreement notes that laws regarding ''State reporting on health care delivery or costs, or for other purposes'' should not be preempted by this rule. States would be likely to require sources of information other than health plans, such as health care providers or clearinghouses, in order to examine health care delivery or costs. Therefore, we do not believe it is appropriate to restrict States' or other governmental agencies' ability to obtain such data. This viewpoint is consistent with the Recommendations, which would permit this disclosure of protected health information by all covered entities.

We also asked what type of law would be required to permit disclosure without individual authorization to governmental health data systems. We considered requiring a specific statute or regulation that requires the collection of protected health information for a specified purpose. A law that explicitly addresses the conditions under which protected health information is collected would provide individuals and covered entities with a better understanding of how and why the information is to be collected and used.

We understand, however, that explicit authority to collect information is not always included in relevant law. Governmental agencies may collect health data using a broad public health or regulatory authority in statute or regulation. For example, a law may call on a State agency to report on health care costs, without providing specific authority for the agency to collect the health care cost data they need do so. Consequently, the agency may use its general operating authority to request health care providers to release the information. We recognize that many governmental agencies rely on broad legal authority for their activities and do not intend this proposed rule to hamper those efforts.

Under § 164.518(c), covered entities would have an obligation to verify the identity of the person requesting protected health information, and the legal authority behind the request before the disclosure would be permitted under this subsection. Preamble section II.G.3. describes these requirements in more detail.

7. Disclosure of Directory Information (§ 164.510(h))

[*Please label comments about this section with the subject: ''Directory information''*]

In § 164.510(h), we propose to permit covered entities to disclose information that could reveal protected health information about an individual for purposes of a facility patient directory, if the individual has indicated consent to such disclosures, or if the individual who is incapacitated had not previously expressed a preference in this regard and a covered entity determines that including such information in the directory would be consistent with good medical practice. Directory information could include only the person's name, location in the institution, and general condition.

a. *Importance of directory information and need for protected health information.* When individuals enter inpatient facilities, they are not always able to contact people who may need to know their whereabouts, want to visit them, or want to send them flowers or some other expression of concern. Today, facilities typically operate patient directories, allowing confirmation of a person's presence in a facility, providing the room number for visits and deliveries, and sometime providing general information on the patient's condition. These services cannot be performed without disclosing protected health information. Since most patients find this a welcome convenience, we believe it would be important to allow these practices to continue. However, not everyone may appreciate this service. We are proposing to accommodate the wishes of such people, where possible.

b. *Proposed requirements.* In § 164.510(h), we would require covered entities to ask individuals whether they wish to be included in the entity's directory. For individuals who are incapacitated or otherwise unable to communicate their wishes and who have not previously expressed a preference, the decision would be left to the discretion of the covered entity, consistent with good medical practice. We note that legal representatives could make such decisions on behalf of persons who are incapacitated or otherwise unable to communicate their wishes, consistent with State or other law, since they would stand as the ''individual.'' In the absence of a legal representative or prior expression of a preference by the individual, the decision would be left to the discretion of the covered entity, consistent with good medical practice.

i. *Individuals capable of making decisions.*

For individuals who are not incapacitated, this rule would require the covered entity to ask whether information about the individual's presence in the facility, room number and general condition can be included in the general patient directory. When individuals are capable of making such a determination, their wishes should be respected.

We considered whether also to require covered entities to allow an individual to specify that information can be provided to specific persons but not others. For example, someone may feel that it is acceptable to release information to family members but not to friends. While we would like to respect individuals' wishes to the greatest extent possible, we are concerned about placing on covered entities the burden of verifying the identify of a person requesting directory information. We are therefore not including this additional requirement, but are requesting comments on current practices and how such requests might be accommodated.

We would not require a formal individual authorization pursuant to § 164.508. A verbal or other informal inquiry and agreement would be sufficient. We require only that individuals be given the choice.

ii. *Incapacitated individuals.*

If an individual is not able to make determinations as to whether location or status information should be released to family and friends, and had not in the past expressed a preference in this regard, we would leave the decision as to whether to include the individual in a directory to the discretion of the covered entity. Often individuals are unconscious or otherwise unable due to a medical condition to communicate their wishes to the entity and no representative is available to act for them. In these cases, we encourage the covered entity to take into consideration a number of factors when deciding whether or not to include such an individual in the directory:

- Could disclosing that an individual is in the facility reasonably cause danger of harm to the individual? For example, if a person is unconscious and receiving treatment for injuries resulting from physical abuse from an unknown source, an entity may determine that revealing that the individual is in the facility could give the attacker enough information to seek out the individual and repeat the abuse.

• Could disclosing the location within the facility of the patient give information about the condition of the patient? If a patient's room number would reveal the nature of the medical condition, the entity may decide that it is inappropriate to give that information. For example, if one floor of a hospital has been specifically designated as the psychiatric floor, simply saying that a patient is located on that floor discloses some information about the condition of the individual.

• Is it necessary or appropriate to give the status of a patient to family or friends? Covered entities often need information from family or friends for the treatment of an incapacitated individual. For example, if a patient is unconscious, family or friends may be able to give valuable information that will assist the care giver in making urgent decisions. Family members or friends may be able to give information on drugs or medications that the individual has been taking. On the other hand, it may be that revealing the status of an individual gives more information than the individual would have disclosed if they could make the determination themselves.

• If an individual had, prior to becoming incapacitated, expressed a desire not to be included in such a directory and the covered entity learns of that statement of preference, the covered entity would be required to act in accordance with the stated preference.

Individuals who enter a facility incapacitated and then improve to the point of being able to make their own determinations should be asked within a reasonable time period for permission to include information in the facility's directory.

When the condition of an individual who has opted not to allow protected health information to be included in the facility's directory deteriorates, and the individual is no longer capable of making disclosure decisions, the covered entity would be required to abide by the individual's initial decision. However, such a decision should not prevent a provider from contacting the family if such contact is required for good medical practice. A provider could need information from the family to treat a newly incapacitated person. If good medical practice would include contacting family or friends, the individual's initial request should not prohibit such contact. But the covered entity would still be prohibited from including information about the individual in its directory.

8. Disclosure for Banking and Payment Processes (§ 164.510(i))

[*Please label comments about this section with the subject: ''Banking and payment processes''*]

In § 164.510(i), we propose to allow covered entities to disclose protected health information to financial institutions, or entities acting for financial institutions, if necessary for processing payments for health care and health care premiums.

a. *Importance of financial transactions and the need for protected health information.* Checks that individuals use to pay for health care typically include the names of providers or provider groups that could implicitly identify the medical condition for which treatment was rendered. Similarly, a credit card transaction will also reveal the identify of the provider and thus potentially the nature of the medical condition involved. While such information would constitute protected health information under this rule, there is no practical way of concealing this information when the provider deposits the check or claims credit card payment. Failure to allow this kind of disclosure of protected health information would impede the efficient operations of the health care system.

b. *Proposed requirements.* We propose that covered entities be permitted to disclose protected health information to financial institutions for the specific purposes listed in the section. The permissible purposes are those identified in the statute, and the regulatory text would copy the statutory list of allowable uses.

Under section 1179 of the Act, activities of financial institutions are exempt from HIPAA's Administrative Simplification requirements to the extent that those activities constitute ''authorizing, processing, clearing, settling, billing, transferring, reconciling, or collecting payments'' for health care or health plan premiums. This section of the statute states that financial institutions can use or disclose protected health information for these purposes. We read this part of the statute as indicating that Congress intended that this regulation not impede the efficient processing of these transactions, and accordingly are allowing covered entities to disclose protected health information to financial institutions for the purposes listed in section 1179 of the statute.

Proposed § 164.510(i) would not allow covered entities to include any diagnostic or treatment information in the data transmitted to financial institutions. Such information is never necessary to process a payment transaction. We believe that, in most cases, the permitted disclosure would include only: (1) The name and address of the account holder; (2) the name and address of the payer or provider; (3) the amount of the charge for health services; (4) the date on which health services were rendered; (5) the expiration date for the payment mechanism, if applicable (i.e., credit card expiration date); and (6) the individual's signature. At this time, we are not proposing to include in the regulation an exclusive list of information that could be lawfully disclosed for this purpose. We are, however, soliciting comment on whether more elements would be necessary for these banking and payment transactions and on whether including a specific list of the protected health information that could be disclosed is an appropriate approach.

We understand that financial institutions may also provide covered entities that accept payment via credit card with software that, in addition to fields for information required to process the transaction, includes blank fields in which health plans or health care providers may enter any type of information regarding their patients, such as diagnostic and treatment information, or other information that the covered entity wished to track and analyze. Other financial institutions could provide services to covered entities that constitute ''health care operations'' as defined in proposed § 164.504.

We do not know whether and to what extent health plans and health care providers are using such software to record and track diagnostic and treatment and similar information. However, we recognize that the capability exists and that if a plan or provider engages in this practice, information not necessary for processing the payment transaction could be forwarded to financial institutions along with other information used to process payments. Disclosing such information to a financial institution (absent a business partner relationship) would violate the provisions of this rule.

We also understand that banks, in addition to offering traditional banking services, may be interested in offering additional services to covered entities such as claims management and billing support. Nothing in this regulation would prohibit banks from becoming the business partners of covered entities in accordance with and subject to the conditions of § 164.506(e). If a bank offers an integrated package of traditional banking services and health claims and billing services, it could do

so through a business partner arrangement that meets the requirements of proposed § 164.506(e). Any services offered by the bank that are not on the list of exempt services in 1179 would be subject to the terms of this rule.

We recognize that financial institutions' role in providing information management systems to customers is evolving and that in the future, banks and credit card companies could develop and market to health plans and health care providers software designed specifically to record and track diagnostic and treatment information along with payment information. In light of the rapid evolution of information management technology available to plans and providers, we seek comment on the types of services that financial institutions are performing or may soon perform for covered entities, and how these services could be best addressed by this proposed rule.

Finally, we note that we would impose no verification requirements for most routine banking and payment activities. However, if a bank or financial institution seeks information outside payment processing transactions (e.g., during a special audit), we would require the covered entity to take reasonable steps to verify the identity of the person requesting the disclosure.

9. Uses and Disclosures for Research (§ 164.510(j))

[*Please label comments about this section with the subject: ''Research''*]

In § 164.510(j), we propose to permit covered entities to use and disclose protected health information for research without individual authorization, provided that the covered entity receives documentation that the research protocol has been reviewed by an Institutional Review Board or equivalent body—a privacy board—and that the board found that the research protocol meets specified criteria (regarding protected health information) designed to protect the subject. Absent such documentation, the subject's protected health information could be disclosed for research only with the individual's authorization, pursuant to the authorization requirements in proposed § 164.508.

Our proposed requirements for this disclosure build on the requirements for such disclosure under the Federal regulation that protects human subjects in research conducted or funded by the Federal government, the Federal Policy for the Protection of Human Subjects (often referred to as the ''Common Rule''), first published for several agencies at 56 FR 28,002–028, 032 (1991), and codified for the Department of Health and Human Services at 45 CFR part 46.

a. *Importance of research and the need for protected health information.* Much important and sometimes lifesaving knowledge has come from studies that used individually identifiable health information, including biomedical and behavioral research, epidemiological studies, health services research, and statistical activities. This type of research has lead to dramatic improvements in the nation's health. For example, the results of such research include the association of a reduction in the risk of heart disease with dietary and exercise habits, the association between the use of diethylstilbestrol (DES) by pregnant women and vaginal cancer in their daughters, and the value of beta-blocker therapy in reducing re-hospitalizations and in improving survival among elderly survivors of acute myocardial infarction.

Likewise, research on behavioral, social, and economic factors that affect health, and the effect of health on other aspects of life may require individually identifiable health information. Studies of this kind can yield important information about treatment outcomes and patterns of care, disease surveillance and trends, health care costs, risk factors for disease, functional ability, and service utilization—which may ultimately lead to improvements in the quality of patient care, the identification and eradication of public health threats, and the development of new devices and pharmaceutical products. For example, such research uncovered the fact that disease screening and treatment patterns vary with the race of the person, which in turn has lead to focused outreach programs to improve health. Such research showed that the results of certain highly invasive surgical treatments are better when the care is provided in hospitals that performed a high volume of these procedures.

It is not always possible for researchers to obtain the consent of every subject that a researcher may wish to include within a study. Thousands of records may be involved. Tracking down the subjects may entail costs that make the research impracticable. The requirement to obtain consent also may lead to biased study results, because those who refuse consent may be more or less likely than average to have a particular health problem or condition. This may be a particular concern where the research topic involves sensitive or potentially embarrassing information. At the same time, the privilege of using individually identifiable health information for research purposes without individual authorization requires that the information be used and disclosed under strict conditions that safeguard individuals' confidentiality.

b. *Definition of research.* In proposed § 164.504, we would define ''research'' as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. This is the definition of ''research'' in the Common Rule. This definition is well understood in the research community and elsewhere, and we propose to use it here to maintain consistency with other federal regulations that affect research.

For purposes of determining whether an activity is research under this proposed rule, it would not be relevant whether the information is given gratis, sold, bartered, rented, or otherwise provided for commercial gain. The purpose of this proposed rule regarding disclosure of protected health information for research is to protect the subjects of the information. Where the activity meets the definition of research and involves use or disclosure of protected health information, the rules in this section would apply. We request comments on any aspect of our proposed definition of research.

We understand that research and health care operations often look alike, and may overlap. We have provided definitions for these terms in § 164.504. We solicit comments on ways to further distinguish between research and operations, or otherwise clarify the application of this rule to such activities.

c. *Privacy board review requirement.* In § 154.510(j), we would require covered entities that wish to use or disclose protected health information for research without individual authorization to obtain documentation that a privacy board has reviewed the research protocol and has determined that specified criteria (described below) for waiver of authorization for use or disclosure of the information have been met. The board could be an IRB constituted under the Common Rule, or an equivalent privacy board that meets the requirements in this proposed rule. We propose to apply these requirements to uses and disclosures of protected health information by all covered entities, regardless of the source of funding of the research.

We propose no requirements for the location or sponsorship of the IRB or privacy board. The covered entity could

create such a board, and could rely on it to review proposals for uses and disclosure of records. An outside researcher could come to the covered entity with the necessary documentation from his or her own university IRB. A covered entity could engage the services of an outside IRB or privacy board to obtain the necessary documentation. The documentation would have to be reviewed by the covered entity prior to a use or disclosure subject to this provision.

Under our proposal, we would require that the documentation provided by the IRB or privacy board state: (1) That the waiver of authorization has been approved by the IRB or privacy board; (2) that the board either is an IRB established in accordance with the HHS regulations (45 CFR 46.107) or equivalent regulations of another federal agency, or is a privacy board whose members (i) have appropriate expertise for review of records research protocols, (ii) do not have a conflict of interest with respect to the research protocol, and (iii) include at least one person not affiliated with the institution conducting the research; (3) that the eight criteria for waiver of authorization (described below) are met by the protocol; and (4) the date of board approval of the waiver of authorization. We would also require that the documentation be signed by the chair of the IRB or privacy board.

i. *Application to disclosures and uses regardless of funding source.*

The Common Rule describes conditions under which research may be conducted when obtaining authorization is not possible. Those conditions are intended to ensure that research on human subjects, including research using their health records, is conducted in a manner that minimizes or eliminates the risk of harm to individuals. The Common Rule has been adopted by seventeen Federal agencies,[3] representing most of the federal agencies sponsoring human subjects research.

However, a significant amount of research involving protected health information is currently conducted in the absence of these federal protections. Pharmaceutical companies, health plans, and colleges and universities conduct research supported by private funds. Identifiable information currently is being disclosed and used by these entities without individual authorization without any assessment of risk or of whether individual privacy interests are being adequately protected.

The Secretary's Recommendations call for the extension of the Common Rule principles for waiver of authorization for research uses and disclosures of identifiable health information to all research. The Recommendations also propose additional principles that directly address waiver of authorization for research use of such information. The Recommendations would require an external board to review proposals for research on health information under criteria designed to ensure that the need for waiver of authorization is real, that the public interest in the research outweighs the individual's privacy interest, and that privacy will be protected as much as possible. In addition, the Secretary's Recommendations proposed important restrictions on use and re-disclosure of information by researchers, and requirements for safeguarding protected information, that are not currently applied under the Common Rule.

Under the Secretary's Recommendations, these requirements would apply to researchers who want to use or obtain identifiable information without first obtaining the authorization of the individual who is the subject of the information. However, under HIPAA, we do not have the authority to regulate researchers unless the researcher is also acting as a provider, as in a clinical trial. We can only directly regulate health care providers, health plans, and health care clearinghouses. This means that for most research-related disclosures of health information, we can directly regulate the entities that disclose the information, but not the recipients of the information. Therefore, in order to implement the principles in the Secretary's Recommendations, we must impose any protections on the health plans and health care providers that use and disclose the information, rather than on the researcher seeking the information.

We understand that this approach involves imposing burdens on covered entities rather than on researchers. However, our jurisdiction under this statute leaves us the choice of taking this approach, or failing to provide any protection for individuals whose information is made the subject of research, or requiring individual authorization whenever a covered entity wants to disclose protected health information for research. The second approach would provide no protection for individuals, and the third approach would make much important research impossible. Therefore, we are proposing a mechanism that we believe imposes as little burden as possible on the covered entity while providing enhanced protection for individuals. This is not the approach we advocate for new federal privacy legislation, where we would propose that standards be applied directly to researchers, but it would be a useful and appropriate approach under the HIPAA legislative authority.

We considered a number of other approaches for protecting information from research subjects, particularly when covered entities use protected health information internally for research. We considered approaches that would apply fewer requirements for internal research uses of protected health information; for example, we considered permitting covered entities to use protected health information for research without any additional review. We also considered options for a more limited review, including requiring that internal uses for research using protected health information be reviewed by a designated privacy official or by an internal privacy committee. Another option that we considered would require covered entities to have an IRB or privacy board review their administrative procedures, either for research or more generally, but not to require such review for each research project. See the preamble section II.E.9.

We are not recommending these approaches because we are concerned about applying fewer protections to subjects of private sector research than are applied to subjects of federally-funded research subject to Common Rule protections, where IRB review is required for internal research uses of protected health information. At the same time, we recognize that the proposed rule would place new requirements on research uses and disclosures for research projects not federally-funded. We solicit comment on the approach that we are proposing, including on whether the benefits of the IRB or privacy board reviews would outweigh the burdens associated with

[3] The following 17 Departments and Agencies have adopted the Common Rule: (1) Department of Agriculture; (2) Department of Commerce; (3) Department of Defense; (4) Department of Education; (5) Department of Energy; (6) Department of Health and Human Services; (7) Department of Housing and Urban Development; (8) Department of Justice; (9) Department of Transportation; (10) Department of Veterans Affairs; (11) International Development Cooperative Agency: Agency for International Development; (12) Consumer Product Safety Commission; (13) Environmental Protection Agency; (14) National Aeronautics and Space Administration; (15) National Science Foundation; (16) Social Security Administration; (17) Central Intelligence Agency. In addition, the White House Office of Science and Technology Policy is a signatory to the Common Rule, but its policy is not codified in the Code of Federal Regulations.

the proposed requirements. We also solicit comment on whether alternative approaches could adequately protect the privacy interests of research subjects. We are interested in the extent to which the proposed rule could affect the amount and quality of research undertaken by covered entities or by researchers receiving information from covered entities. People commenting on the proposed rule also may wish to address the appropriateness of applying different procedures or different levels of protection to federally and nonfederally-funded research. We would note that, as discussed below, privacy boards or IRBs could adopt procedures for ''expedited review'' similar to those provided in the Common Rule (Common Rule § ____.110) for review of records research that involves no more than minimal risk. The availability of expedited review may affect the burden associated with the proposed approach.

ii. *Documentation of privacy board approval.* We considered several options for applying Common Rule principles to research not reviewed by Common Rule IRBs through imposing requirements on covered entities. We chose the use of the privacy board because it gives covered entities the maximum flexibility consistent with protecting research subjects. Under this approach, each covered entity that wants to use or disclose protected health information for research without individual authorization could obtain the required documentation directly from an existing privacy board, an internal privacy board created by the covered entity, or from a privacy board used by the researcher.

We considered prohibiting disclosure of protected health information for research unless covered entities enter into contracts, enforceable under law, which would require the researcher to meet the review criteria. Under this approach, the covered entity would be required to enter into a contract with the researcher in order to be permitted to disclose protected health information without individual authorization. In the contract, the researcher would agree to meet the criteria described below, as well as the additional restrictions on reuse and disclosure and the physical safeguards (also described below), in exchange for obtaining the information from the covered entity.

We did not adopt this approach because of the potentially burdensome administrative costs that could stem from the need to negotiate the contracts and ensure that they are legally enforceable under law. In addition, the covered entity may have little incentive to enforce these contracts. However, we seek comments on whether the benefits of this approach outweigh the burdens, whether we could expect the burdens to be eased by the development of model contracts by local universities or professional societies, and whether covered entities could be expected to enforce these contracts. We also seek comments on whether covered entities could be given a choice between the documentation approach proposed in this NPRM and a contract approach. We are particularly interested in comments on this approach, because it appears to be the only mechanism for including restrictions on reuse and disclosure by researchers in this proposed rule.

iii. *Use of boards that are not IRBs.* The Secretary's Recommendations state that privacy protections for private sector records research should be modeled on the existing Common Rule principles. The cornerstone of the Common Rule approach to waiver of authorization is IRB approval. At the same time, we understand that Common Rule IRBs are not the only bodies capable of performing an appropriate review of records research protocols. In working with the Congress to develop comprehensive privacy legislation, we have explored the use of limited purpose privacy boards to review research involving use or disclosure of health information. If the review criteria and operating rules of the privacy board are sufficiently consistent with the principles stated in the Secretary's Recommendations to afford the same level of protection, there would be no need to insist that the review board be a formal Common Rule IRB.

Among the Common Rule requirements for IRB membership, as stated in 45 CFR 46.107, are the following:

- Each IRB must have members with varying backgrounds and appropriate professional competence as necessary to review research protocols.
- Each IRB must include at least one member who is not affiliated with the institution or related to a person who is affiliated with the institution.
- No IRB member may participate in review of any project in which the member has a conflict of interest.

We propose to require that a covered entity could not use or disclose protected health information for research without individual authorization if the board that approved the waiver of authorization does not meet these three criteria.

We considered applying the additional criteria for IRB membership stated in the Common Rule. However, many of the additional criteria are relevant to research generally, but less relevant for a board whose sole function is to review uses or disclosures of health information. In addition, the Common Rule IRB membership criteria are more detailed than the criteria for privacy board membership we propose here. Since our legislative authority reaches to covered entities, but not to the privacy board directly, we decided that imposing additional or more detailed requirements on privacy boards would impose added burdens on covered entities that did not clearly bring concomitant increases in patient protections. We continue to support more complete application of Common Rule criteria directly to these privacy boards through federal legislation. We believe the approach we propose here strikes the appropriate balancing between protecting individuals' privacy interests and keeping burdens on covered entities to a minimum.

d. *Criteria.* In § 164.510(j)(2)(iii), we propose to prohibit the use or disclosure of protected health information for research without individual authorization unless the covered entity has documentation indicating that the following criteria are met:

- The use or disclosure of protected health information involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration;
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation;
- The research would be impracticable to conduct without the protected health information;
- The research project is of sufficient importance to outweigh the intrusion into the privacy of the individual whose information would be disclosed;
- There is an adequate plan to protect the identifiers from improper use and disclosure; and
- There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers.

The first four criteria are in the Common Rule. (The Common Rule § ____.116(d)).[4] These criteria were

[4] It should be noted that for the Department of Defense, 10 U.S.C. 980 prohibits the waiver of informed consent. Only those studies that qualify for exemption per 45 CFR 46.101(b), or studies that do not meet the 45 CFR part 46 definition of human subjects research can be performed in the absence

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designed for research generally, and not specifically to protect individuals' privacy interests regarding medical records research. For this reason, the Secretary's Recommendations include the last four criteria, which were developed specifically for research on medical records.

As part of the IRB or privacy board's review of the use of protected health information under the research protocol, we assume that in case of a clinical trial, it would also review whether any waiver of authorization could also include waiver of the subject's right of access to such information during the course of the trial. See § 164.514(b)(iv).

We recognize that the fourth criterion may create awkward situations for some researchers. Where authorization has been waived, it may be difficult to later approach individuals to give them information about the research project. However, in some cases the research could uncover information that would be important to provide to the individual (e.g., the possibility that they are ill and should seek further examination or treatment). For this reason, we are including this criterion in the proposed rule.

We also recognize that the fifth criterion, which would ask the board to weigh the importance of the research against the intrusion of privacy, would require the board to make a more subjective judgment than that required by the other criteria. This balancing, we feel, goes to the heart of the privacy interest of the individual. We understand, however, that some may view this criterion as a potential impediment to certain types of research. We solicit comment on the appropriateness of the criterion, the burden it would place on privacy boards and IRBs, and its potential effects on the ability of researchers to obtain information for research.

The Secretary's Recommendations propose that a researcher who obtains protected health information this way should be prohibited from further using or disclosing it except when necessary to lessen a serious and imminent threat to the health or safety of an individual or to the public health, or for oversight of the research project, or for a new research project approved by an IRB or similar board. In addition the Recommendations propose an obligation on researchers to destroy the identifiers unless an IRB or similar board determines that there is a research or health justification for retaining them and an adequate plan to protect them from improper disclosure.

We do not have the authority under HIPAA to place such requirements directly on researchers. While criteria to be met in advance can be certified in documentation through board review of a research protocol, a board would have no way to assess or certify a researcher's behavior after completion of the protocol (e.g., whether the researcher was engaging in improper reuse or disclosure of the information, or whether the researcher had actually destroyed identifiers). We instead propose to require the researcher to show a plan for safeguarding the information and destroying the identifiers, which the privacy board or IRB can review and evaluate in determining whether the requested disclosure is proper. We solicit comment on how to include ongoing protections for information so disclosed under this legislative authority without placing excessive burdens on covered entities.

We note that privacy boards or IRBs could adopt procedures for ''expedited review'' similar to those provided in the Common Rule (Common Rule § _____.110) Under the Common Rule's expedited review procedure, review of research that involves no more than minimal risk, and involves only individuals' medical records may be carried out by the IRB chairperson or by one or more reviewers designated by the chairperson from among the members of the IRB. The principle of expedited review could be extended to other privacy boards for disclosures for records-based research. Like expedited review under the Common Rule, a privacy board could choose to have one or more members review the proposed research.

e. *Additional provisions of this proposed rule affecting research.*

i. *Research including health care.*

To the extent that the researcher studying protected health information is also providing treatment as defined in proposed § 164.504, such as in a clinical trial, the researcher would be a covered health care provider for purposes of that treatment, and would be required to comply with all the provisions of this rule applicable to health care providers.

ii. *Individual access to research information.*

The provisions of § 164.514 of this proposed rule, regarding individual access to records, would also apply where the research includes the delivery of health care. We are proposing an exception for clinical trials where the information was obtained by a covered provider in the course of a clinical trial, the individual has agreed to the denial of access when consenting to participate in the trial (if the individual's consent to participate was obtained), and the trial is in still in progress.

iii. *Research on records of deceased persons.*

In § 164.506(f), we propose that, unlike the protections provided by the remainder of this rule, the protections of this proposed rule will end at the death of the subject for the purpose of disclosure of the subject's information for research purposes. In general, this proposed rule would apply to the protected health information of an individual for two years after the individual's death. However, requiring IRB or privacy board review of research studies that use only health information from deceased persons would be a significant change from the requirements of the Common Rule, which apply to individually identifiable information about living individuals only. In addition, some of the Common Rule criteria for waiver of authorization are not readily applicable to deceased persons. To avoid a conflict between Common Rule requirements and the requirements of this proposed rule, we are proposing that the protections of this proposed rule end at the death of the subject for the purpose of disclosure of the subject's information for research purposes.

iv. *Verification.*

In § 164.518(c), we propose to require covered entities to verify the identity of most persons making requests for protected health information and, in some cases, the legal authority behind that request. For disclosures of protected health information for research purposes under this subsection, the required documentation of IRB or privacy board approval would constitute sufficient verification. No additional verification would be necessary under § 164.518(c).

f. *Application to research covered by the Common Rule.* Some research projects would be covered by both the Common Rule and the HIPAA regulation. This proposed rule would not override the Common Rule. Thus, where both the HIPAA regulation and the Common Rule would apply to research conducted by a covered entity, both sets of regulations would need to be followed. Because only half of the substantive criteria for board approval proposed in this rule are applied by IRBs today, this would entail new responsibilities for IRBs in these situations. However, we believe that the additional burden would be minimal, since the IRBs will already be reviewing the research protocol, and will be asked

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of a process to provide informed consent to prospective subjects. This proposed rule would not affect DOD's implementation of 10 U.S.C. 980.

only to assess the protocol against some additional criteria. This burden is justified by the enhancement of privacy protections gained by applying rules specifically designed to protect the subjects of medical records research.

We considered excluding research covered by the Common Rule from the provisions of this proposed rule. We rejected this approach for two reasons. First, the additional proposed requirements applied through HIPAA are specifically designed to protect the privacy interests of the research subjects, and the small additional burden on IRBs would be outweighed by the improved protections for individuals. Second, such an approach would allow federally-funded research to proceed under fewer restrictions than privately funded research. We believe that the source of funding of the research should not determine the level of protection afforded to the individual.

We note that the definition of ''identifiable'' information proposed in § 164.504 of this rule differs from the interpretation of the term under the Common Rule. In particular, if a covered entity encodes identifiers as required under § 164.506(d) before undertaking a disclosure of health information for research purposes, the requirements of this section would not apply. However, the encoded information would still be considered ''identifiable'' under the Common Rule and therefore may fall under the human subjects regulations.

g. *Obtaining the individual's authorization for research use or disclosure of protected health information.* If a covered entity chooses to obtain individual authorization for use or disclosure of information for research, the requirements applicable to individual authorizations for release of protected health information would apply. These protections are described in § 164.508.

For research projects to which both the Common Rule and this proposed rule would apply, both sets of requirements for obtaining the authorization of the subject for research would apply. As with criteria for waiver of authorization, this proposed rule would impose requirements for obtaining authorization that are different from Common Rule requirements for obtaining consent. In particular, the regulation would require more information to be given to individuals regarding who could see their information and how it would be used. For the reasons explained above, we are proposing that both sets of requirements apply, rather than allow federally-funded research to operate with fewer privacy protections than privately-funded research.

h. *Need to assess the Common Rule.* In general, the Common Rule was designed to protect human subjects participating in research projects from physical harm. It was not specifically designed to protect an individual's medical records when used for research. For research in which only the medical information of the human subject is used, i.e., records research, there are several ways in which the Common Rule protections could be enhanced.

In developing these proposed regulations, and in reviewing the comprehensive medical privacy legislation pending before Congress, it has become clear that the Department's human subject regulations (45 CFR part 46, 21 CFR part 50, and 21 CFR part 56) may not contain all of the safeguards necessary to protect the privacy of research participants. Because the source of research funding should not dictate the level of privacy protection afforded to a research subject, the Secretary of HHS will immediately initiate plans to review the confidentiality provisions of the Common Rule.

To further that process, we solicit comments here on how Common Rule protections for the subjects of records review should be enhanced. For example, we will consider the adequacy of the Common Rule's provisions regarding conflict of interest, expedited review, exemptions (such as the exemption for certain research on federal benefits programs), deceased subjects, and whether IRB's should place greater emphasis on confidentiality issues when reviewing research protocols. We also seek comment on whether the Common Rule requirements for obtaining consent for records research should be modified to reflect the specific risks entailed in such research.

In addition, because seventeen other Departments and Agencies are signatories to the Common Rule and each has its own human subject regulations, the Secretary of HHS will consult with these Departments and Agencies regarding potential changes to the Common Rule.

10. Uses and Disclosures in Emergency Circumstances (§ 164.510(k))

[*Please label comments about this section with the subject: ''Emergency circumstances''*]

In § 164.510 (k), we propose to permit covered entities to use or disclose protected health information in emergencies, consistent with applicable law and standards of ethical conduct, based on a reasonable belief that the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of any person or the public.

a. *Importance of emergency response and the need for protected health information.* Circumstances could arise that are not otherwise covered in the rules proposed in §§ 164.510(b) and 164.510(f) for law enforcement and public health, where covered entities may need to disclose protected health information to prevent or lessen a serious and imminent threat of harm to persons or the public. Persons at risk include the individual who is the subject of the protected health information as well as others. Through their professional activities, covered entities, particularly health care providers, may obtain information that leads them to believe that an individual is at risk of harm to him or herself, or poses a threat to others. This information could be needed by emergency and first responders (including law enforcement officials) to deal with or prevent an emergency situation posing a serious and imminent threat of harm to such persons or the public.

b. *Proposed requirements.* We would permit covered entities, consistent with applicable law and standards of ethical conduct, to disclose protected health information based on a reasonable belief that the disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public. Covered entities would only be permitted to make such disclosures to persons who are reasonably able to prevent or lessen the threat, including to the target of the threat.

Anticipating all circumstances under which emergency disclosure could be necessary is not possible. This section must be stated in somewhat general terms. We intend to permit covered entities to respond to emergency requests for protected health information, where it is reasonable for the covered entity to believe that such disclosure would prevent or reduce a serious emergency situation. Such emergencies may threaten a single person or the general public. We do not intend to permit disclosure of protected health information in response to hypothetical scenarios or potential emergencies that are not imminent and serious. This permitted disclosure would be narrow; it should not become a loophole for disclosures not permitted by the other provisions of the proposed rule.

This provision would permit disclosure of relevant information in response to credible requests from law enforcement, public health, or other government officials. The covered entity would be permitted to reasonably rely on credible representations that an emergency exists and that protected health information could lessen the threat. If the disclosure was made in a good faith belief that these circumstances exist, it would be lawful under this section. A covered entity could also disclose protected health information on its own initiative if it determined that the disclosure were necessary, consistent with other applicable legal or ethical standards. Our proposed rule is intended to permit such disclosures where they are otherwise permitted by law or ethical standards. We do not intend to permit disclosures by health care providers or others that are currently prohibited by other law or ethical standards.

Disclosure for emergency circumstances could be authorized by statute or common law and could also be addressed in medical professional ethics and standards. For example, the American Medical Association Principles of Medical Ethics on Confidentiality provides that:

> [T]he obligation to safeguard patient confidences is subject to certain exceptions that are ethically and legally justified because of overriding social consideration. Where a patient threatens to inflict serious bodily harm to another person or to him or herself and there is a reasonable probability that the patient may carry out the threat, the physician should take reasonable precautions for the protection of the intended victim, including notification of law enforcement authorities.

The duty to warn third persons at risk has been addressed in court cases, and the provision proposed permits disclosures in accord with such legal duties. The leading case on this issue is *Tarasoff* v. *Regents of the University of California*, 17 Cal. 3d 425 (1976). In that case, a therapist's patient made credible threats against the physical safety of a specific person. The Supreme Court of California found that the therapist involved in the case had an obligation to use reasonable care to protect the intended victim of his patient against danger, including warning the victim of the peril. Many States have adopted (judicially or legislatively) versions of the *Tarasoff* duty to warn, but not all States have done so. This proposed rule is not intended to create a duty to warn or disclose but would simply permit the disclosure under the emergency circumstances consistent with other applicable legal or ethical standards.

An emergency disclosure provision does present some risks of improper disclosure. There will be pressures and uncertainties when disclosures are requested under emergency circumstances, and decisions must often be made instantaneously and without the ability to seek individual authorization or to perform complete verification of the request. We believe that this risk would be warranted when balancing the individual's interest in confidentiality against the societal interests to preserve life and protect public safety in those rare emergency circumstances where disclosure is necessary. A covered entity that makes a reasonable judgement under such pressure and discloses protected health information in good faith would not be held liable for wrongful disclosure if circumstances later prove not to have warranted the disclosure.

We would also exempt emergency disclosures from provisions that allow individuals to request restrictions on uses and disclosures of their protected health information for treatment, payment and health care operations. In emergency situations, health care professionals need to have any information that will allow them to respond to the emergency circumstance, and cannot be expected to take the time to remind themselves of restrictions on particular information. See proposed § 164.506(c).

11. Disclosure to Next-of-Kin (§ 164.510(l))

[*Please label comments about this section with the subject: ''Next-of-kin''*]

In § 164.510(l), we propose to require health care providers to obtain a verbal agreement from the individual before disclosing protected health information to next-of-kin, to other family members, or to others with whom the individual has a close personal relationship. Where it is not practical or feasible to request and obtain such verbal agreement, providers could disclose to next-of-kin, to other family members, or to others with whom an individual has a close personal relationship, protected health information that is directly relevant to the person's involvement in the individual's care, consistent with good professional health practice and ethics.

a. *Importance of disclosures to next-of-kin and the need for protected health information.* In some cases, disclosure of protected health information to next-of-kin, to other relatives, or to persons with whom the individual has a close personal relationship and who are involved in caring for or helping the individual, can facilitate effective health care delivery. We do not intend to impede the disclosure of protected health information to relatives or friends when expeditious disclosure of such information clearly would be in the individual's best interest.

b. *Proposed requirements.* We propose that when an individual has the capacity to make his or her own health decisions, providers could disclose protected health information to the individual's next-of-kin, to other relatives, or to persons with whom the individual has a close personal relationship, if the individual has verbally agreed to such disclosure. Verbal agreement could be indicated informally, for example, from the fact that the individual brought a family member or friend to the physician appointment and is actively including the family member or friend in the discussion with the physician. If, however, the situation is less clear and the provider is not certain that the individual intends for the family member or friend to be privy to protected health information about the individual, the provider would be required to ask the individual. In these cases, when verbal agreement can be obtained, that agreement would be sufficient verification of the identity of the person to meet the requirements of § 164.518(c).

We would also permit health care providers to disclose protected health information without verbal agreement to next-of-kin, to other relatives, or to persons with whom the individual has a close personal relationship, if such agreement cannot practicably or reasonably be obtained and the disclosure is consistent with good health professional practice and ethics. When verbal agreement cannot be obtained, the provider would be required to take reasonable steps to verify the identity of the family member or friend in order to meet the verification requirement under § 164.518(c). Verbal inquiry would suffice; we would not require any specific type of identity check.

We considered requiring a written authorization for each disclosure in these situations, but rejected that option because it is not practicable and does not provide sufficient additional privacy protection to justify the burden it would place on health care providers and individuals. Many of these conversations are unscheduled and of short duration, and requiring a written authorization may impede treatment and detain the individual. Therefore we would allow a one-time verbal agreement and (where required) verification to suffice for disclosure of protected health information relevant to

the individual's care. For example, a health care provider could disclose protected health information about an individual's treatment plan to the individual's adult child who is taking the individual home from the hospital, if the provider has verbally requested and individual has agreed to providing the adult child with relevant information about aspects of the individual's health care. Disclosure also could be appropriate in cases where a verbal agreement cannot practicably be obtained. For example, a pharmacist could be guided by his or her professional judgment in dispensing a filled prescription to someone who claims to be picking it up on behalf of the individual for whom the prescription was filled.

In such cases, disclosures would have to follow the ''minimum necessary'' provisions of proposed § 164.506(b). For example, health care providers could not disclose without individual authorization extensive information about the individual's surgery or past medical history to the neighbor who is simply driving the individual home and has no need for this information. We request comment on this approach.

The proposed definition of ''individual'' addresses related disclosures regarding minors and incapacitated individuals.

12. Additional Uses and Disclosures Required by Other Law (§ 164.510(n))

[*Please label comments about this section with the subject: ''Additional uses and disclosures required by other law''*]

In § 164.510(n) we propose to allow covered entities to use or disclose protected health information if such use or disclosure is not addressed elsewhere in § 164.510, is required by other law, and the disclosure meets all the relevant requirements of such law.

Other laws may require uses or disclosures of protected health information for purposes not captured by the other provisions of proposed § 164.510. An example is State workers' compensation laws, which could require health care providers to disclose protected health information to a workers' compensation insurer or to an employer. Covered entities generally could make uses and disclosures required by such other laws.

Where such a use or disclosure would also be addressed by other provisions of this regulation, the covered entity would also have to follow the requirements of this regulation. Where the provisions of the other law requirements are contrary to the provisions in this proposed rule and more protective of the individual's privacy, the provisions of the other law would generally control. See discussion in section II.I below.

We have included this section because it is not our intention to obstruct access to information deemed important enough by other authorities to require it by law. We considered omitting this provision because we are concerned that we do not know enough about the required disclosures it would encompass, but decided to retain it in order to raise the issue of permitting disclosures for other, undetermined purposes. We solicit comment on the possible effects of omitting or narrowing this provision.

Under this section, health care providers could make reports of abuse of any person that are required by State law. All States require reports of abuse. All States require reporting to child protective agencies of instances of child abuse or neglect that they identify, and most States require similar reports of abuse or neglect of elderly persons. These are valuable requirements which we support and encourage. The Act (in section 1178(b)) specifically requires that this regulation not interfere with State requirements for reporting of abuse. Additionally, all States require health care providers to report gunshot wounds and certain other health conditions related to violence; this provision would permit such reports.

Section 164.518(c), requiring verification of the identity and legal authority of persons requesting disclosure of protected health information would apply to disclosures under § 164.510(n). As noted above, we are not familiar with all of the disclosures of protected health information that are mandated by State law, so we cannot be certain that the verification requirements in § 164.518(c) would always be appropriate. We solicit comments on whether those requirements would be appropriate for all disclosures that would be permitted here.

13. Application to Specialized Classes (§ 164.510(m))

In the following categories we propose use and disclosure provisions that respond to the unique circumstances of certain federal programs. We request comment on whether additional provisions are necessary to comply with the suitability and national security determination requirements of Executive Order 10450, as amended, and other national security laws.

a. *Application to military services.*

[*Please label comments about this section with the subject: ''Military services''*]

To address the special circumstances of the Armed Forces and their health care systems, we propose to permit military and other federal providers and health plans to use and disclose protected health information about active duty members of the Armed Forces for certain purposes, and to exclude from coverage under this rule health information about certain persons who receive care from military providers.

i. *Members of the Armed Forces.*

The primary purpose of the health care system of the military services differs in its basic character from that of the health care system of society in general. The special nature of military service is acknowledged by the Constitutional provision for separate lawmaking for them (U.S. Constitution, article I, section 8, clause 14) and in their separate criminal justice system under the Uniform Code of Military Justice (10 U.S.C. 801, *et seq.*).

The military health care system, like other federal and civilian health care systems, provides medical care and treatment to its beneficiary population. However, it also serves a critical national defense purpose, ensuring that the Armed Forces are in a state of medical readiness to permit the discharge of those responsibilities as directed by the National Command Authority.

The health and well-being of military members is key and essential. This is true whether such personnel are serving in the continental United States or overseas or whether such service is combat-related or not. In all environments, operational or otherwise, the Armed Forces must be assured that its personnel are medically qualified to perform their responsibilities. This is critical as each and every person performs a vital service upon which others must rely in executing a specified defense requirement. Unqualified personnel not only jeopardize the possible success of an assignment or operation, but they pose an undue risk and danger to others.

To assure that such persons are medically fit, health information is provided to proper command authorities regarding military members performing certain critical functions for medical screening and other purposes so that determinations can be made regarding the ability of such personnel to perform assigned duties. For example, health information is provided regarding:

• A pilot receiving medication that may affect alertness;

• An Armed Forces member with an intolerance for a vaccine necessary for deployment to certain geographical areas;

• Any significant medical or psychological changes in a military member who is a member of the Nuclear Weapons Personnel Reliability Program;

• A military recruit or member with an illness or injury which disqualifies him or her from military service;

• Compliance with controlled substances policies.

The military and the Coast Guard obtain such information from their own health care systems, as well as from other agencies that provide health care to service members, such as the Department of Transportation (DOT), which is responsible for the United States Coast Guard and other federal agencies which provide medical care to members of the Armed Forces (*e.g.*, the Department of State (DOS) provides such care to military attaches and Marine security personnel assigned to embassies and consulates overseas, the Department of Veterans Affairs provides care in certain areas of the country or in cases involving specialized services). Other health care providers could also provide information, for example, when a private sector physician treats a member injured in an accident.

The special needs of the DOD and DOT for accessing information for purposes other than treatment, payment or health care operations were recognized in the Secretary's Recommendations. We considered several options for accommodating the unique circumstances of a military health care environment. We considered providing special rule-making authority to the DOD and other federal agencies which provide care to members of the military, but HIPAA does not allow for such delegation by the Secretary of HHS. Therefore, we propose that health care providers and health plans of the DOD, the DOT, the DOS, the Department of Veterans Affairs as well as any other person or entity providing health care to Armed Forces personnel, could use or disclose protected health information without individual authorization for activities deemed necessary by appropriate military command authorities to assure the proper execution of the military mission.

The appropriate military command authorities, the circumstances in which use or disclosure without individual authorization would be required, and the activities for which such use or disclosure would occur in order to assure proper execution of the military mission, would be identified through **Federal Register** notices promulgated by the DOD or the DOT (for the Coast Guard). The verification requirements in § 164.518(c) would apply to disclosures permitted without authorization.

This proposal would not confer authority on the DOD or the DOT to enact rules which would permit use or disclosure of health information that is restricted or controlled by other statutory authority.

ii. *Foreign diplomatic and military personnel.*

The Department of Defense, as well as other federal agencies, provide medical care to foreign military and diplomatic personnel, as well as their dependents. Such care is provided pursuant to either statutory authority (*e.g.*, 10 U.S.C. 2549) or international agreement. The care may be delivered either in the United States or overseas. Also, where health care is provided in the United States, it may be furnished by non-government providers when government delivered care is not available or the beneficiary elects to obtain private as opposed to government health care. Examples include:

• Foreign military personnel being trained, or assigned to U.S. military organizations, in the United States who receive care from either government or private health care providers;

• The DOD operated medical clinic which provides care to all allied military and diplomatic personnel assigned to NATO SHAPE Headquarters in Brussels, Belgium;

• The DOS, which also is engaged in arranging health care for foreign diplomatic and military personnel and their families, could also have legitimate needs for information concerning the health services involved.

We believe that the statute was not intended to cover this unique class of beneficiaries. These persons are receiving U.S., either private or governmental, furnished health care, either in the United States or overseas, because of the beneficiary's military or diplomatic status. For such personnel, we believe that the country-to-country agreements or federal statutes which call for, or authorize, such care in furtherance of a national defense or foreign policy purpose should apply. We propose to exclude foreign military and diplomatic personnel and their dependents who receive health care provided by or paid for by the DOD or other federal agency, or by an entity acting on its behalf pursuant to a country-to-country agreement or federal statute, from the definition of an ''individual'' in § 164.504. Therefore, the health information created about such persons by a DOD or other federal agency health care provider would not be protected under this rule. However, information created about such persons by covered health care providers whose services are not paid for by or provided on behalf of a federal agency would be protected health information.

iii. *Overseas foreign national beneficiaries.*

The Department of Defense, as well as other federal agencies and U.S.-based non-governmental organizations, provide health care to foreign nationals overseas incident to U.S. sponsored missions or operations. Such care is provided pursuant to federal statute, international agreement, international organization sponsorship, or incident to military operations (including humanitarian and peacekeeping operations). Examples include:

• The DOD provides general health care to an indigenous population incident to military deployment;

• The DOD provides health care to captured and detained personnel as a consequence of overseas combat operations. Such care is mandated by international agreement, i.e., the Geneva Conventions. The most recent example involves the surrender or capture of Iraqi soldiers during the conduct of Operation Desert Storm;

• A number of federal agencies and non-governmental organizations provide health care services as part of organized disaster relief or other humanitarian programs and activities around the world.

We believe that the statute did not contemplate these unique beneficiary populations. Under circumstances where healthcare is being furnished to foreign nationals incident to sanctioned U.S. activities overseas, application of these proposed rules could have the unintended effect of impeding or frustrating the conduct of such activities, and producing incongruous results. Examples include:

• Requiring preparation of a notice advising the local population of the information practices of the DOD incident to receiving free medical care as part of disaster relief.

• Medical information involving a prisoner of war could not be disclosed, without the prisoner's consent, to U.S. military authorities who have responsibility for operating the POW camps.

Therefore, we propose to exclude overseas foreign national beneficiaries of health care provided by the DOD or other federal agency, or by non-governmental organizations acting on behalf of a federal agency, from the

definition of an individual. This exclusion would mean that any health information created when providing health care to this population would not be protected health information and therefore not covered by these rules.

iv. *Disclosure to the Department of Veterans Affairs.*

Upon completion of an individual's military service, the DOD routinely transfers that person's entire military service record, including protected health information, to the Department of Veterans Affairs so the file can be retrieved quickly if the individual or his/her dependents apply for veterans benefits. This practice was initiated in an effort to expedite veterans benefits eligibility determinations by ensuring timely access to complete, accurate information on the veteran's military service. Under the proposed rule, the transfer of these files would require individual authorization if protected health information is included. While this change could increase the time necessary for benefits processing in some cases, we believe the privacy interests outweigh the related administrative challenges. We invite comment on whether our assessment of costs and benefits is accurate. We also invite comment on alternative methods for ensuring privacy while expediting benefits processing.

b. *Application to the Department of Veterans Affairs.*

[*Please label comments about this section with the subject: ''Department of Veterans Affairs''*]

We propose to permit protected health information to be used without individual authorization by and among components of the Department of Veterans Affairs that determine eligibility for or entitlement to, or that provide, benefits under laws administered by the Secretary of Veterans Affairs.

This exemption recognizes that the Veterans Administration is two separate components: The Veterans Health Administration (which operates health care facilities) and the Veterans Benefits Administration (which operates the Veterans disability program). The close integration of the operations of the two components may make requiring individual authorizations before transferring protected health information particularly disruptive. Further, the Veterans Health Administration transfers medical information on a much larger scale than most other covered entities, and requiring individual authorization for transfers among components could compromise the Department of Veterans Affairs' ability to fulfill its statutory mandates.

Nonetheless, we invite comments on this approach. In particular, we are interested in whether the requirement for individual authorization for disclosure of medical records for use in benefits calculations would increase privacy protections for veterans, or whether it would be of questionable value since most veterans would authorize disclosure if it were tied to their benefits. We also are interested in comments on whether the proposed approach would unreasonably hamper the Department of Veterans Affairs in its ability to make accurate benefits determinations in cases in which individuals chose not to authorize disclosure.

c. *Application to the Department of State.*

[*Please label comments about this section with the subject: ''Department of State''*]

We propose to permit the Department of State to use and disclose protected health information for certain purposes unrelated to its role as a health care provider but necessary for the achievement of its mission.

i. *Importance of Foreign Service determinations and the need for protected health information.*

The Secretary of State administers and directs the Foreign Service. As contemplated in the Foreign Service Act, the Foreign Service is ''to serve effectively the interests of the United States'' and ''provide the highest caliber of representation in the conduct of foreign affairs;'' members of the Foreign Service are to be available to serve in assignments throughout the world. As called for under the Foreign Service Act, the DOS has established a health care program to promote and maintain the physical and mental health of members of the Service and that of other Government employees serving abroad under chief of mission authority, as well as accompanying family members. The DOS provides health care services to thousands of Foreign Service officers, other government employees and their families serving abroad, many of whom are frequently changing posts or assignments.

Worldwide availability for service is a criterion for entrance into the Foreign Service, so that applicants with conditional offers of employment must undergo medical clearance examinations to establish their physical fitness to serve in the Foreign Service on a worldwide basis prior to entrance into the Foreign Service. Employees and accompanying family members also must be medically cleared before assignments overseas, to preclude assignment to posts where existing medical conditions would be exacerbated or where resources to support an existing medical condition are inadequate.

The DOS uses protected health information gained through its role as a health care provider to fulfill its other responsibilities. The information is used to make medical clearance and fitness decisions as well as other types of determinations requiring medical information (such as fitness for duty or eligibility for disability retirement of Foreign Service members). Such information is also used to determine whether to immediately evacuate an individual for evaluation or treatment, or to determine whether to allow an employee or family member to remain in a position or at post abroad. An individual's record can include medical information provided to the DOS with the individual's authorization by outside health care providers, protected health information about treatment provided or paid for by the DOS, and medical information collected from non-treatment processes such as the clearance process.

ii. *Proposed requirements.*

We are proposing to exempt the DOS from the requirement to obtain individual authorization (§ 164.508) in order to use or disclose protected health information maintained by its health care program in certain cases. Specifically, the exemption would apply to the disclosure or use of protected health information of the following individuals for the following purposes: (1) Of applicants to the Foreign Service for medical clearance determinations of physical fitness to serve in the Foreign Service on a worldwide basis, including: medical and mental conditions limiting assignability abroad; conformance to occupational physical standards, where applicable; and suitability;

(2) of members of the Foreign Service and other United States Government employees assigned to serve abroad under Chief of Mission authority, for (a) medical clearance determinations for assignment to posts abroad, including: medical and mental conditions limiting such assignment; conformance to occupational physical standards, where applicable; continued fitness for duty, suitability, and continuation of service at post (including decisions on curtailment); (b) separation medical examinations; and (c) determinations of eligibility of members of the Foreign Service for disability retirement (whether on application of the employee or the Secretary);

(3) of eligible family members of Foreign Service or other United States Government employees, for medical clearance determinations like those described in (2) above to permit such family members to accompany employees to posts abroad on Government orders, as well as determinations regarding family members remaining at post and separation medical examinations.

The proposed exemption is intended to maintain the DOS's procedures regarding internal of medical information in conformance with the Privacy Act of 1974, as amended, and 42 CFR Part 2, which would continue to apply to the DOS. The verification requirements of § 164.518(c) would apply to these disclosures.

The DOS is considering the need to add national security determinations under Executive Order 10450, as amended, and other suitability determinations to the exempted purposes listed above. We therefore request comment as to the purposes for which use or disclosure of protected health information without individual authorization by the DOS would be appropriate.

d. *Application to employees of the intelligence community.*

[*Please label comments about this section with the subject: ''Intelligence community''*]

We propose to permit covered entities to disclose protected health information about individuals who are employees of the intelligence community (as defined in Section 4 of the National Security Act, 50 U.S.C. 401a), and their dependents, to intelligence community agencies without individual authorization when authorized by law.

This provision addresses the special circumstances of the national intelligence community. The preservation of national security depends to a large degree on the health and well-being of intelligence personnel. To determine fitness for duty, including eligibility for a security clearance, these agencies must have continued access to the complete health records of their employees. To ensure continued fitness for duty, it is critical that these agencies have access to the entire medical record on a continuing basis. An incomplete medical file that excluded mental health information, for instance, could result in an improper job placement and a potential breach in security.

The term ''intelligence community'' is defined in section 4 of the National Security Act, 50 U.S.C. 401a, to include: the Office of the Director of Central Intelligence, which shall include the Office of the Deputy Director of Central Intelligence, the National Intelligence Council (as provided for in 50 U.S.C. 403–5(b)(3) [1]), and such other offices as the Director may designate; the Central Intelligence Agency; the National Security Agency; the Defense Intelligence Agency; the National Imagery and Mapping Agency; the National Reconnaissance Office; other offices within the DOD for the collection of specialized national intelligence through reconnaissance programs; the intelligence elements of the Army, the Navy, the Air Force, the Marine Corps, the Federal Bureau of Investigation, the Department of the Treasury, and the Department of Energy; the Bureau of Intelligence and Research of the Department of State; and such other elements of any other department or agency as may be designated by the President, or designated jointly by the Director of Central Intelligence and the head of the department or agency concerned, as an element of the intelligence community.

We would permit covered entities to disclose protected health information concerning employees of the intelligence community and their dependents where authorized by law. The verification requirements of § 164.518(c) would apply to these disclosures.

F. Rights of individuals.

[*Please label comments about this section with the subject: ''Introduction to rights of individuals''*]

The following proposed sections are intended to facilitate individual understanding of and involvement in the handling of their protected health information. Four basic individual rights would be created under this section: the right to a notice of information practices; the right to obtain access to protected health information about them; the right to obtain access to an accounting of how their protected health information has been disclosed; and the right to request amendment and correction of protected health information.

The rights described below would apply with respect to protected health information held by health care providers and health plans. We are proposing that clearinghouses not be subject to all of these requirements. We believe that as business partners of covered plans and providers, clearinghouses would not usually initiate or maintain direct relationships with individuals. The contractual relationship between a clearinghouse (as a business partner) and a covered plan or provider would bind the clearinghouse to the notice of information practices developed by the plan or provider and it will include specific provisions regarding inspection, copying, amendment and correction. Therefore, we do not believe the clearinghouses should be required to provide a notice or provide access for inspection, copying, amendment or correction. We would require clearinghouses to provide an accounting of any disclosures for purposes other than treatment, payment and health care operations to individuals upon request. See proposed § 164.515. It is our understanding that the vast majority of the clearinghouse function falls within the scope of treatment, payment, and health care operations and therefore we do not believe providing this important right to individuals will impose a significant burden on the industry. We invite comment on whether or not we should require clearinghouses to comply with all of the provisions of the individual rights section.

1. *Rights and Procedures for a Written Notice of Information Practices.* (§ 164.512)

[*Please label comments about this section with the subject: ''Notice of information practices''*]

a. *Right to a written notice of information procedures.* We are proposing that individuals have a right to an adequate notice of the information practices of covered plans and providers. The notice would be intended to inform individuals about what is done with their protected health information and about any rights they may have with respect to that information. Federal agencies must adhere to a similar notice requirement pursuant to the Privacy Act of 1974 (5 U.S.C. 552a(e)(3)).

We are not proposing that business partners (including health care clearinghouses) be required to develop a notice of information practices because, under this proposed rule, they would be bound by the information practices of the health plan or health care provider with whom they are contracting.

We considered requiring covered plans or providers to obtain a signed copy of the notice form (or some other signed indication of receipt) when they give the form to individuals. There are advantages to including such a requirement. A signed acknowledgment would provide evidence that the notice form has been provided to the individual. Further, the request to the individual to formally acknowledgment receipt would highlight the importance of the notice, providing additional encouragement for the individual to

read it and ask questions about its content.

We are concerned, however, that requiring a signed acknowledgment would significantly increase the administrative and paperwork burden of this provision. We also are unsure of the best way for health plans to obtain a signed acknowledgment because plans often do not have face-to-face contact with enrollees. It may be possible to collect an acknowledgment at initial enrollment, for example by adding an additional acknowledgment to the enrollment form, but it is less clear how to obtain it when the form is revised. We solicit comment on whether we should require a signed acknowledgment. Comments that address the relative advantages and burdens of such a provision would be most useful. We also solicit comment on the best way to obtain signed acknowledgments from health plans if such a provision is included in the final rule. We also solicit comments on other strategies, not involving signed acknowledgments, to ensure that individuals are effectively informed about the information practices of covered plans or providers.

b. *Revising the notice.* We are proposing that covered plans and providers be permitted to change their policies and procedures at any time. Before implementing a change in policies and procedures, the covered plan or provider must revise its notice accordingly. However, where the covered plan or provider determines that a compelling reason exists to take an action that violates its notice, it may do so only if it documents the reason supporting the action and revises its notice within 30 days of taking such action. The distribution requirements that would apply when the notice has been materially revised are discussed in detail below.

c. *Content of the notice.* In § 164.512, we propose the categories of information that would be required in each notice of information practices, the specific types of information that would have to be included in each category, and general guidance as to the presentation of written materials. A sample notice is provided in the Appendix to this preamble. This sample notice is provided as an example of how the policies of a specific covered health care provider could be presented in a notice. Each covered health plan and health care provider would be required to create a notice that complies with the requirements of this proposed rule and reflects its own unique information practices. It does not indicate all possible information practices or all issues that could be addressed in the notice. Covered plans and providers may want to include significantly more detail, such as the business hours during which an individual could review their records or its standard time frame for responding to requests to review records; entities could choose to list all types of mandatory disclosures.

In a separate section of this proposed rule, we would require covered plans or providers to develop and document policies and procedures relating to use, disclosure, and access to protected health information. See proposed § 164.520. We intend for the documentation of policies and procedures to be a tool for educating the entity's personnel about its policies and procedures. In addition, the documentation would be the primary source of information for the notice of information practices. We intend for the notice be a tool for educating individuals served by the covered plan or provider about the information practices of that entity. The information contained in the notice would not be as comprehensive as the documentation, but rather provide a clear and concise summary of relevant policies and procedures.

We considered prescribing specific language that each covered plan or provider would include in its notice. The advantages of this approach would be that the recipient would get exactly the same information from each covered plan or provider in the same format, and that it would be convenient for covered plans or providers to use a uniform model notice.

There are, however, several disadvantages to this approach. First, and most important, no model notice could fully capture the information practices of every covered plan or provider. Large entities will have different information practices than small entities. Some health care providers, for example academic teaching hospitals, may routinely disclose identifiable health information for research purposes. Other health care providers may rarely or never make such disclosures. To be useful to individuals, each entity's notice of information practices should reflect its unique privacy practices.

Another disadvantage of prescribing specific language is that it would limit each covered plan or provider's ability to distinguish itself in the area of privacy protections. We believe that if information on privacy protections were readily available, individuals might compare and select plans or providers based on their information practices. In addition, a uniform model notice could easily become outdated. As new communication methods or technologies are introduced, the content of the notices might need to reflect those changes.

A covered plan or provider that adopts and follows the notice content and distribution requirements described below, we would presume, for the purposes of compliance, that the plan or provider has provided adequate notice. However, the proposed requirements for the content of the notice are not intended to be exclusive. Covered plans or providers could include additional information and additional detail, beyond that required. In particular, all federal agencies must still comply with the Privacy Act of 1974. For federal agencies that are covered plans or providers, this would mean that the notice must comply with the notice requirements provided in the Privacy Act as well as those included in this proposed rule.

i. *Uses and disclosures of protected health information.*

In proposed § 164.512, we would require each covered plan and provider to include in the notice an explanation of how it uses and discloses protected health information. The explanation must be provided in sufficient detail as to put the individual on notice of the uses and disclosures expected to be made of his or her protected health information. As explained above in section II.C.5, covered plans and providers may only use and disclose protected health information for purposes stated in this notice.

This section of the notice might be as simple as a statement that information will be used and disclosed for treatment, payment, administrative purposes, and quality assurance. If the entity will be using or disclosing the information for other purposes, the notice must include a brief explanation. For example, some entities might include a statement that protected health information will be used for clinician education and disclosed for research purposes. We are soliciting comment on the level of detail that should be required in describing the uses and disclosures, specifically with respect to uses and disclosures for health care operations.

In addition we would require that notices distinguish between those uses and disclosures the entity makes that are required by law and those that are permitted but not required by law. By distinguishing between uses and disclosures that an entity is required to make those that the entity is choosing to make, the notice would provide the

individual with a clearer understanding of the entity's privacy practices.

For uses and disclosures required by law, the notice need only list the categories of disclosures that are authorized by law, and note that it complies with such requirements. This language could be the same for every covered entity within a State, territory or other locale. We encourage states, state professional associations, and other organizations to develop model language to assist covered plans or providers in preparing this section of the notice.

For each type of permissible use or disclosure that the entity makes (e.g., research, public health, and next-of-kin), the notice would include a brief statement explaining the entity's policy with respect to that type of disclosure. For example, if all relevant laws permit health care providers to disclose protected health information to public health without individual authorization, the entity would need to develop policies and procedures regarding when and how it will make such disclosures. The entity would then document those policies and procedures as required by § 164.520 and the notice would include a statement of these policies. For example, the notice might state ''we will disclose your protected health information to public health authorities upon request.''

We considered requiring the notice to include not only a discussion the actual disclosure practices of the covered entity, but also a listing or discussion of all additional disclosures that are authorized by law. We considered this approach because, under this proposed rule, covered plans or providers would be permitted to change their information practices at any time, and therefore individuals would not be able to rely on the entity's current policies alone to understand how their protected health information may be used in the future. We recognize that in order to be fully informed, individuals need to understand when their information could be disclosed.

We rejected this approach because we were concerned that a notice with such a large amount of information could be burdensome to both the individuals receiving the notices and the entities required to prepare and distribute them. There are a substantial number of required and permitted disclosures under State or other applicable law, and this rule generally would permit them to be made.

Alternatively, we considered requiring that the notice include all of the types of permissible disclosures under this rule (e.g., public health, research, next-of-kin). We rejected that approach for two reasons. First, we felt that providing people with notice of the intended or likely disclosures of their protected health information was more useful than describing all of the potential types of disclosures. Second, in many States and localities, different laws may affect the permissible disclosures that an entity may make, in which case a notice only discussing permissible disclosures under the federal rule would be misleading. While it would be possible to require covered plans or providers to develop notices that discuss or list disclosures that would be permissible under this rule and other law, we were concerned that such a notice may be very complicated because of the need to discuss the interplay of federal, State or other law for each type of permissible disclosure. We invite comments on the best approach to provide most useful information to the individuals without overburdening either covered plans or providers or the recipients of the notices.

In § 164.520, we are proposing to require all covered entities to develop and document policies and procedures for the use of protected health information. The notice would simply summarize those documented policies and procedures and therefore would entail little additional burden.

ii. *Required statements.*

We are proposing that the notice include several basic statements to inform the individual of their rights and interests with respect to protected health information. First, we propose to require the notice to inform individuals that the covered plan or provider will not use or disclose their protected health information for purposes not listed in the notice without the individual's authorization. Individuals need to understand that they can authorize a disclosure of their protected health information and that the covered entity may request the individual to authorize a disclosure, and that such disclosures are subject to their control. The notice should also inform individuals that such authorizations can be revoked.

Second, we propose that the notice inform individuals that they have the right to request that the covered plan or provider restrict certain uses and disclosures of protected health information about them. The notice would also inform individuals that the covered plan or provider is not required to agree to such a request.

Third, we propose that the notice also inform individuals about their right of access to protected health information for inspection and copying and to an accounting of disclosures as provided in proposed §§ 164.514 and 164.515. In addition, the notice would inform individuals about their right to request an amendment or correction of protected health information as proposed in § 164.516. The notice would include brief descriptions of the procedures for submitting requests to the covered plan or provider.

Fourth, the notice would be required to include a statement that there are legal requirements that require the covered plan or provider to protect the privacy of its information, provide a notice of information practices, and abide by the terms of that notice. Individuals should be aware that there are government requirements in place to protect their privacy. Without this statement, individuals may not realize that covered plans or providers are required to take measures to protect their privacy, and may therefore be less interested in pursuing their rights or finding out more information.

Fifth, the notice would be required to include a statement that the entity may revise its policies and procedures with respect to uses or disclosures of protected health information at any time and that such a revision could result in additional uses or disclosures without the individual's authorization. The notice also should inform the individual how a revised notice would be made available when material revisions in policies and procedures are made. For example, when a provider makes a material change to its notice, proposed § 164.512(e) would require the provider to post a new notice.

Finally, we propose that the notice inform individuals that they have the right to complain to the covered entity and to the Secretary if they believe that their privacy rights have been violated.

iii. *Identification of a contact person for complaints and additional information.*

We propose that the notice be required to identify a contact person or office within the covered plan or provider to receive complaints, as provided in proposed § 164.518(a)(2), and to help the individual obtain further information on any of the issues identified in the notice. A specific person would not need to be named in the notice. It could be an office or general number where someone who can answer privacy questions or concerns can be reached.

In § 164.518(d), we are proposing that covered plans and providers permit individuals to submit complaints to the covered entity. We are proposing that the contact person identified in the

notice be responsible for initially receiving such complaints. The contact person might or might not be responsible for processing and resolving complaints, but, if not, he or she would forward the complaints to the appropriate personnel or office. See discussion of the complaint process in section II.G.4, below.

In addition to receiving complaints, the contact person would be able to help the individual obtain further information on any of the issues identified in the notice. The contact person would be able to refer to the documented policies and procedures required by proposed § 164.520. We would not prescribe a formal method for responding to questions.

The administrative requirements section below, proposed § 164.518(a), would also require the entity to designate an official to develop policies for the use and disclosure of protected health information and to supervise personnel with respect to use and disclosure of protected health information. We would not require this official to also be the contact person. Depending on the size and structure of the entity, it might be appropriate to require one person to fill both roles.

iv. *Date the notice was produced.*

We are proposing that covered plans and providers include the date that the notice was produced on the face of the notice. We would also encourage the provider to highlight or otherwise emphasize any changes to help the individual recognize such changes.

d. *Requirements for distribution of the notice.* It is critical to the effectiveness of this proposed rule that individuals be given the notice often enough to remind them of their rights, but without overburdening covered plans or providers. We propose that all covered plans and providers would be required to make their notice available to any individual upon request, regardless of whether the requestor is already a patient or enrollee. We believe that broad availability would encourage individuals or organizations to compare the privacy practices of plans or providers to assist in making enrollment or treatment choices. We also propose additional distribution requirements for updating notices, which would be different for health plans and health care providers. The requirements for health plans and health care providers are different because we recognize that they have contact with individuals at different points in time in the health care system.

i. *Health plans.*

We considered a variety of combinations of distribution practices for health plans and are proposing what we believe is the most reasonable approach. We would require health plans to distribute the notice by the effective date of the final rule, at enrollment, within 60 days of a material change to the plan's information practices, and at least once every three years.

We considered requiring health plans to post the notice either in addition to or instead of distribution. Because most individuals rarely visit the office of their health plan, we do not believe that this would be an effective means of communication. We also considered either requiring distribution of the notice more or less frequently than every three years. As compared to most health care providers, we believe that health plans often are larger and have existing administrative systems to cost effectively provide notification to individuals. Three years was chosen as a compromise between the importance of reminding individuals of their plans' information practices and the need to keep the burden health plans to the minimum necessary to achieve this objective. We are soliciting comment on whether requiring a notice every three years is reasonable for health plans.

ii. *Health care providers.*

We are proposing to require that covered health care providers provide a copy of the notice to every individual served at the time of first service delivery, that they post the notice in a clear and prominent location where it is reasonable to expect individuals seeking service from the provider to be able to read the notice, and that copies be available on-site for individuals to take with them. In addition, we are proposing to require that covered health care providers provide a copy of the notice to individuals they are currently serving at their first instances of service delivery within a year of the effective date of the final rule.

We would not require health care providers to mail or otherwise disseminate their notices after giving the notice to individuals at the time of the first service delivery. Health care providers' patient lists may include individuals they have not served in decades. It would be difficult for providers to distinguish between ''active'' patients, those who are seen rarely, and those who have moved to different providers. While some individuals will continue to be concerned with the information practices of providers who treated them in the distant past, overall the burden of an active distribution requirement would not be outweighed by improved individual control and privacy protection.

We recognize that some health care providers, such as clinical laboratories, pathologists and mail order pharmacies, do not have face-to-face contact with individuals during service delivery. Such providers would be required to provide the required notice in a reasonable period of time following first service delivery, through mail, electronic notice (i.e. e-mail), or other appropriate medium. For example, a web-based pharmacy could meet this distribution requirement by providing a prominent and conspicuous link to its notice on its home page and by requiring review of that notice before processing an order.

If a provider wishes to make a material change in the information practices addressed in the notice, it would be required to revise its notice in advance. After making the revision, the provider would be required to post the new notice promptly. We believe that this approach creates the minimum burden for health care providers consistent with giving individuals a clear source of accurate information.

e. *Plain language requirement.* We are proposing to apply a plain language requirement to notices developed by covered plans or providers under these proposed rules. A covered plan or provider could satisfy the plain language requirement if it made a reasonable effort to: organize material to serve the needs of the reader; write sentences in the active voice, use ''you'' and other pronouns; use common, everyday words in sentences; write in short sentences; and divide material into short sections.

We also considered proposing formatting specifications such as requiring the covered plan or provider to use easy-to-read design features (e.g., lists, tables, graphics, contrasting colors, and white space), type face, and font size in the notice. We are soliciting comment on whether these additional format specifications should be required.

The purpose of the notice proposed in the rules below is to tell the recipient how protected health information collected about them will be used. Recipients who cannot understand the entity's notice would miss important information about their privacy rights and how the entity is protecting health information about them. One of the goals of this proposed rule is to create an environment of open communication and transparency with respect to the use and disclosure of protected health information. A lack of clarity in the notice could undermine this goal and

create misunderstandings. Covered plans or providers have an incentive to make their notice statements clear and concise. We believe that the more understandable notices are, the more confidence the public will have in the entity's commitment to protecting the privacy of health information.

It is important that the content of the notice be communicated to all recipients and therefore we would encourage the covered plan or provider to consider alternative means of communicating with certain populations. We note that any covered entity that is a recipient of federal financial assistance is generally obligated under title VI of the Civil Rights Act of 1964 to provide material ordinarily distributed to the public in the primary languages of persons with limited English proficiency in the recipients' service areas. Specifically, this title VI obligation provides that, where a significant number or proportion of the population eligible to be served or likely to be directly affected by a federally assisted program need service or information in a language other than English in order to be effectively informed of or participate in the program, the recipient shall take reasonable steps, considering the scope of the program and the size and concentration of such population, to provide information in language appropriate to such persons. For entities not subject to title VI, the title VI standards provide helpful guidance for effectively communicating the content of their notices to non-English speaking populations.

We also would encourage covered plans or providers to be attentive to the needs of individuals who cannot read. For example, an employee of the entity could read the notice to individuals upon request or the notice could be incorporated into a video presentation that is played in the waiting area.

The requirement of a printed notice should not be interpreted as a limitation. For example, if an individual who is requesting a notice from a covered plan or providers were to ask to receive the notice via e-mail, the requirements of this proposed rule could be met by providing the notice via e-mail. The proposed rule would not preclude the use of alternative forms of providing the notice and we would encourage covered plans or providers to use other forms of distribution, such as posting their privacy notices on their web sites. While this will not substitute for paper distribution when that is requested by an individual, it may reduce the number of requests for paper copies.

2. Rights and Procedures for Access for Inspection and Copying (§ 164.514)

a. *Right of access for inspection or copying.* (§ 164.514(a))

[Please label comments about this section with the subject: ''Access for inspection or copying'']

In § 164.514, we are proposing that, with very limited exceptions, individuals have a right to inspect and copy protected health information about them maintained by a covered health plan or health care provider in a designated record set. Individuals would also have a right of access to protected health information in a designated record set that is maintained by a business partner of a covered plan or provider when such information is not a duplicate of the information held by the plan or provider, including when the business partner is the only holder of the information or when the business partner has materially altered the protected health information that has been provided to it.

This right of access means that an individual would be able to either inspect or obtain copies of his or her health information maintained in a designated record set by covered plans and providers and, in limited circumstances, by their business partners. Inspection and copying is a fundamental aspect of protecting privacy; this right empowers individuals by helping them to understand the nature of the health information about them that is held by their providers and plans and to correct errors. In order to facilitate an open and cooperative relationship with providers and allow the individual a fair opportunity to know what information is held by an entity, inspection and copying should be permitted in almost every case.

While the right to have access to one's information may appear somewhat different from the right to keep information private, these two policy goals have always been closely tied. For example, individuals are given an almost absolute right of access to information in federal health record systems under the Privacy Act of 1974 (5 U.S.C. 552a(d)). The Privacy Protection Study Commission recommended that this right be available. (Personal Privacy in an Information Society 299 (1977)). The right of access was a key component of the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry recommendations in the Consumer Bill of Rights and Responsibilities. The Commission's report stated that consumers should ''have the right to review and copy their own medical records and request amendments to their records.'' (Consumer Bill of Rights and Responsibilities, Chapter Six: Confidentiality of Health Information, November 1997). Most recently, the Health Privacy Project issued a statement of ''Best Principles for Health Privacy'' that included the same recommendation. Health Privacy Project, Institute for Health Policy Solutions, Georgetown University (June 1999) (http://www.healthprivacy.org).

Open access to health information can benefit both the individuals and the covered entities. It allows individuals to better understand their own diagnosis and treatment, and to become more active participants in their health care. It can increase communication, thereby enhancing individuals' trust in their health care providers and increasing compliance with the providers' instructions. If individuals have access to and understand their health information, changing providers may not disrupt health care or create risks based on lack of information (e.g., drug allergies or unnecessary duplication of tests).

i. *Information available for inspection and copying.*

In § 164.514(a), we are proposing to give the individual a right of access to information that is maintained in a designated record set. We intend to provide a means for individuals to have access to any protected health information that is used to affect their rights and interests. This would include, for example, information that would be used to make health care decisions or information that would be used in determining whether an insurance claim would be paid. Covered plans or providers often incorporate the same protected health information that is used to make these types of decisions into a variety of different data systems. Not all of those data systems will be utilized to make determinations about specific individuals. For example, information systems that are used for quality control analyses are not usually used to make determinations about a specific patient. We would not require access to these other systems.

In order to ensure that individuals have access to the protected health information that is used, we are introducing the concept of a ''designated record set.'' In using the term ''designated record set,'' we are drawing on the concept of a ''system of records'' that is used in the Privacy Act. Under the Privacy Act, federal agencies must provide an individual with access to ''information pertaining to him which

is contained in (a system of records).'' 5 U.S.C. 552a(d)(1). A ''system of records'' is defined as ''a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.'' 5 U.S.C. 552a(a)(5). Under this rule, a ''designated record set'' would be ''a group of any records under the control of any covered entity from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.'' See discussion in section II.B.

Files used to backup a primary data system or the sequential files created to transmit a batch of claims to a clearinghouse are clear examples of data files which do not fall under this definition. We rejected requiring individual access to all records in which she or he was identifiable because of the extreme burden it would place on covered plans or providers without providing additional information or protection for the individual. We also rejected using the subset of such records which were accessed directly by individual identifiers because of the redundancy of information involved and the increasing use of database management systems to replace legacy systems that do sequential processing. These would be accessed by individual identifier but would contain redundant data and be used for routine processing that did not directly affect the individual. We concluded that access to only such record sets that were actually accessed by individual identifier and that were used to make substantive decisions that affect individuals would provide the desired information with a minimum of burden for the covered plans or providers.

We note that the standard would apply to records that are ''retrieved'' by an identifier and not records that are only ''retrievable'' by an identifier. In many cases, technology will permit sorting and retrieving by a variety of fields and therefore the ''retrievable'' standard would be relatively meaningless. We intend to limit access to those sets of records actually used to affect the interests of the individual.

We believe that by providing access to protected health information maintained in a designated record set, we would be ensuring that individuals will be able to inspect or copy relevant and appropriate information without placing too significant of a burden on covered plans or providers. We are soliciting comment on whether limiting access to information maintained in a designated record set is an appropriate standard when applied to covered plans and providers and their business partners.

ii. *Right of access to information maintained by business partners.*

In § 164.506(e), we are proposing that covered plans and providers include specific terms in their contract with each business partner. One of the required terms would be that the business partner must provide for inspection and copying of protected health information as provided in this section. Because our authority is limited by HIPAA to the covered entities, we must rely upon covered plans and providers to ensure that all of the necessary protected health information provided by the individual to the plan or provider is available for inspection and copying. We would require covered plans and providers to provide access to information held in the custody of a business partner when it is different from information maintained by the covered plan or provider. We identified two instances where this seemed appropriate: when the protected health information is only in the custody of a business partner and not in the custody of the covered plan or provider; and when protected health information has been materially altered by a business partner. We are soliciting comment on whether there are other instances where access should be provided to protected health information in the custody of a business partner.

Other than in their capacity as business partners, we are not proposing to require clearinghouses to provide access for inspection and copying. As explained above in section II.C.5, clearinghouses would usually be business partners under this proposed rule and therefore they would be bound by the contract with the covered plan or provider. See proposed § 164.506(e). We carefully considered whether to require clearinghouses to provide access for inspection and copying above and beyond their obligations as a business partner, but determined that the typical clearinghouse activities of translating record formats and batching transmissions do not involve setting up designated record sets on individuals. Although the data maintained by the clearinghouse is protected health information, it is normally not accessed by individual identifier and an individual's records could not be found except at great expense. In addition, although clearinghouses process protected health information and discover errors, they do not create the data and make no changes in the original data. They, instead, refer the errors back to the source for correction. Thus, individual access to clearinghouse records provides no new information to the individual but could impose a significant burden on the industry.

As technology improves it is likely that clearinghouses will find ways to take advantage of databases of protected health information that aggregate records on the basis of the individual subject of the information. This technology would allow more cost-effective access to clearinghouse records on individuals and therefore access for inspection and copying could be appropriate and reasonable.

iii. *Duration of the right of access.*

We are proposing that covered plans and providers be required to provide access for as long as the entity maintains the protected health information. We considered requiring covered plans and providers to provide access for a specific period or defining a specific retention period. We rejected that approach because many laws and professional standards already designate specific retention periods and we did not want to create unnecessary confusion. In addition, we concluded that individuals should be permitted to have access for as long as the information is maintained by the covered plan or provider. We are soliciting comments on whether we should include a specific duration requirement in this proposed rule.

b. *Grounds for denial of access for inspection and copying.* Proposed § 164.514 would permit denial of inspection and copying under very limited circumstances. The categories of denials would not be mandatory; the entity could always elect to provide all of the requested health information to the individual. For each request by an individual, the entity could provide all of the information requested or it could evaluate the requested information, consider the circumstances surrounding the individual's request, and make a determination as to whether that request should be granted or denied. We intend to create narrow exceptions to the stated rule of open access and we would expect covered plans and providers to employ these exceptions rarely, if at all.

In proposing these categories of permissible denials, we are not intending to create a legal duty for the entity to review all of the health information before releasing it. Rather, we are proposing them as a means of preserving the flexibility and judgment of covered plans or providers under appropriate circumstances.

Entities subject to the Privacy Act would not be able to deny a request for inspection and copying under all of the circumstances permitted by this proposed rule. They would continue to be governed by the denials permitted by the Privacy Act and applicable regulations. See section II.I.4.a for further discussion.

i. *Disclosures reasonably likely to endanger life or physical safety.*

In § 164.514(b)(1)(i), we propose that covered plans and providers be permitted to deny a request for inspection or copying if a licensed health care professional has determined that, in the exercise of reasonable professional judgment, the inspection and copying requested is reasonably likely to endanger the life or physical safety of the individual or another person. Denial based on this provision, as with all of the provisions in this section, would be discretionary. While it is important to protect the individual and others from physical harm, we are also concerned about the subjectivity of the standard and are soliciting comments on how to incorporate a more objective standard into this provision.

We are proposing that covered plans and providers should only consider denying a request for inspection and copying under this provision in situations where a licensed health care professional (such as a physician, physician's assistant or nurse) makes the determination that access for inspection and copying would be reasonably likely to endanger life or physical safety. We are proposing to require a licensed health care professional to make the determination because it would rely entirely on the existing standards and ethics in the medical profession. In some instances, the covered plan or provider would be a licensed health care professional and therefore, he or she could make the determination independently. However, when the request is made to a health plan, the entity would need to consult with a health care professional in order to deny access under this provision.

We are soliciting comments as to whether the determination under this provision should be limited to health care professionals who have an existing relationship with the individual. While such a limitation would significantly restrict the scope of this provision and could reduce the number of denials of requests for inspection and copying, it could also ensure that the determination of potential harm is as accurate as possible.

By proposing to allow covered plans and providers to deny a request for inspection and copying based on potential endangerment, we are not suggesting that entities should deny a request on that basis. This provision is not intended to be used liberally as a means of denial of individual inspection and copying rights for all mental health records or other ''sensitive'' health information. Each request for access would have to be assessed on its own merits. We would expect the medical community to rely on its current professional standards for determining what constitutes a threat to life or physical safety.

As explained above, we are not proposing to create a new ''duty'' whereby entities can be held liable for failure to deny inspection and copying. We simply are acknowledging that some providers, based on reasonable professional judgment, may already assume a duty to protect an individual from some aspect of their health information because of the potential for physical harm. The most commonly cited example is when an individual exhibits suicidal or homicidal tendencies. If a health care professional determines that an individual exhibits such tendencies and that permitting inspection or copying of some of their health information could reasonably result in the individual committing suicide, murder or other physical violence, then the individual could be denied access to that information.

We considered whether covered plans and providers should be permitted to deny access on the basis of sensitivity of the health information or the potential for causing emotional or psychological harm. Many States allow denial of access on similar grounds. In balancing the desire to provide individual access against the need to protect the individual, we concluded that the individual access should prevail because in the current age of health care , it is critical that the individual is aware of his or her health information.

Therefore, if a health care professional determines that inspection and copying of the requested information may cause emotional or psychological harm, but is not reasonably likely to endanger the life or physical safety of the individual or another person, then the covered plan or provider would not be permitted to deny the individual's request. If the entity is concerned about the potential for emotional or psychological harm, we would encourage it to offer special procedures for explaining the information or counseling the individual. For example, an entity could offer to have a nurse or other employee review the information or the format with the individual or provide supplemental written materials explaining a diagnosis. If the entity elects to offer such special procedures, the entity would not be permitted to condition inspection and copying upon compliance with the procedures. We are not proposing to require covered plans or providers to establish any informational or counseling procedures and we are not proposing that individuals be required to comply with any procedures in order to obtain access to their protected health information. We invite comment on whether a standard such as emotional distress or psychological harm should be included as a reason for which a covered plan or provider could deny a request for inspection or copying.

ii. *Disclosures likely to cause harm to another individual.*

We propose that covered plans and providers be permitted to deny a request for inspection or copying if the information requested is about another person (other than a health care provider) and a licensed health care professional has determined that inspection or copying is reasonably likely to cause substantial harm to that other person. We believe that it is rare that information about one person would be maintained within the health records of another without one or both of their knowledge. On some occasions when health information about one person is relevant to the care of another, a physician may incorporate it into the latter's record, such as information from group therapy sessions and illnesses with a genetic component. In some instances the information could be shared without harm, or may already be known to the individual. There may, however, be situations where disclosure could harm the other person, such as by implicitly revealing facts about past sexual behavior, nonpaternity, or similarly sensitive information. This provision would permit withholding of information in such cases.

We believe that this determination should be based on the existing standards and ethics in the medical profession. We are soliciting comments on whether the determination under this provision should be limited to health care professionals who have an existing relationship with the person who is expected to be harmed as a result of the inspection or copying.

Information about a third party may appear in an individual's records unbeknownst to the individual. In such cases if the individual chooses to exercise her right to inspect her protected health information, the covered plan or provider providing her access would be making an

unauthorized disclosure unless the third party has provided a written authorization. We considered requiring that access to such information be denied because the third party had not provided an authorization. We considered proposing that the covered plan or provider would be required to deny an individual's request for access to any information about another person, unless there was a potential for harm to the individual who would be denied. This would have been the only instance where we would require that access be denied as a general rule. We recognized that such requirements would ultimately require covered plans and providers to review every piece of protected health information before permitting inspection and copying to determine if information about another person was included and whether the requester would be harmed without such information. We concluded that this would impose a significant burden on covered plans and providers. We seek comment on whether and how often individual health records contain identifiable information about other persons, and current practice relating to the handling of such information in response to individual requests for access.

iii. *Disclosures of confidential information likely to reveal the source.*

We propose that covered plans or providers be permitted to deny a request for inspection and copying if the entity determines that the requested information was obtained under a promise of confidentiality from someone other than a health care provider and such access would be likely to reveal the source of the information. This provision is intended to preserve an entity's ability to maintain an implicit or explicit promise of confidentiality.

Covered plans and providers would not be permitted to deny access when the information has been obtained from another health care provider. An individual is entitled to have access to all information about him or her generated by the health care system (apart from the other exceptions we propose here), and confidentiality promises by health care providers to other providers should not interfere with that access.

iv. *Disclosures of clinical trial information.*

While a clinical trial is research, it is also health care as defined in § 160.103, and the information generated in the course of the trial would be protected health information. In § 164.514(b)(iv), we are proposing that a researcher/provider could deny a request for inspection and copying of the clinical trial record if the trial is still in progress, and the subject-patient had agreed to the denial of access in conjunction with the subject's consent to participate in the trial. The IRB or privacy board would determine whether such waiver of access to information is appropriate, as part of its review of the research protocol. In the rare instances in which individuals are enrolled in trials without consent (such as those permitted under FDA regulations, at 21 CFR 50.23), the covered entity could deny access to information during the course of the trial even without advance subject consent.

Clinical trials are often masked—the subjects do not know the identity of the medication they are taking, or of other elements of their record while the trial is in progress. The research design precludes their seeing their own records and continuing in the trial. Thus it is appropriate for the patient to waive the right to see the record while the trial is in progress. This understanding would be an element of the patient's consent to participate in the trial; if the consent signed by the patient did not include this fact, the patient would have the normal right to see the record. In all cases, the subject would have the right to see the record after the trial is completed.

As with all grounds for denial of access, denial would not be required under these circumstances. We would expect all researchers to maintain a high level of ethical consideration for the welfare of trial participants and provide access where appropriate. For example, if a participant has a severe adverse reaction, disclosure of information during the course of the trial may be necessary to give the participant adequate information for proper treatment decisions.

v. *Disclosure of information compiled for a legal proceeding.*

In § 164.514(b)(1)(v), we are proposing that covered plans and providers be permitted to deny a request for inspection and copying if the information is compiled in reasonable anticipation of, or for use in, a legal proceeding. This provision would permit the entity to deny access to any information that relates specifically to legal preparations but not to the individual's underlying health information. For example, when a procedure results in an adverse outcome, a hospital's attorney may obtain statements or other evidence from staff about the procedure, or ask consultants to review the facts of the situation for potential liability. Any documents containing protected health information that are produced as a result of the attorney's inquiries could be kept from the individual requesting access. This provision is intended to incorporate the attorney work-product privilege. Similar language is contained in the Privacy Act and has been interpreted to extend beyond attorneys to information prepared by ''lay investigators.''

We considered limiting this provision to ''civil'' legal proceedings but determined that such a distinction could create difficulties in implementation. In many situations, information is gathered as a means of determining whether a civil or criminal violation has occurred. For example, if several patients were potentially mistreated by a member of a provider's staff, the provider may choose to get copies of the patients' records and interview other staff members. The provider may not know at the time they are compiling all of this information whether any investigation, civil or criminal, will take place. We are concerned that if we were to require the entity to provide the individual with access to this information, we might unreasonably interfere with this type of internal monitoring.

c. *Provision of other protected health information where access for inspection and copying is denied.* In proposed § 164.514(b)(2), we would require a covered plan or provider that elects to deny a request for inspection or copying as provided above to make any other protected health information requested available to the individual to the extent possible consistent with the denial. The plan or provider could redact or otherwise exclude only the information that falls within one or more of the denial criteria described above and would be required to permit inspection and copying of all remaining information. This provision is key to the right to inspect and copy one's health information. We intend to create narrow exceptions to the stated rule of open access for inspection and copying and we would expect covered plans or providers to employ these exceptions rarely, if at all. In the event that a covered plan or provider would find it necessary to deny access, then the denial would need to be as limited in scope as possible.

d. *Procedures to effect right of access for inspection and copying.* In § 164.514(c) and (d), we are proposing that covered plans and providers be required to have procedures that enable individuals to exercise their rights to inspect and obtain a copy of protected health information as explained above.

We considered whether this proposed rule should include detailed procedures governing a individual's request for inspection and copying. Because this proposed rule will affect such a wide range of entities, we concluded that it should only provide general guidelines and that each entity should have the discretion to develop procedures consistent with its own size, systems, and operations.

i. *Time limits.*

In § 164.514(d)(2), we are proposing that the covered plans and providers would take action upon the request as soon as possible but not later than 30 days following receipt of the request. We considered the possibility of not including a time limitation but rather imposing a ''reasonableness'' requirement on the covered plans or providers. We concluded that the individual is entitled to know when to expect a response. This is particularly important in the context of health information, where an individual may need access to his or her information in order to make decisions about care. Therefore, in order to determine what would be ''reasonable,'' we examined the time limitations provided in the Privacy Act, the Freedom of Information Act (FOIA), and several State laws.

If the entity had fulfilled all of its duties under this proposed rule within the required time period, then the entity should not be penalized for any delay by the individual. For example, if, within the 30 days, a provider approves a request for inspection and copying, makes copies of the requested information, and notifies the individual that this information is available to be picked up and paid for at the provider's office, then the provider's duty would be discharged under the rule. The individual might not be able to pick up the information for another two weeks, but this extra time should not be counted against the provider.

The Privacy Act requires that upon receipt of a request for amendment (not access), the agency would send an acknowledgment to the individual within 10 working days. (5 U.S.C. 552a (d)(2)). We considered several options that included such an acknowledgment requirement. An acknowledgment would be valuable because it would assure the individual that their request was received. Despite the potential value of requiring an acknowledgment, we concluded that it could impose a significant administrative burden on some of the covered plans and providers. This proposed rule will cover a wide range of entities with varying capacities and therefore, we are reluctant to create requirements that would overwhelm smaller entities or interfere too much with procedures already in place. We would encourage plans and providers to have an acknowledgment procedure in place, but would not require it at this point. We are soliciting comment on whether this proposed rule should require such an acknowledgment.

We also considered whether to include specific procedures governing ''urgent'' or ''emergency'' requests. Such procedures would require covered plans and providers to respond in a shorter time frame. We recognize that circumstances may arise where an individual will request inspection and copying on an expedited basis and we encourage covered plans or providers to have procedures in place for handling such requests. We are not proposing additional regulatory time limitations to govern in those circumstances. The 30-day time limitation is intended to be an outside deadline, rather than an expectation. Rather, we would expect a plan or provider to always be attentive to the circumstances surrounding each request and respond in an appropriate time frame, not to exceed 30 days.

Finally, we considered including a section governing when and how an entity could have an extension for responding to a request for inspection and copying. For example, the FOIA provides that an agency may request additional time to respond to a request if the agency needs to search for and collect the requested records from facilities that are separate from the office processing the request; to search for, collect, and appropriately examine a voluminous amount of separate and distinct records; and to consult with another entity or component having a substantial interest in the determination of the request. We determined that the criteria established in the FOIA are tailored to government information systems and therefore may not be appropriate for plans and providers covered by this proposed rule. Furthermore, we determined that the 30-day time period would be sufficient for responding to requests for inspection and copying and that extensions should not be necessary. We are soliciting comments on whether a structured extension procedure should be included in this proposed rule.

ii. *Notification of accepted requests.*

In § 164.514(d)(3), we are proposing that covered plans or providers be required to notify the individual of the decision to provide access and of any steps necessary to fulfill the request. In addition we propose that the entity provide the information requested in the form or format requested if it is readily producible in such form or format. Finally, if the covered plan or provider accepts an individual's request, it would be required to facilitate the process of inspection and copying.

For example, if the plan or provider will be making copies and sending them directly to the individual with an invoice for copying costs, then it would need to ensure that the individual is aware of this procedure in advance and then send the information within the 30-day time period. If the plan or provider has procedures that require the individual to inspect the health information on site, then in addition to notifying the individual of the procedure, the entity would need to ensure that there are representatives available during reasonable business hours at the usual business address who can assist with inspection and copying. If the plan or provider maintains health information electronically and the individual requests an electronic copy, the plan or provider would need to accommodate such request if possible.

iii. *Copying fees.*

In proposed § 164.514(d)(3)(iv), we would permit a covered plan or provider to charge a reasonable, cost-based fee for copying health information provided pursuant to this section. We considered whether we should follow the practice in the FOIA and include a structured fee schedule. We concluded that the FOIA was developed to reflect the relatively uniform government costs and that this proposed rule would apply to a broader range of entities. Depending on the size of the entity, copying costs could vary significantly. Therefore, we propose that the entity simply charge a reasonable, cost-based fee.

The inclusion of a fee for copying is not intended to impede the ability of individuals to copy their records. Rather, it is intended to reduce the burden on covered plans and providers. When establishing a fee for copying, we encourage covered plans and providers to consider the impact on individuals of such a cost. If the cost is excessively high, some individuals would not be able to obtain a copy. We would encourage covered plans or providers to make efforts to keep the fee for copying within reach of all individuals.

iv. *Statement of denial of access for inspection and copying.*

In § 164.514(d)(4), we propose that a covered plan or provider that denies an individual's request for inspection and copying in whole or in part be required to provide the individual with a written statement in plain language explaining the reason for the denial. The statement could include a direct reference to the section of the regulation relied upon for

the denial, but the regulatory citation alone would not sufficiently explain the reason for the denial. The statement would need to include the name and number of the contact person or office within the entity who is responsible for receiving complaints. In addition, the statement would need to include information regarding the submission of a complaint with the Department pursuant to § 164.522(b).

We considered proposing that covered plans and providers provide a mechanism for appealing a denial of inspection and copying. We believe, however, that the requirement proposed in § 164.518(d) that covered plans and providers have complaint procedures to address patient and enrollee privacy issues generally would allow the individual to raise the issue of a denial with the covered plan or provider. We would expect the complaint procedures to be scalable; for example, a large plan might develop a standard complaint process in each location where it operates whereas, a small practice might simply refer the original request and denial to the clinician in charge for review. We would encourage covered plans and providers to institute a system of appeals, but would not require it by regulation. In addition, the individual would be permitted to file a complaint with the Department pursuant to § 164.522(b).

3. Rights and Procedures With Respect to an Accounting of Disclosures. (§ 164.515)

[*Please label comments about this section with the subject: ''Accounting of disclosures''*]

a. *Right to accounting of disclosures.* In this rule, we propose that individuals have a right to receive an accounting of all instances where protected health information about them is disclosed by a covered entity for purposes other than treatment, payment, and health care operations, subject to certain time-limited exceptions for disclosures to law enforcement and oversight agencies as discussed below. Providing such an accounting would allow individuals to understand how their health information is shared beyond the basic purposes of treatment, payment and health care operations.

We considered whether to require covered entities to account for all disclosures, including those for treatment, payment and health care operations. We rejected this approach because it would be burdensome and because it would not focus on the disclosures of most interest to individuals. Upon entering the health care system, individuals are generally aware that their information will be used and shared for the purpose of treatment, payment and health care operations. They have the greatest interest in an accounting of circumstances where the information was disclosed for other purposes that are less easy to anticipate. For example, an individual might not anticipate that his or her information would be shared with a university for a research project, or would be requested by a law enforcement agency.

We are not proposing that covered entities include uses and disclosures for treatment, payment and health care operations in the accounting. We believe that it is appropriate for covered entities to monitor all uses and disclosures for treatment, payment and health care operations, and they would be required to do so for electronically maintained information by the Security Standard. However, we do not believe that covered entities should be required to provide an accounting of the uses and disclosures for treatment payment and health care operations.

The proposed Security Standard would require that ''[e]ach organization * * * put in place audit control mechanisms to record and examine system activity. They would be important so that the organization can identify suspect data access activities, assess its security program, and respond to potential weaknesses.'' The purpose of the audit control mechanism, or audit trail, in the Security Standard would be to provide a means for the covered entity to police access to the protected health information maintained in its systems. By contrast, the purpose of the accounting would be to provide a means for individuals to know how the covered entity is disclosing protected health information about them. An audit trail is critical to maintaining security within the entity and it could be constructed in such a way to enable the covered plan or provider to satisfy the requirements of both regulations. For example, every time protected health information was used or disclosed, the audit mechanism could prompt the user for a ''purpose.'' If the disclosure was for a purpose other than treatment, payment or health care operations, then the information could be flagged or copied into a separate database. This would allow the entity to both monitor security and have the ability to provide an accurate accounting upon request.

Covered entities should know how all protected health information is used and disclosed, but should not be required to provide an exhaustive accounting of all uses and disclosures to individuals upon request. Such an accounting could be extremely long and detailed. It would place a tremendous burden on the covered entities and it could be far too detailed to adequately inform the individual. We determined that when individuals seek health care, they understand that information about them will be used and disclosed in order to provide treatment or obtain payment and therefore, they would have the most significant interest in knowing how protected health information was used and disclosed beyond the expected realm of treatment, payment and health care operations. We are soliciting comment on whether the scope of accounting strikes an appropriate balance between providing information to the individual and imposing requirements on covered entities.

We are proposing that covered entities be required to provide an accounting of disclosures for as long as the entity maintains the protected health information. We considered only requiring the accounting for a specified period of time, but concluded that individuals should be permitted to learn how their information was disclosed for as long as the information is maintained by the covered plan or provider. We are soliciting comments on whether we should include a specific time period in this proposed rule.

b. *Procedures for providing an accounting of disclosures.*

i. *Form or format.*

This proposed rule does not specify a particular form or format for the accounting. In order to satisfy the accounting requirement, a covered entity could elect to maintain a systematic log of disclosures or it could elect to rely upon detailed record keeping that would permit the entity to readily reconstruct the history when it receives a request from an individual. We would require that covered entities be able to respond to a request for accounting within a reasonable time period. In developing the form or format of the accounting, covered entities should adopt policies and procedures that will permit them to respond to requests within the 30-day time period in this proposed rule.

ii. *Content of the accounting of disclosures.*

We are proposing that the accounting include all disclosures for purposes other than treatment, payment, and health care operations, subject to certain exceptions for disclosures to law enforcement and oversight agencies, discussed below. This would also include disclosures that are authorized by the individual. The accounting would include the date of each disclosure; the name and address of the

organization or person who received the protected health information; and a brief description of the information disclosed. For all disclosures that are authorized by the individual, we are proposing that the covered entity maintain a copy of the authorization form and make it available to the individual with the accounting.

We considered whether the accounting of disclosures should include the name of the person who authorized the disclosure of information. The proposed Security Standard would require covered entities to have an audit mechanism in place to monitor access by employees. We concluded that it was unnecessary and inappropriate to require the covered entity to include this additional information in the accounting. If the individual identifies an improper disclosure by an entity, he or she should hold the entit—not the employee of the entity—accountable. It is the responsibility of the entity to train its workforce about its policies and procedures for the disclosure of protected health information and to impose sanctions if such policies and procedures are violated.

We are proposing that protected health information that is disclosed to a health oversight or law enforcement agency would be excluded from the accounting if the oversight or law enforcement agency provides a written request stating that the exclusion is necessary for a specified time period because access by the individual during that time period would be reasonably likely to impede the agency's activities. The written request must specifically state how long the information should be excluded. At the expiration of that period, the covered entity would be required to include the information in an accounting for the individual.

We are proposing this time-limited exclusion for law enforcement and oversight activities because we do not intend to unreasonably interfere with investigations and other activities that are in the public interest. The Recommendations simply provide that disclosures to law enforcement and oversight agencies should be excluded from the accounting where access by the individual could be reasonably likely to impede the agency's activities. We were concerned that it would be difficult for covered entities to determine whether access by the individual was ''reasonably likely to impede the agency's activities.'' In order to address this concern, we considered excluding all disclosures to law enforcement and oversight from the accounting, but concluded that such an exclusion would be overly broad. As a means of creating a clearly defined rule for the covered entity to follow, we are proposing that covered entities require a time-limited, written statement from the oversight or law enforcement agency. We are soliciting comment on whether this time-limited exclusion strikes the appropriate balance between ensuring individual access to an accounting of disclosures and preserving the integrity of law enforcement and oversight investigations.

iii. *Time limits.*

We are proposing that the accounting of disclosures, including copies of signed authorization forms, be made available to the individual as quickly as the circumstances require, but not later than 30 days following receipt of the request.

4. Rights and Procedures for Amendment and Correction (§ 164.516)

[*Please label comments about this section with the subject: ''Amendment or correction''*]

a. *Right to request amendment or correction of protected health information.* This proposed rule would provide an individual with the right to request a covered plan or provider to amend or correct protected health information relating to the individual. A covered plan or provider would be required to accommodate requests with respect to any information that the covered plan or provider determines to be erroneous or incomplete, that was created by the plan or provider, and that would be available for inspection and copying under proposed § 164.514.

i. *Accuracy and completeness.*

The first criteria that a covered entity would need to consider is whether the protected health information at issue is either erroneous or incomplete. The basic concept comes from the Privacy Act of 1974, governing records held by Federal agencies, which permits an individual to request correction or amendment of a record ''which the individual believes is not accurate, relevant, timely, or complete.'' (5 U.S.C. 552a(d)(2)). We would adopt the standards of ''accuracy'' and ''completeness'' and draw on the clarification and analysis of these terms that has emerged in administrative and judicial interpretations of the Privacy Act over the last 25 years.

We are not proposing to permit correction on the basis of an individual's belief that information is irrelevant or untimely. The Privacy Act of 1974 imposes affirmative obligations on Federal agencies to maintain records with accuracy, relevance, timeliness, and completeness, and permits individuals to seek correction of records that do not meet that standard. The amendment and correction right complements and helps to enforce the agency obligation.

Our view is that the relevance and timeliness standards, while very appropriate for Federal agencies generally, would be difficult to impose by regulation upon health record keeping, which depends to a large extent on clinical judgment. The increasingly-recognized impact of lifestyle and environmental factors on health may, for example, motivate physicians to record information which appears irrelevant, but which may in fact serve as a diagnostic clue, or which may alert later users of the record to clinically relevant aspects of the patient's life. We invite comment on how any such standard might be structured to avoid interfering inappropriately with clinical judgment.

We also are concerned about the burden that requests for amendment or correction may place on covered plans and providers and have tried to limit the process to those situations where amendment or correction would appear to be most important. We invite comment on whether our approach reasonably balances burden with adequately protecting individual interests.

We note that for Federal agencies that are also covered plans or providers, the rule we are proposing would not diminish their present obligations under the Privacy Act of 1974, under which all four factors are bases for amendment and correction.

ii. *Original creator of the information.*

We propose to require a covered plan or provider to accommodate a request for amendment or correction if the plan or provider created the information in dispute.

We considered requiring covered plans and providers to amend or correct any erroneous or incomplete information it maintains, regardless of whether it created the information. Under this approach, if the plan or provider did not create the information, then it would have been required to trace the information back to the original source to determine accuracy and completeness. We rejected this option because we concluded that it would not be appropriate to require the plan or provider that receives a request to be responsible for verifying the accuracy or completeness of information that it did not create. We also were concerned about the burden that would be imposed on covered plans and providers if they were required to trace the source of any erroneous or

incomplete information transmitted to them.

We would rely on a combination of three other requirements to ensure that protected health information remains as accurate as possible as it travels through the health care system. First, we are proposing that a covered plan or provider that makes an amendment or correction be required to notify any relevant persons, organizations, or other entities of the change or addition. Second, we are proposing that other covered plans or providers that receive such a notification be required to incorporate the necessary amendment or correction. Finally, we are proposing that covered plans or providers require their business partners who receive such notifications to incorporate any necessary amendments or corrections. See discussion in section II.F.4.c.iii. We are soliciting comments whether this approach would effectively ensure that amendments and corrections are communicated appropriately.

iii. *Information available for amendment or correction.*

We are proposing that the right to request amendment or correction extend to all protected health information that would be available for inspection and copying under § 164.514. We would only require covered plans and providers to amend or correct that information maintained in a designated record set but would encourage the development of systems that would accommodate these types of changes for all data collections. For protected health information that is maintained solely by a business partner or that has been materially altered by a business partner, the covered plan or provider would need to make arrangements with the business partner to accommodate any requests.

This right would not be intended to interfere with medical practice, or modify standard business record keeping practices. Perfect records are not required, but instead a standard of reasonable accuracy and completeness should be used. In addition, this right would not be intended to provide a procedure for substantive review of decisions such as coverage determinations by payers. It would only affect the content of records, not the underlying truth or correctness of materials recounted therein. Attempts under the Privacy Act of 1974 to use this correction mechanism as a basis for collateral attack on agency determinations have generally been rejected by the courts. The same results would be intended here.

iv. *Duration of the right to request amendment or correction.*

We are proposing that covered plans and providers be required to accommodate requests for amendment or correction for as long as the entity maintains the protected health information. We considered requiring covered plans and providers to accommodate requests for a specific period or defining a specific retention period. We rejected that approach because many laws and professional standards already designate specific retention periods and we did not want to create confusion. In addition, we concluded that individuals should be permitted to request amendments or corrections for as long as the information is maintained by the covered plan or provider. We are soliciting comments on whether we should include a specific duration requirement in this proposed rule.

b. *Grounds for denial of request for amendment or correction.* We are proposing that a covered plan or provider would be permitted to deny a request for amendment or correction if, after a reasonable review, the plan or provider determines that it did not create the information at issue, the information would not be available for inspection and copying under proposed § 164.514, the information is accurate and complete, or if it is erroneous or incomplete, it would not adversely affect the individual.

c. *Procedures for requesting amendment or correction.*

i. *Individual requests for amendment or correction.*

In § 164.516, we are proposing that covered plans and providers be required to have procedures that enable individuals to exercise their rights to request amendment or correction, including a means by which individuals can request amendment or correction of protected health information about them. We considered whether this proposed rule should include detailed procedures governing an individual's request. But as with the procedures for requesting inspection and copying, we are only providing a general requirement and permitting each plan or provider to develop procedures in accordance with its needs. Once the procedures are developed, the plan or provider would document them in accordance with section § 164.520 and include a brief explanation in the notice that is provided to individuals pursuant to section § 164.512.

ii. *Time limits.*

We are proposing that the covered plan or provider would take action on a request for amendment or correction as quickly as the circumstances require, but not later than 60 days following the request. The justification for establishing a time limitation for amendment and correction is virtually identical to that provided for the time limitation for inspection and copying. We concluded that the entity should be provided with some additional flexibility in this context. Depending on the nature of the request, an amendment or correction could require significantly more time than a request for inspection and copying. If a covered plan or provider needed more than 30 days to make a decision, we would encourage, but not require, it to send an acknowledgment of receipt to the individual including an explanation of the reasons for the delay and a date when the individual can expect a final decision.

iii. *Acceptance of a request for amendment or correction.*

If a covered plan or provider accepts an individual's request for amendment or correction, it would be required to make the appropriate amendments or corrections. In making the change, the entity would have to either add the amended or corrected information as a permanent part of the record or mark the challenged entries as amended or corrected entries and, if appropriate, indicate the place in the record where the amended or corrected information is located. Covered plans or providers would not be required to expunge any protected health information, but rather mark it as erroneous or incomplete.

We also propose in § 164.506(e) that entities include a contract requirement that when the covered plan or provider notifies the business partner of an amendment or correction, the business partner must make the necessary amendments or corrections to protected health information in its custody.

In § 164.516(c)(3), we are proposing that, upon accepting an amendment or correction, the covered plan or provider would be required to make reasonable efforts to notify relevant persons, organizations, or other entities of the change or addition. An entity would be required to notify such persons that the individual identifies, or that the covered plan or provider identifies as (1) a recipient of the erroneous or incomplete information, and (2) a person who:

- Has relied upon that information to the detriment of the individual; or
- Is a person who may foreseeably rely on such erroneous or incomplete information to the detriment of the individual.

We are concerned about the potential burden that this notification requirement would impose on covered plans and providers. We do not, however, anticipate that a significant

number of requests would be submitted to any entity and therefore the need for such notifications would be rare. In addition, we determined that because health information can travel so quickly and efficiently in the modern health care system, the need for notification outweighed the potential burden. It is important to note that a reasonableness standard should be applied to the notification process—if the recipient has not relied upon the erroneous or incomplete information to the detriment of the individual or if it is not foreseeable that the recipient will do so, then it would not be reasonable for the covered plan or provider to incur the time and expense of notification. If, however, the incorrect information is reasonably likely to be used to the detriment of the individual, the entity should make every effort to notify the recipients of the information of the changes as quickly as possible.

iv. *Denial of a request for amendment or correction.*

In proposed § 164.516(c)(4), we would require a covered plan or provider to provide the individual with a written statement in plain language of the reason for the denial and permit the individual to file a written statement of disagreement with the decision to deny the request.

The statement prepared by covered plan or provider would be required to explain the basis for the denial. The statement would include a description of how the individual may complain to the covered plan or provider as provided in § 164.518(d). The statement would include the name and number of the contact person within the plan or provider who is responsible for receiving complaints. The statement also would include information regarding filing a complaint with the Secretary pursuant to § 164.522(b)(1), including the mailing address and any forms that may be available. Finally, the statement would explain that the individual has the right to file a written statement of disagreement that would be maintained with the disputed information and the procedure for filing such a statement of disagreement.

If the individual chooses to file a statement of disagreement, then the covered plan or provider must retain a copy of the statement with the protected health information in dispute. The covered plan or provider could require that the statement be a reasonable length, provided that the individual has reasonable opportunity to state the nature of the disagreement and offer his or her version of accurate and complete information. In all subsequent disclosures of the information requested to be amended or corrected, the covered plan or provider would be required to include a copy of its statement of the basis for denial and, if provided by the individual, a copy of his or her statement of disagreement. If the statement submitted by the individual is unreasonably long, the covered plan or provider could include a summary in subsequent disclosures which reasonably explains the basis of the individual's position. The covered plan or provider would also be permitted to provide a rebuttal to the individual's statement of disagreement and include the rebuttal statement in any subsequent disclosures.

We considered requiring the covered plan or provider to provide a mechanism for appealing denials of amendment or correction but concluded that it would be too burdensome. We are soliciting comment on whether the approach we have adopted reasonably balances the burdens on covered plans or providers with the rights of individuals.

v. *Receipt of a notification of amendment or correction.*

If a covered plan or provider receives a notification of erroneous or incomplete protected health information as provided in proposed § 164.516(d), we are proposing that the covered plan or provider or be required to make the necessary amendment or correction to protected health information in its custody that would be available for inspection and copying. This affirmative duty to incorporate amendments and corrections would be necessary to ensure that individuals' protected health information is as accurate and complete as possible as it travels through the health care system.

G. Administrative Requirements (§ 164.518)

[*Please label comments about this section with the subject: ''Introduction to administrative requirements''*]

In § 164.518, we are proposing general administrative requirements for covered entities. We would require all covered entities to designate a privacy official, train members of their workforce regarding privacy requirements, safeguard protected health information, and establish sanctions for members of the workforce who do not abide by the entity's privacy policies and procedures. In addition, we are proposing that covered plans and providers be required to establish a means for individuals to complain to the covered plan or provider if they believe that their privacy rights have been violated. In the discussions of each proposed provision, we provide examples of how different kinds of covered entities could satisfy these requirements.

1. Designation of a Privacy Official (§ 164.518(a))

[*Please label comments about this section with the subject: ''Privacy official''*]

In proposed § 164.518(a)(1), we would require covered entities to designate an employee or other person to serve as the official responsible for the development of policies and procedures for the use and disclosure of protected health information. The designation of an official would focus the responsibility for development of privacy policy.

We considered whether covered entities should be required to designate a single official or an entire board. We concluded that a single official would better serve the purposes of focusing the responsibility and providing accountability within the entity. The implementation of this requirement would depend on the size of the entity. For example, a small physician's practice might designate the office manager as the privacy official, and he or she would assume this as one of his or her broader administrative responsibilities. A large entity might appoint a person whose sole responsibility is privacy policy, and he or she might choose to convene a committee representing several different components of the entity to develop and implement privacy policy.

In proposed § 164.518(a)(2), we would require a covered entity to designate a contact person or office to receive complaints and provide information about the matters covered by the entity's notice. The covered entity could, but would not be required to, designate the designated privacy official as the entity's contact person.

In proposed § 164.512, we would require the covered plan or provider's privacy notice to include the name of a contact person for privacy matters. We would not require that the contact person and the designated privacy official be the same person. This would be left to the discretion of each covered entity.

2. Training (§ 164.518(b))

[*Please label comments about this section with the subject: ''Training''*]

In proposed § 164.518(b), we would require covered entities to provide training on the entities policies and procedures with respect to protected health information. Each entity would be required to provide initial training by the date on which this proposed rule becomes applicable. After that date, each covered entity would have to

provide training to new members of the workforce within a reasonable time period after joining the entity. In addition, we are proposing that when a covered entity makes material changes in its privacy policies or procedures, it would be required to retrain those members of the workforce whose duties are directly affected by the change within a reasonable time of making the change.

The entities would be required to train all members of the workforce (e.g., all employees, volunteers, trainees, and other persons under the direct control of a persons working on behalf of the covered entity on an unpaid basis who are not business partners) who are likely to have contact with protected health information.

Upon completion of the training, the person would be required to sign a statement certifying that he or she received the privacy training and will honor all of the entity's privacy policies and procedures. Entities would determine the most effective means of communicating with their workforce. For example, in a small physician practice, the training requirement could be satisfied by providing each new member of the workforce with a copy of the practice's information policies and requiring members of the workforce to acknowledge that they have reviewed the policies. A large health plan could provide for a training program with live instruction, video presentations or interactive software programs. The small physician practice's solution would not protect the large plan's data, and the plan's solution would be neither economically feasible nor necessary for the small physician practice.

At least once every three years after the initial training, covered entities would be required to have each member of the workforce sign a new statement certifying that he or she will honor all of the entity's privacy policies and procedures. The initial certification would be intended to make members of the workforce aware of their duty to adhere to the entity's policies and procedures. By requiring a recertification every three years, they would be reminded of this duty.

We considered several different options for recertification. We considered proposing that members of the workforce be required to recertify every six months, but concluded that such a requirement would be too burdensome. We considered proposing that recertification be required annually consistent with the recommendations of The American Health Information Management Association (Brandt, Mary D., Release and Disclosure: Guidelines Regarding Maintenance and Disclosure of Health Information, 1997). We concluded that annual recertification could also impose a significant burden on covered entities.

We also considered requiring that the covered entity provide ''refresher'' training every three years in addition to the recertification. We concluded that our goals could be achieved by only requiring recertification once every three years, and retraining in the event of material changes in policy. We are soliciting comment on this approach.

3. Safeguards (§ 164.518(c))

[*Please label comments about this section with the subject: ''Safeguards''*]

In proposed § 164.518(c), we would require covered entities to put in place administrative, technical, and physical safeguards to protect against any reasonably anticipated threats or hazards to the privacy of the information, and unauthorized uses or disclosures of the information. We proposed similar requirements for certain electronic information in the Notice of Proposed Rulemaking entitled the Security and Electronic Signature Standards (HCFA–0049–P), which can be found at 63 FR 43241. We are proposing parallel and consistent requirements for safeguarding the privacy of protected health information.

a. *Verification procedures.* As noted in section II.E. above, for many permitted disclosures the covered entity would be responding to a request for disclosure of protected health information. For most categories of permitted disclosures, when the request for disclosure of protected health information is from a person with whom the covered entity does not routinely do business, we would require the covered entity to verify the identity of the requestor. In addition, for certain categories of disclosures, covered entities would also be required to verify the requestor's legal authority to make the request.

Under § 164.514, a covered entity would be required to give individuals access to protected health information about them (under most circumstances). The covered entity would also be required to take reasonable steps to verify the identity of the individual making the request for access. We do not propose to mandate particular identification requirements (*e.g.*, drivers licence, photo ID, etc), but rather would leave this to the discretion of the covered entity.

Covered entities would be required to verify both the identity of persons requesting protected health information and their authority for requesting such information when the request is from a person with whom the covered entity does not routinely do business and the disclosure would be permitted by the following subsections of § 164.510: under § 164.510(b) for public health, under § 164.510(c) for oversight, under § 164.510(e) to coroners and medical examiners, under § 164.510(f) for law enforcement, under § 164.510(g) for governmental health data systems, under § 164.510(m) for special classes, and for disclosures required by other laws under § 164.510(n). Covered entities would be required to verify the identity of the requester by examination of reasonable evidence, such as a written statement of identity on agency letterhead, an identification badge, or similar proof of official status. Similarly, covered entities would be required to verify the legal authority supporting the request by examination of reasonable evidence, such as a written request provided on agency letterhead that describes the legal authority for requesting the release. Unless § 164.510 explicitly requires written evidence of legal process or other authority before a disclosure may be made, a public official's proof of identity and the official's oral statement that the request is authorized by law would be presumed to constitute the required reasonable evidence of legal authority. Where § 164.510 does require written evidence of legal process or authority, only the required written evidence will suffice.

We considered specifying the type of documentation or proof that would be acceptable, but decided that the burden of such specific regulatory requirements on covered entities would be unnecessary. Therefore, we propose only a general requirement for reasonable verification of identity and legal authority.

In § 164.522, we would require disclosure to the Secretary for purposes of enforcing this regulation. When a covered entity is asked by the Secretary to disclose protected health information for compliance purposes, the covered entity should verify the same information that it would verify for any other law enforcement or oversight request for disclosure.

In some circumstances a person or entity acting on behalf of a government agency may make a request for disclosure of protected health information under these subsections. For example, public health agencies may contract with a nonprofit agency to collect and analyze certain data. In such cases the covered entity would be required to verify the requestor's identity and authority through

examination of reasonable documentation that the requestor is acting on behalf of the government agency. Reasonable evidence would include a written request provided on agency letterhead that describes the legal authority for requesting the release and states that the person or entity is acting under the agency's authority, or other documentation, including a contract, a memorandum of understanding, or purchase order that confirms that the requestor is acting on behalf of the government agency.

For disclosures permitted under § 164.510(k) for emergency circumstances and under § 164.510(l) to next-of-kin, legal authority for the request would not be an issue. Therefore covered entities would only be required to verify the identity of the person requesting the disclosure. Where protected health information is requested by next-of-kin, covered entities would be required to make reasonable verbal attempts to establish the identity of the person making the request. Written proof would not be required. Covered entities could rely on prior acquaintance with the next-of-kin; verbal verification of identity would not be required at each encounter. Where protected health information is requested in an emergency, the covered entity would similarly not be required to demand written proof that the person requesting the protected health information is legally authorized. Reasonable reliance on verbal representations would be appropriate in such situations.

When another person is acting as the individual through power of attorney or other legal authority, covered entities would also be required to make reasonable attempts to ascertain that the person making the request has the necessary legal authority or relationship in order to make the disclosure. For example, a health care provider could require a copy of a power of attorney, or could ask questions to determine that an adult acting for a young child has the requisite relationship to the child.

Most disclosures under § 164.510(i) are routine transactions with banking and other financial institutions. As noted above, for routine transactions there would be no verification requirements. However, should such financial institution make a special request for information in addition to the information routinely provided for payment purposes (*e.g.*, pursuant to a fraud or similar investigation), the covered entity would be required to obtain reasonable evidence of the identity of the person requesting the information.

The conditions for disclosures for judicial and administrative proceedings and research are discussed in § 164.510 (d) and § 164.510(j), respectively. Conditions for permitted disclosures under § 164.510(h) for facility directories include no verification requirements.

b. *Whistleblowers.* In Section § 164.518(c)(4), we would address the issue of disclosures by employees or others of protected health information in whistleblower cases. We would clarify that under the proposed rule, a covered entity would not be held in violation because a member of their workforce or a person associated with a business partner of the covered entity discloses protected health information that such person believes is evidence of a civil or criminal violation, and the disclosure is: (1) Made to relevant oversight agencies and law enforcement or (2) made to an attorney to allow the attorney to determine whether a violation of criminal or civil law has occurred or to assess the remedies or actions at law that may be available to the person disclosing the information.

Allegations of civil and criminal wrongdoing come from a variety of sources. Sometimes an individual not otherwise involved in law enforcement uncovers evidence of wrongdoing, and wishes to bring that evidence to the attention of appropriate authorities. Persons with access to protected health information sometimes discover evidence of billing fraud or similar violations; important evidence of unlawful activities may be available to employees of covered entities, such as billing clerks or nurses.

Some whistleblower activities can be accomplished without individually identifiable health information. There are, however, instances in which only identifiable information will suffice to demonstrate that an allegation of wrongdoing merits the investment of legal or investigatory resources. A billing clerk who suspects that a hospital has engaged in fraudulent billing practices may need to use billing records for a set of specific cases to demonstrate the basis of his suspicion to an oversight agency.

The persons who find such evidence are likely to be employees of the suspect entity. Congress and the states have recognized the importance of whistleblowing activities by acting to protect whistleblowers from retaliation. Federal statutes that include protections for whistleblowers who contact appropriate authorities include the Clear Air Act, the Federal Water Pollution Control Act, the Toxic Substances Control Act, and the Safe Drinking Water Act. Congress also passed the Whistleblower Protection Act, to protect federal employees who complain about improper personnel practices at federal agencies. At least eleven states have passed whistleblower protection laws that protect both private and public employees who provide evidence of wrongdoing to the appropriate authorities, and many more states have laws that provide such protections only for public employees.

The qui tam provisions of the Federal False Claims Act go further, and provide a mechanism for the individual to prosecute a case against a person who has allegedly defrauded the government. Like traditional whistleblower actions, qui tam actions were created by the Congress to further the public interest in effective government. Qui tam suits are an important way that individuals can protect the public interest, by investing their own time and resources to help reduce fraud. And, also like whistleblower actions, the individual may need protected health information to convince an attorney that a viable qui tam case exists.

We would note that this section would not apply to information requested by oversight agencies, law enforcement officials, or attorneys, even prior to initiation of an investigation or law suit. It would apply only to a disclosure initiated by a member of an entity's workforce or a person associated with one of its business partners.

We are concerned that a person, in the guise of ''whistleblowing,'' might, maliciously or otherwise, disclose protected health information without any actual basis to believe that there has been a violation of the law. We are concerned, however, with adding qualifying language that may restrict such disclosures and, therefore, impede the pursuit of law violators. We seek comments regarding whether this provision should include any limitations (*e.g.*, a requirement that only the minimum amount of information necessary for these purposes can be disclosed).

4. Internal Complaint Process (§ 164.518(d))

In proposed § 164.518(d), we would require covered plans and providers to have some mechanism for receiving complaints from individuals regarding the covered plan's or provider's compliance with the requirements of this proposed rule. The covered plan or provider would be required to accept complaints about any aspect of their practices regarding protected health information. For example, individuals would be able to file a complaint when

they believe that protected health information relating to them has been used or disclosed improperly, that an employee of the plan or provider has improperly handled the information, that they have wrongfully been denied access to or opportunity to amend the information, or that the entity's notice does not accurately reflect its information practices. We would not require that the entity develop a formal appeals mechanism, nor that ''due process'' or any similar standard be applied. We would not require that covered entities respond in any particular manner or time frame. We are proposing two basic requirements for the complaint process. First, the covered plan or provider would be required to identify a contact person or office in the notice of information practices for receiving complaints. This person or office could either be responsible for handling the complaints or could put the individual in touch with the appropriate person within the entity to handle the particular complaint. See proposed § 164.512. This person could, but would not have to be, the entity's privacy official. See § 164.518(a)(2). Second, the covered plan or provider would be required to maintain a record of the complaints that are filed and a brief explanation of the resolution, if any.

Covered plans and providers could implement this requirement through a variety of mechanisms based on their size and capabilities. For example, a small practice could assign a clerk to log in written and/or verbal complaints as they are received, and assign one physician to review all complaints monthly, address the individual situations and make changes to policies or procedures as appropriate. Results of the physician's review of individual complaints then could be logged by the clerk. A larger provider or health plan could choose to implement a formal appeals process with standardized time frames for response.

We considered requiring covered plans and providers to provide a formal internal appeal mechanism, but rejected that option as too costly and burdensome for some entities. We also considered eliminating this requirement entirely, but rejected that option because a complaint process would give covered plans or providers a way to learn about potential problems with privacy policies or practices, or training issues. We also hope that providing an avenue for covered plans or providers to address complaints would lead to increased consumer satisfaction. We believe this approach strikes a reasonable balance between allowing covered plans or providers flexibility and accomplishing the goal of promoting attention to improvement in privacy practices. If an individual and a covered plan or provider are able to resolve the individual's complaint, there may be no need for the individual to file a complaint with the Secretary under proposed § 164.522(b). However, an individual has the right to file a complaint with the Secretary at any time. An individual may file a complaint with the Secretary before, during, after, or concurrent with filing a compliant with the covered plan or provider or without filing a complaint with the covered plan or provider.

We are considering whether modifications of these complaint procedures for intelligence community agencies may be necessary to address the handling of classified information and solicit comment on the issue.

5. Sanctions (§ 164.518(e))

[*Please label comments about this section with the subject: ''Sanctions''*]

In proposed § 164.518(e), we would require all covered entities to develop and apply when appropriate sanctions for failure to comply with policies or procedures of the covered entity or with the requirements of this proposed rule. All members of the workforce who have regular contact with protected health information should be subject to sanctions, as would the entity's business partners. Covered entities would be required to develop and impose sanctions appropriate to the nature of the issue. The type of sanction applied would vary depending on factors such as the severity of the violation, whether the violation was intentional or unintentional, and whether the violation indicates a pattern or practice of improper use or disclosure of protected health information. Sanctions could range from a warning to termination.

We considered specifying particular sanctions for particular kinds of violations of privacy policy, but rejected this approach for several reasons. First, the appropriate sanction will vary with the entity's particular policies. Because we cannot anticipate every kind of privacy policy in advance, we cannot predict the response that would be appropriate when that policy is violated. In addition, it is important to allow covered entities to develop the sanctions policies appropriate to their business and operations.

6. Duty To Mitigate (§ 164.518(f))

[*Please label comments about this section with the subject: ''Duty to mitigate''*]

We propose that covered entities be required to have procedures for mitigating, to the extent practicable, any deleterious effect of a use or disclosure of protected health information by their members of their workforce or business partners.

With respect to business partners, we also propose that covered entities have an affirmative duty to take reasonable steps in response to breaches of contract terms. For example, a covered entity that becomes aware that a business partner has improperly disclosed protected health information could require that business partner to take steps to retrieve the disclosed information. The covered entity also could require that business partner to adopt new practices to better assure that protected health information is appropriately handled. Covered entities generally would not be required to monitor the activities of their business partners, but would be required to take steps to address problems of which they become aware, and, where the breach is serious or repeated, would also be required to monitor the business partner's performance to ensure that the wrongful behavior has been remedied. For example, the covered entity could require the business partner to submit reports or subject itself to audits to demonstrate compliance with the contract terms required by this rule. Termination of the arrangement would be required only if it becomes clear that a business partner cannot be relied upon to maintain the privacy of protected health information provided to it.

We expect that sanctions would be more formally described and consistently carried out in larger, more sophisticated entities. Smaller, less sophisticated entities would be given more latitude and flexibility. For such smaller entities and less sophisticated entities, we would not expect a prescribed sanctions policy, but would expect that actions be taken if repeated instances of violations occur.

H. Development and Documentation of Policies and Procedures (§ 164.520)

[*Please label comments about this section with the subject: ''Policies and procedures''*]

In proposed § 164.520, we would require covered entities to develop and document their policies and procedures for implementing the requirements of this rule. This requirement is intended as a tool to facilitate covered entities' efforts to develop appropriate policies to implement this rule, to ensure that the members of its workforce and business partners understand and carry out expected privacy practices, and to assist

covered entities in developing a notice of information practices.

The scale of the policies developed should be consistent with the size of the covered entity. For example, a smaller employer could develop policies restricting access to health plan information to one designated employee, empowering that employee to deny release of the information to corporate executives and managers unless required for health plan administration. Larger employers could have policies that include using contractors for any function that requires access to protected health information or requiring all reports they receive for plan administration to be de-identified unless individual authorization is obtained.

Clearly, implementation of these requirements would differ significantly based on the size, capabilities and activities of each covered entity. A solo practitioner's documentation of her policies and procedures could provide relatively straightforward statements, such as:

> This practice does not use or disclose any protected health information that is not authorized or permitted under the federal privacy regulation and therefore does not request any authorized disclosures from patients. Staff R.N. reviews all individually authorized requests for disclosures to ensure they contain all required elements and reviews the copied information to ensure only authorized information is released in response. Information requests that would require extensive redaction will be denied.

Larger entities with many functions and business relationships and who are subject to multi-state reporting and record-keeping requirements would need to develop and document more extensive policies. A health plan would need to describe all activities that would be considered health care operations and identify the use and disclosure requirements of each activity. A health plan may determine that underwriting department employees must provide a written request, approved by a team leader, to access any identifiable claims information; that such requests must be retained and reviewed every quarter for appropriateness; and the underwriting department must destroy such information after use for an approved activity. We urge professional associations to develop model policies, procedures and documentation for their members of all sizes.

We are proposing general guidelines for covered entities to develop and document their own policies and procedures. We considered a more uniform, prescriptive approach but concluded that a single approach would be neither effective in safeguarding protected health information nor appropriate given the vast differences among covered entities in size, business practices and level of sophistication. It is important that each covered entity's internal policies and procedures for implementing the requirements of this regulation are tailored to the nature and number of its business arrangements, the size of its patient population, its physical plant and computer system, the size and characteristics of its workforce, whether it has one or many locations, and similar factors. The internal policies and procedures appropriate for a clearinghouse would not be appropriate for a physician practice; the internal policies and procedures appropriate for a large, multi-state health plan would not be appropriate for a smaller, local health plan.

After evaluating the requirements of federal, State, or other applicable laws, covered entities should develop policies and procedures that are appropriate for their size, type, structure, and business arrangements. Once a covered plan or provider has developed and documented all of the policies and procedures as required in this section, it would have compiled all of the information needed to develop the notice of information practices required in § 164.512. The notice is intended to include a clear and concise summary of many of the policies and procedures discussed in this section. Further, if an individual has any questions about the entity's privacy policies that are not addressed by the notice, a representative of the entity can easily refer to the documented policies and procedures for additional information.

Before making a material change in a policy or procedure, the covered entity would, in most instances, be required to make the appropriate changes to the documentation required by this section before implementing the change. In addition, covered plans and providers would be required to revise the notice of information practices in advance. Where the covered entity determines that a compelling reason exists to take an action that is inconsistent with its documentation or notice before making the necessary changes, it may take such action if it documents the reasons supporting the action and makes the necessary changes within 30 days of taking such action.

In an attempt to ensure that large entities develop coordinated and comprehensive policies and procedures as required by this section, we considered proposing that entities with annual receipts greater than $5 million [5] be required to have a privacy board review and approve the documentation of policies and procedures. As originally conceived, the privacy board would only serve to review research protocols as described in § 164.510(j). We believe that such a board could also serve as ''privacy experts'' for the covered entity and could review the entity's documented policies and procedures. In this capacity, the overriding objective of the board would be to foster development of up-to-date, individualized policies that enable the organization to protect health information without unnecessarily interfering with the treatment and payment functions or business needs. This type of review is particularly important for large entities who would have to coordinate policies and procedures among a large staff, but smaller organizations would be encouraged, but not required, to take a similar approach (*i.e.*, have a widely representative group participate in the development and/or review of the organization's internal privacy policies and the documentation thereof). We solicit comment on this proposal.

We also considered requiring the covered entity to make its documentation available to persons outside the entity upon request. We rejected this approach because covered entities should not be required to share their operating procedures with the public, or with their competitors.

We recognize that the documentation requirement in this proposed rule would impose some paperwork burden on covered plans and providers. However, we believe that it is necessary to ensure that covered plans and providers establish privacy policies procedures in advance of any requests for disclosure, authorization, or subject access. It is also necessary to ensure that covered entities and members of their workforce have a clear understanding of the permissible uses and disclosures of protected health information and their duty to protect the privacy of such information under specific circumstances.

1. Uses and Disclosures of Protected Health Information

We propose that covered entities be required to develop and document policies and procedures for how protected health information would be used and disclosed by the entity and its

[5] The Small Business Administration defines small businesses in the health care field as those generating less than $5 million annually. Small businesses represent approximately 85% of health care entities.

business partners. The documentation would include policies to ensure the entity is in compliance with the requirements for use and disclosure pursuant to an individual's authorization. This would also include documentation of how the covered entity would comply with individual's revocation of an authorization, as provided in proposed § 164.508(e). For example, upon receipt of a revocation, the entity may need to take steps to notify each business partner that is responsible for using or disclosing protected health information on behalf of the covered entity based on the individual's authorization. Because the entity is ultimately responsible for the protected health information, it may want written confirmation from the business partner that it received notice of the revocation.

The covered entity would be required to include policies and procedures necessary to address disclosures required by applicable law. For example, the covered entity may want to include a list of the relevant reporting requirements such as those for abuse, neglect and communicable disease and its policies and procedures for complying with each requirement.

It would also include policies and procedures for uses and disclosures without the individual's authorization, including uses and disclosures for treatment, payment and health care operations under § 164.506(a)(1)(i). The documentation should address all of the legally permissible uses and disclosures that the covered entity is reasonably likely to make and should clearly specify the policy of the entity with respect to each. For example, all covered plans and providers face a reasonable likelihood of a request for disclosure from a health oversight agency, so every covered plan and provider should develop and document policies and procedures for responding to such requests. However, a provider that only treats adults would not need to specify a policy with respect to state laws that authorize disclosure relating to measles in young children. In this latter case, the provider knows that he or she is not reasonably likely to make such a disclosure and therefore, could wait until he or she is presented with such a request before developing the necessary policies and procedures.

The documentation would include the entity's policies and procedure for complying with the requirements of proposed § 164.506(e) for disclosing protected health information to business partners, including policies and procedures for monitoring the business partners, mitigating harm, and imposing sanctions where appropriate.

It would address the policies and procedures for implementation of the minimum necessary requirement as provided in proposed § 164.506(b). It would also include policies and procedures addressing the creation of de-identified information pursuant to § 164.506(d). For example, a plan could have a policy that requires employees to remove identifiers from protected health information for all internal cost, quality, or performance evaluations. The plan would document this policy and the procedures for removing the identifiers.

2. Individual Requests for Restricting Uses and Disclosures

We propose to require covered health care providers to document how they would implement an individual's request to restrict uses and disclosures. Under proposed § 164.506(c)(1)(iii), a covered entity need not agree to such restrictions. This section of the documentation would describe who (if anyone) in the covered entity is permitted to agree to such restrictions, and if such restrictions were accepted, how they would be implemented. For example, a provider may require that once an individual has requested a limitation on a use or disclosure, the affected information is stamped, marked or kept in a separate file. The provider could also have a policy of never agreeing to requests for such restrictions.

3. Notice of Information Practices

We propose to require covered plans and providers to document their policies and procedures for complying with the requirement in § 164.512 to develop, make available or disseminate, and amend their notices of information practices. This documentation would address, at a minimum, who is responsible for developing and updating the notice, who would serve as the ''contact'' person on the notice, how the notice would be disseminated to individuals, and how to respond to inquiries regarding information practices.

4. Inspection and Copying

We propose to require covered plans and providers to document policies and procedures to address how they would receive and comply with individual requests for inspection, and copying, in compliance with § 164.514 of this proposed rule. Policies and procedures should address, at a minimum, a listing of the designated record sets to which access will be provided, any fees to be charged, and the reasons (if any) that the entity would deny a request for inspection and copying.

5. Amendment or Correction

We propose to require covered plans and providers to develop and document policies and procedures to address how they would receive and comply with individual requests for amendment or correction of their records, in compliance with § 164.516 of this proposed rule. Policies and procedures should include the process for determining whether a request for amendment or correction should be granted, the process to follow if a request is denied, and how the entity would notify other entities, including business partners, if the request is accepted. For example, if a covered entity accepts an individual's request for an amendment or correction, the entity could document specific procedures regarding how to make the appropriate additions or notations to the original information. Without such documentation, members of the workforce could accidentally expunge or remove the incorrect information.

6. Accounting for Disclosures

We propose to require covered entities to develop and document their policies and procedures for complying with the requirement in § 164.515 to provide on request an accounting for disclosures for purposes other than treatment, payment or health care operations. In order to respond to requests for accounting within a reasonable period of time, the entity would need to have a system for accounting in place well in advance of any potential requests. The entity would need to evaluate its record keeping system and determine how best to build in the capacity to respond to such a request. For example, if the entity chooses to keep a regular log of disclosures, it would have to begin keeping such logs routinely. If instead the entity chooses to rely on a record keeping system to reconstruct an accounting, it should develop appropriate procedures for members of the workforce to follow when faced with an individual's request.

7. Administrative Requirements

We propose to require covered entities to document their policies and procedures for complying with the applicable administrative requirements in proposed § 164.518. This would include designation of the privacy official required by § 164.518(a) including a description of his or her responsibilities; a description of how the entity would comply with the

training and certification requirements for members of its workforce under § 164.518(b); a description of the covered entity's safeguards required by § 164.518(c); a description of how the covered plan or provider would meet the requirements of § 164.518(d) to receive individual's complaints; a description of how the covered entity would meet the requirements for sanctioning members of its workforce under § 164.518(e); and a description of how the covered entity would take steps to mitigate any deleterious effect of a use or disclosure of protected health information as required by § 164.518(f).

The documentation would also address how access to protected health information is regulated by the entity, including safeguards, including the procedures that would be required by proposed § 164.518. For covered entities that are part of a larger organization that is not a covered entity (*e.g.*, an on-site clinic at a university or the group health plan component of an employer), we would require such entities to develop and document policies and procedures that ensure that protected health information does not flow outside the health care component of the organization in violation of this proposed rule. For example, a school-based health clinic should have policies and procedures to prevent treatment information from crossing over into the school's record system.

Many disclosures would require verification of the identity of the person making the request, and sometimes also verification of the legal authority behind the request. The documentation required by this section would include a description of the entity's verification policies (*e.g.*, what proof would be acceptable), and who would be responsible for ensuring that the necessary verification has occurred before the information is disclosed.

8. Record Keeping Requirements

We propose record keeping requirements related to several provisions. In addition to the documentation of policies and procedures described above, we would require covered entities, as applicable, to: document restrictions on uses and disclosures agreed to pursuant to § 164.506(c); maintain copies of authorization forms and signed authorizations (§ 164.508) and contracts used with business partners (§ 164.506(e)); maintain notices of information practices developed under § 164.512; maintain written statements of denials of requests for inspection and copying pursuant to § 164.514; maintain any response made to a request from an individual for amendment or correction of information, either in the form of the correction or amendment or the statement of the reason for denial and, if supplied, the individual's statement of disagreement, for as long as the protected health information is maintained (§ 164.516); maintain signed certifications by members of the workforce required by § 164.518(b); and, maintain a record of any complaints received (§ 164.518(d)). Unless otherwise addressed in this proposal, covered entities would be required to retain these documents for six years, which is the statute of limitations period for the civil penalties. We note that additional records or compliance reports may be required by the Secretary for enforcement of this rule. (§ 164.522(d)(1)).

I. Relationship to Other Laws

1. Relationship to State Laws

[*Please label comments about this section with the subject: ''Relationship to State laws''*]

Congress addressed the issue of preemption of State law explicitly in the statute, in section 1178 of the Act. Consonant with the underlying statutory purpose to simplify the financial and administrative transactions associated with the provision of health care, the new section 1178(a)(1) sets out a ''general rule'' that State law provisions that are contrary to the provisions or requirements of part C of title XI or the standards or implementation specifications adopted or established thereunder are preempted by the federal requirements. The statute provides three exceptions to this general rule: (1) For State laws which the Secretary determines are necessary to prevent fraud and abuse, ensure appropriate State regulation of insurance and health plans, for State reporting on health care delivery, and other purposes; (2) for State laws which address controlled substances; and (3) for State laws relating to the privacy of individually identifiable health information which, as provided for by the related provision of section 264(c)(2), are contrary to and more stringent than the federal requirements. Section 1178 also carves out, in sections 1178(b) and 1178(c), certain areas of State authority which are not limited or invalidated by the provisions of part C of title XI; these areas relate to public health and State regulation of health plans.

Section 264 of HIPAA contains a related preemption provision. Section 264(c)(2) is, as discussed above, an exception to the ''general rule'' that the federal standards and requirements preempt contrary State law. Section 264(c)(2) provides, instead, that contrary State laws that relate to the privacy of individually identifiable health information will not be preempted by the federal requirements, if they are ''more stringent'' than those requirements. This policy, under which the federal privacy protections act as a floor, but not a ceiling on, privacy protections, is consistent with the Secretary's Recommendations.

Aside from the cross-reference to section 264(c)(2) in section 1178(a)(2)(B), several provisions of section 1178 relate to the proposed privacy standards. These include the general preemption rule of section 1178(a)(1), the carve-out for public health and related reporting under section 1178(b), and the carve-out for reporting and access to records for the regulation of health plans by States under section 1178(c). Other terms that occur in section 264(c)(2) also appear in section 1178: The underlying test for preemption—whether a State law is ''contrary'' to the federal standards, requirements or implementation specifications—appears throughout section 1178(a), while the issue of what is a ''State law'' for preemption purposes applies throughout section 1178. In light of these factors, it seems logical to develop a regulatory framework that addresses the various issues raised by section 1178, not just those parts of it implicated by section 264(c)(2). Accordingly, the rules proposed below propose regulatory provisions covering these issues as part of the general provisions in proposed part 160, with sections made specifically applicable to the proposed privacy standard where appropriate.

a. *The ''general rule'' of preemption of State law.* Section 1178(a)(1) provides the following ''general rule'' for the preemption of State law:

> Except as provided in paragraph (2), a provision or requirement under this part (part C of title XI), or a standard or implementation specification adopted or established under sections 1172 through 1174, shall supersede any contrary provision of State law, including a provision of State law that requires medical or health plan records (including billing information) to be maintained or transmitted in written rather than electronic form.

As we read this provision, the provisions and requirements of part C of title XI, along with the standards and implementation specifications adopted thereunder, do not supplant State law, except to the extent such State law is ''contrary'' to the federal statutory or regulatory scheme. Moreover, the provisions and requirements of part C of

title XI, along with the standards and implementation specifications adopted thereunder, do not preempt contrary State law where one of the exceptions provided for by section 1178(a)(2) applies or the law in question lies within the scope of the carve-outs made by sections 1178(b) and (c). Thus, States may continue to regulate in the area covered by part C of title XI and the regulations and implementation specifications adopted or established thereunder, except to the extent States adopt laws that are contrary to the federal statutory and regulatory scheme, and even those contrary State laws may continue to be enforceable, if they come within the statutory exceptions or carve-outs.

We note, however, that many of the Administrative Simplifications regulations will have preemptive effect. The structure of many of the regulations, particularly those addressing the various administrative transactions, is to prescribe the use of a particular form or format for the transaction in question. Where the prescribed form or format is used, covered entities are required to accept the transaction. A State may well not be able to require additional requirements for such transactions consistent with the federally prescribed form or format.

b. *Exceptions for State laws the Secretary determines necessary for certain purposes.* Section 1178(a)(2) lists several exceptions to the general preemption rule of section 1178(a)(1). The first set of exceptions are those listed at sections 1178(a)(2)(A)(i) and 1178(a)(2)(A)(ii). These exceptions are for provisions of State law which the Secretary determines are necessary: (1) To prevent fraud and abuse; (2) to ensure appropriate State regulation of insurance and health plans; (3) for State reporting on health care delivery or costs; (4) for other purposes; or (5) which address controlled substances.

Proposed § 160.203(a) below provides for determinations under these statutory provisions. The criteria at proposed § 160.203(a) follow the statute. As is more fully discussed below, however, two of the terms used in this section of the proposed rules are defined terms: ''contrary'' and ''State law.'' The process for making such determinations is discussed below.

c. *Exceptions for State laws relating to the privacy of individually identifiable health information.* The third exception to the ''general rule'' that the federal requirements, standards, and implementation specifications preempt contrary State law concerns State laws relating to the privacy of individually identifiable health information. Section 1178(a)(2)(B) provides that a State law is excepted from this general rule, which, ''subject to section 264(c)(2) of the Health Insurance Portability and Accountability Act of 1996, relates to the privacy of individually identifiable health information.'' Section 264(c)(2) of HIPAA provides that the HIPAA privacy regulation, which is proposed in the accompanying proposed subpart B of proposed part 160, will not supersede ''a contrary provision of State law, if the provision of State law imposes requirements, standards, or implementation specifications that are more stringent than the requirements, standards, or implementation specifications imposed'' under the regulation at proposed subpart E of proposed part 164.

It is recognized that States generally have laws that relate to the privacy of individually identifiable health information. These laws continue to be enforceable, unless they are contrary to part C of title XI or the standards, requirements, or implementation specifications adopted or established pursuant to the proposed subpart x. Under section 264(c)(2), not all contrary provisions of State privacy laws are preempted; rather, the law provides that contrary provisions that are also ''more stringent'' than the federal regulatory requirements or implementation specifications will continue to be enforceable.

d. *Definitions.* There are a number of ambiguities in sections 1178(a)(2)(B) and 264(c)(2) of HIPAA. Clarifying the statute through the regulations will generally provide substantially more guidance to the regulated entities and the public as to which requirements, standards, and implementation specifications apply. For these reasons, the rules propose below to interpret several ambiguous statutory terms by regulation.

There are five definitional questions that arise in considering whether or not a State law is preempted under section 264(c)(2): (1) What is a ''provision'' of State law? (2) What is a ''State law''? (3) What kind of State law, under section 1178(a)(2)(B), ''relates to the privacy of individually identifiable health information?'' (4) When is a provision of State law at issue ''contrary'' to the analogous provision of the federal regulations? (5) When is a provision of State law ''more stringent than'' the analogous provision of the federal regulations? We discuss these questions and our proposed regulatory answers below.

i. *What is a ''provision'' of State law?*

The initial question that arises in the preemption analysis is, what does one compare? The statute directs this analysis by requiring the comparison of a ''provision of State law [that] imposes requirements, standards, or implementations specifications'' with ''the requirements, standards, or implementation specifications imposed under'' the federal regulation. The statute thus appears to contemplate that what will be compared are the State and federal requirements that are analogous, i.e., that address the same subject matter. Accordingly, a dictionary-type definition of the term ''provision'' does not seem appropriate, as the contours of a given ''provision'' will be largely defined by the contours of the specific ''requirement[], standard[], or implementation specification'' at issue.

What does one do when there is a State provision and no comparable or analogous federal provision, or the converse is the case? The short answer would seem to be that, since there is nothing to compare, there cannot be an issue of a ''contrary'' requirement, and so the preemption issue is not presented. Rather, the stand-alone requirement—be it State or federal—is effective. There may, however, be situations in which there is a federal requirement with no directly analogous State requirement, but where several State requirements in combination would seem to be contrary in effect to the federal requirement. This situation usually will be addressed through the tests for ''contrary,'' discussed below.

At this juncture, it is difficult to frame options for dealing with this issue, because it is not clear that more of a structure is needed than the statute already provides. Rather, we solicit comment on how the term ''provision'' might be best defined for the purpose of the preemption analysis under the statute, along with examples of possible problems in making the comparison between a provision of State law and the federal regulations.

ii. *What is a ''State law''?*

It is unclear what the term ''provision of State law'' in sections 1178 and 264(c) means. The question is whether the provision in question must, in order to be considered to have preemptive effect, be legislatively enacted or whether administratively adopted or judicially decided State requirements must also be considered. Congress explicitly addressed the same issue in a different part of HIPAA, section 102. Section 102 enacted section 2723 of the Public Health Service Act, which is a preemption provision that applies to issuers of health insurance to ERISA plans. Section 2723 contains in subsection (d)(1) the following definition of ''State law'': ''The term

''State law'' includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States applicable only to the District of Columbia shall be treated as a State law rather than a law of the United States.

By contrast, Congress provided no definition of the term ''State law'' in section 264. This omission suggests two policy options. One is to adopt the above definition, as a reasonable definition of the term and as an indication of what Congress probably intended in the preemption context (the policy embodied in section 2723 is analogous to that embodied in section 264(c)(2), in the sense that the State laws that are not preempted are ones that provide protections to individuals that go above and beyond the federal requirements). The other option is to argue by negative implication that, since Congress could have but did not enact the above definition in connection with sections 264 and 1178, it intended that a different definition be used, and that the most reasonable alternative is to limit the State laws to be considered to those that have been legislatively enacted.

The Department does not consider the latter option to be a realistic one. It is legally questionable and is also likely to be extremely confusing and unworkable as a practical matter, as it will be difficult to divorce State ''laws'' from implementing administrative regulations or decisions or from judicial decisions. Also, much State ''privacy law''—e.g., the law concerning the physician/patient privilege—is not found in statutes, but is rather in State common law. Finally, since health care providers and others are bound by State regulations and decisions, they would most likely find a policy that drew a line based on where a legal requirement originated very confusing and unhelpful. As a result, we conclude that the language in section 102 represents a legally supportable approach that is, for practical reasons, a realistic option, and it is accordingly proposed in proposed § 160.202 below.

iii. *What is a law that ''relates to the privacy of individually identifiable health information''?*

The meaning of the term ''relate to'' has been extensively adjudicated in a somewhat similar context, the issue of the preemption of State laws by ERISA. Section 514(a) of ERISA (29 U.S.C. 1144(a)) provides that ERISA ''shall supersede any and all State laws insofar as they may now or hereafter *relate to* any employee benefit plan.'' (Emphasis added.) The U.S. Supreme Court alone has decided 17 ERISA preemption cases, and there are numerous lower court cases. The term also has been interpreted in other contexts. Thus, there would seem to be several options for defining the term ''relates to'': (1) By using the criteria developed by the Supreme Court as they evolve, (2) by using the criteria developed by the Supreme Court, but on a static basis, and (3) based on the legislative history, by setting federal criteria.

The first option would be based on the definition adopted in an early ERISA case, *Shaw* v. *Delta Airlines, Inc.*, 463 U.S. 85 (1983), as it continues to evolve. In *Shaw*, a unanimous Supreme Court adopted a very broad reading of the term, holding that a law ''relates to'' an employee benefit plan ''if it has a connection with or reference to'' such a plan. Later cases have developed a more particularized and complex definition of this general definition. The Supreme Court has also applied the *Shaw* definition outside of the ERISA context. In *Morales* v. *Trans World Airlines*, 504 U.S. 374 (1992), the Court defined the term ''relating to'' in the Airline Deregulation Act by using the definition of the term ''relates to'' developed under the ERISA cases above. While this option would appear to be a supportable reading of the statutory term, tying the agency interpretation to an evolving court interpretation will make it more difficult to make judgments, and particular judgments may change as the underlying court interpretations change.

The second option we considered would ''freeze'' the definition of ''relates to'' as the Court has currently defined it. This option also is a supportable reading of the statutory term, but is less of a moving target than the prior option. The complexity of the underlying court definition presents problems.

The option selected and reflected in the rules proposed below grows out of the movement in recent years of the Supreme Court away from the literal, textual approach of *Shaw* and related cases to an analysis that looks more at the purposes and effects of the preemption statute in question. In *New York State Conference of Blue Cross* v. *Travelers Insurance Co.*, 514 U.S. 645 (1995), the Court held that the proper inquiry in determining whether the State law in question related to an employee benefit plan was to look to the objectives of the (ERISA) statute as a guide to the scope of the State law that Congress understood would survive. The Court drew a similar line in *Morales*, concluding that State actions that affected airline rates, routes, or services in ''too tenuous, remote, or peripheral a manner'' would not be preempted. 504 U.S. at 384. The Court drew a conceptually consistent line with respect to the question of the *effect* of a State law in *English* v. *General Electric Co.*, 496 U.S. 72, 84 (1990); see also, *Gade* v. *National Solid Wastes Management Ass'n.*, 505 U.S. 88 (1992). The Court held that deciding which State laws were preempted by the OSH Act required also looking at the effect of the State law in question, and that those which regulated occupational safety and health in a ''clear, direct, and substantial way'' would be preempted. These cases suggest an approach that looks to the legislative history of HIPAA and seeks to determine what kinds of State laws Congress meant, in this area, to leave intact and also seeks to apply more of a ''rule of reason'' in deciding which State laws ''relate to'' privacy and which do not.

The legislative history of HIPAA offers some insight into the meaning of the term ''relates to.'' The House Report (House Rep. No. 496, 104th Cong., 2d Sess., at 103) states that—

> The intent of this section is to ensure that State privacy laws that are more stringent than the requirements and standards contained in the bill are not superseded.

Based on this legislative history, one could argue that the ''State laws'' covered by the ''relates to'' clause are simply those that are specifically or explicitly designed to regulate the privacy of personal health information, and not ones that might have the incidental effect of doing so. Thus, the option selected below appears to be consistent with the Court's approach in *Travelers*, and, together with the ''effect'' test, seems to be closer to how the Court is analyzing preemption issues. It makes sense on a common sense basis as well, and appears, from the little legislative history available, to be what Congress intended in this context.

iv. *When is a provision of State law ''contrary'' to the analogous federal requirement?*

The statute uses the same language in both section 1178(a)(1) and section 264(c)(2) to delineate the general precondition for preemption: the provision of State law must be ''contrary'' to the relevant federal requirement, standard, or implementation specification; the term ''contrary,'' however, is not defined. It should be noted that this issue (the meaning of the term ''contrary'') does not arise solely in the context of the proposed privacy standard. The term ''contrary'' appears throughout section 1178(a) and is a precondition for any preemption analysis done under that section.

The definition set out at proposed § 160.202 embodies the tests that the courts have developed to analyze what is known as ''conflict preemption.'' In this analysis, the courts will consider a provision of State law to be in conflict with a provision of federal law where it would be impossible for a private party to comply with both State and federal requirements or where the provision of State law ''stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'' This latter test has been further defined as, where the State law in question ''interferes with the methods by which the federal statute was designed to reach (its) goal.'' *International Paper Co.* v. *Ouellette,* 479 U.S. 481, 494 (1987). In *Gade,* the Supreme Court applied this latter test to preempt an Illinois law and regulations that imposed additional, non-conflicting conditions on employers, holding that the additional conditions conflicted with the underlying congressional purpose to have one set of requirements apply. This test, then, is particularly relevant with respect to the other HIPAA regulations, where Congress clearly intended uniform standards to apply nationwide.

The Department is of the view that this definition should be workable and is probably what Congress intended in using the term—as a shorthand reference to the case law. We considered a broader definition (''inconsistent with''), but rejected it on the grounds that it would have less legal support and would be no easier to apply than the statutory term ''contrary'' itself.

v. *What is the meaning of ''more stringent''?*

The issue of when a provision of State law is ''more stringent'' than the comparable ''requirements, standards, or implementation specifications'' of the HIPAA privacy regulation is not an easy one. In general, it seems reasonable to assume that ''more stringent'' means ''providing greater privacy protection'' but, such an interpretation leads to somewhat different applications, depending on the context. For example, a State law that provided for fewer and more limited disclosures than the HIPAA privacy regulation would be ''more stringent.'' At the same time, a State law that provides for more and/or greater penalties for wrongful disclosures than does the HIPAA privacy regulation would also be ''more stringent.'' Thus, in the former case, ''more stringent'' means less or fewer, while in the latter case, ''more stringent'' means more or greater. In addition, some situations are more difficult to characterize. For example, if the HIPAA privacy regulation requires disclosure to the individual on request and a State law prohibits disclosure in the circumstance in question, which law is ''more stringent'' or ''provides more privacy protection'?

A continuum of regulatory options is available. At one end of the continuum is the minimalist approach of not interpreting the term ''more stringent'' further or spelling out only a general interpretation, such as the ''provides more privacy protection'' standard, and leaving the specific applications to later case-by-case determinations. At the other end of the continuum is the approach of spelling out in the regulation a number of different applications, to create a very specific analytic framework for future determinations. We propose below the latter approach for several reasons: specific criteria will simplify the determination process for agency officials, as some determinations will be already covered by the regulation, while others will be obvious; specific criteria will also provide guidance for determinations where issue of ''stringency'' is not obvious; courts will be more likely to give deference to agency determinations, leading to greater uniformity and consistency of expectation; and the public, regulated entities, and States will have more notice as to what the determinations are likely to be.

The specific criteria proposed at proposed § 160.202 are extrapolated from the principles of the fair information practices that underlie and inform these proposed rules and the Secretary's Recommendations. For example, limiting disclosure of personal health information obviously protects privacy; thus, under the criteria proposed below, the law providing for less disclosure is considered to be ''more stringent.'' Similarly, as the access of an individual to his or her protected health information is considered to be central to enabling the individual to protect such information, the criteria proposed below treat a law granting greater rights of access as ''more stringent.'' We recognize that many State laws require patients to authorize or consent to disclosures of their health information for treatment and/or payment purposes. We consider individual authorization generally to be more protective of privacy interests than the lack of such authorization, so such State requirements would generally stand, under the definition proposed below.

However, we would interpret a State law relating to individual authorization to be preempted if the law requires, or would permit a provider or health plan to require, as a condition of treatment or payment for health care, an individual to authorize uses or disclosures for purposes other than treatment, payment and health care operations, and if such authorization would override restrictions or limitations in this regulation relating to the uses and disclosures for purposes other than treatment, payment and health care operations. For example, if a State law permitted or required a provider to obtain an individual authorization for disclosure as a condition of treatment, and further permitted the provider to include in the authorization disclosures for research or for commercial purposes, the State law would be preempted with respect to the compelled authorization for research or commercial purposes. At the same time, if a State law required a provider to obtain an individual authorization for disclosure as a condition of treatment, and further required the provider to include an authorization for the provider to disclosure data to a State data reporting agency, such a law would not be preempted, because State laws that require such data reporting are saved from preemption under section § 1178(c) of the statute.

In addition, to the extent that a State consent law does not contain other consent or authorization requirements that parallel or are stricter than the applicable federal requirements, those detailed federal requirements would also continue to apply. We solicit comment in particular on how these proposed criteria would be likely to operate with respect to particular State privacy laws.

e. *The process for making administrative determinations regarding the preemption of State health information privacy laws.* Because States generally have laws that relate to the privacy of individually identifiable health information, there may be conflicts between provisions of various State laws and the federal requirements. Where such conflicts appear to exist, questions may arise from the regulated entities or from the public concerning which requirements apply. It is possible that such questions may also arise in the context of the Secretary's enforcement of the civil monetary penalty provisions of section 1176. The Secretary accordingly proposes to adopt the following process for responding to such comments and making the determinations necessary to carry out her responsibilities under section 1176.

The rules proposed below would establish two related processes: one for making the determinations called for by

section 1178(a)(2)(A) of the Act and the other for issuing advisory opinions regarding whether a provision of State law would come within the exception provided for by section 1178(a)(2)(B).

i. *Determinations under section 1178(a)(2)(A).*

The rules proposed below should not usually implicate section 1178(a)(2)(A), which provides that a State law will not be preempted where the Secretary determines it is necessary for one or more of five specific purposes: (1) To prevent fraud and abuse; (2) to ensure appropriate State regulation of insurance and health plans; (3) for State reporting on health care delivery or costs; (4) for other purposes; or (5) which address controlled substances. The process for implementing this statutory provision is proposed here, because the issue of how such preemption issues will be handled has been raised in prior HIPAA rulemakings and needs to be addressed, and, as explained above, the statutory provision itself is fairly intertwined (in terms of the specific terms used), with the preemption provisions of the statute that relate to privacy.

The process proposed below for determinations by the Secretary would permit States to request an exception to the general rule of preemption. The decision to limit, at least as an initial matter, the right to request such determinations to States was made for several reasons. First, States are obviously most directly concerned by preemption, in that it is State legislative, judicial, or executive action that the federal requirements supersede. Principles of comity dictate that States be given the opportunity to make the case that their laws should not be superseded. Second, States are in the best position to address the issue of how their laws operate and what their intent is, both of which are relevant to the determination to be made. Third, we need to control the process as an initial matter, so that the Secretary is not overwhelmed by requests. Fourth, where particular federal requirements will have a major impact on providers, plans, or clearinghouses within a particular State, we assume that they will be able to work with their State governments to raise the issue with the Secretary; the discussion process that such negotiations should entail should help crystallize the legal and other issues for the Secretary and, hence, result in better determinations. We emphasize that HHS may well revisit this issue, once it has gained some experience with the proposed process.

Proposed § 160.204(a)(1) sets out a number of requirements for requests for determinations. In general, the purpose of these requirements is to provide as complete a statement as possible of the relevant information as an initial matter, to minimize the time needed for the Secretarial determination.

The remaining requirements of proposed § 160.204(a) generally are designed to set out an orderly process and effect of the determinations. Of particular note is proposed § 160.204(a)(5), which provides that such determinations apply only to transactions that are wholly intrastate. We recognize that in today's economy, many, perhaps most, transactions will be interstate, so that the effect of a positive determination could be minimal under this provision. Nonetheless, we think that there is no practical alternative to the proposed policy. We do not see how it would be practical to split up transactions that involved more than one State, when one State's law was preempted and the other's was not. We do not see why the non-preempted law should govern the transaction, to the extent it involved an entity in a State whose law was preempted. Quite aside from the sovereignty issues such a result would raise, such a result would be very confusing for the health care industry and others working with it and thus inconsistent with the underlying goal of administrative simplification. Rather, such a situation would seem to be a classic case for application of federal standards, and proposed § 160.204(a)(5) would accordingly provide for this.

ii. *Advisory opinions under section 1178(a)(2)(B).*

The rules proposed below lay out a similar process for advisory opinions under section 1178(a)(2)(B). That section of the statute provides that, subject to the requirements of section 264(c)(2) (the provision of HIPAA that establishes the ''more stringent'' preemption test), State laws that ''relate to the privacy of individually identifiable health information'' are excepted from the general rule that the HIPAA standards, requirements, and implementation specifications preempt contrary State law.

Unlike section 1178(a)(2)(A), section 1178(a)(2)(B) does not provide for the making of a determination by the Secretary. Nonetheless, it is clear that the Secretary may make judgments about the legal effect of particular State privacy laws in making compliance and enforcement decisions. It is also foreseeable that the Secretary will be asked to take a position on whether particular State privacy laws are preempted or not. We have concluded that the best way of addressing these concerns is to provide a mechanism by which the Secretary can issue advisory opinions, so that the public may be informed about preemption judgments the Secretary has made. See proposed § 160.204(b).

The process proposed below for requesting advisory opinions is limited to States, for the reasons described in the preceding section. The requirements for requests for advisory opinions are similar to the requirements for determinations in proposed § 160.204(a), but are tailored to the different statutory requirements of sections 1178(a)(2)(A) and 264(c)(2). As with proposed § 164.204(a), the process proposed below would provide for publication of advisory opinions issued by the Secretary on an annual basis, to ensure that the public is informed of the decisions made in this area.

f. *Carve-out for State public health laws.* Section 1178(b) provides that ''Nothing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.'' This section appears to carve out an area over which the States have traditionally exercised oversight and authority—the collection of vital statistics, the enforcement of laws regarding child abuse and neglect, and the conduct of public health surveillance, investigation, and intervention. State laws in these areas may involve reporting of individually identifiable health information to State or local authorities. Section 1178(b) indicates that existing or future State laws in these areas are enforceable, notwithstanding any privacy requirements adopted pursuant to section 264(c). In addition, covered entities should not be inhibited from complying with requests authorized by State law for release of information by public health authorities for the stated purposes.

It should be noted that the limitation of section 1178(b) applies to the ''authority, power, or procedures established under any law.'' Public health laws often convey broad general authorities for the designated agency to protect public health, including enforcement powers, and these State authorities and powers would remain enforceable. Further, section 1178(b) also covers ''procedures'' authorized by law; we read this language as including State administrative regulations and guidelines.

The proposed rules propose to address these concerns by treating the

disclosures covered by section 1178(b) as allowable disclosures for public health activities under proposed § 164.510(b). Thus, those disclosures permitted under proposed § 164.510(b) are intended to be, with respect to disclosures authorized by State law, at least as broad as section 1178(b). This means that disclosures that are authorized by State law but which do not come within the scope of proposed § 164.510(b) are considered to fall outside of the limitation of section 1178(b). In addition, since similar activities and information gathering are conducted by the federal government, disclosures to public health authorities authorized by federal law would be permitted disclosures under this proposed rule and applicable federal law will govern the use and re-disclosure of the information.

g. *Carve-out for State laws relating to oversight of health plans.* Section 1178(c) provides that nothing in part C of title XI limits the ability of States to require health plans ''to report, or to provide access to, information for management audits, financial audits, program monitoring and evaluation, facility licensure or certification, or individual licensure or certification.'' This section thus also carves out an area in which the States have traditionally regulated health care as an area which the statute intends to leave in place. State laws requiring the reporting of or access to information of the type covered by section 1178(c) will in certain cases involve the reporting of, or access to, individually identifiable health information. Accordingly, provision has been made for such reporting and access by making such reporting and access permitted disclosures and uses under this proposed rule. See proposed § 164.510(c).

2. Relationship to Other Federal Laws

[*Please label comments about this section with the subject: ''Relationship to other federal laws''*]

The rules proposed below also would affect various federal programs, some of which may have requirements that are, or appear to be, inconsistent with the requirements proposed below. Such federal programs include those programs that are operated directly by the federal government, such as the health benefit programs for federal employees or the health programs for military personnel. They also include a wide variety of health services or benefit programs in which health services or benefits are provided by the private sector or by State or local government, but which are governed by various federal laws. Examples of the latter types of programs would be the Medicare and Medicaid programs, the health plans governed by the Employee Retirement Income Security Act of 1974, 29 U.S.C. 1001, *et seq.* (ERISA), the various clinical services programs funded by federal grants, and substance abuse treatment programs.

Some of the above programs are explicitly covered by HIPAA. Section 1171 of the Act defines the term ''health plan'' to include the following federally conducted, regulated, or funded programs: group plans under ERISA which either have 50 or more participants or are administered by an entity other than the employer who established and maintains the plan; federally qualified health maintenance organizations; Medicare; Medicaid; Medicare supplemental policies; the health care program for active military personnel; the health care program for veterans; the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); the Indian health service program under the Indian Health Care Improvement Act, 25 U.S.C. 1601, *et seq.;* and the Federal Employees Health Benefits Program. There also are many other federally conducted, regulated, or funded programs in which individually identifiable health information is created or maintained, but which do not come within the statutory definition of ''health plan.'' While these latter types of federally conducted, regulated, or assisted programs are not explicitly covered by part C of title XI in the same way that the programs listed in the statutory definition of ''health plan'' are covered, the statute may nonetheless apply to transactions and other activities conducted under such programs. This is likely to be the case where the federal entity or federally regulated or funded entity provides health services; the requirements of part c are likely to apply to such an entity as a ''health care provider.'' Thus, the issue of how different federal requirements apply is likely to arise in numerous contexts.

When two federal statutes appear to conflict, the courts generally engage in what is called an ''implied repeal'' analysis. The first step in such an analysis is to look for some way in which to reconcile the apparently conflicting requirements. Only if the conflicting provisions cannot be reconciled do courts reach the second step of the analysis, in which they look to see whether the later statute repealed the prior statute (to the extent of the conflict) by implication. In making such a determination, the courts look to the later statute and its legislative history, to see if there is evidence as to whether Congress intended to leave the prior statute in place or whether it intended the later statute to supersede the prior statute, to the extent of the conflict between the two. It is not a foregone conclusion that a later statute will repeal inconsistent provisions of a prior statute. Rather, there are cases in which the courts have held prior, more specific statutes not to be impliedly repealed by later, more general statutes.

As noted above, the section 1171 of the Act explicitly makes certain federal programs subject to the standards and implementation specifications promulgated by the Secretary, while entities carrying out others are implicitly covered by the scope of the term ''health care provider.'' The legislative history of the statute is silent with respect to how these requirements were to operate in the federal sector vis-à-vis these and other federal programs with potentially conflicting requirements. Congress is presumed to have been aware that various federal programs that the privacy and other standards would reach would be governed by other federal requirements, so the silence of the legislative history and the limited reach of the statute would seem to be significant. On the other hand, Congress' express inclusion of certain federal programs in the statute also has significance, as it constitutes an express Congressional statement that the HIPAA standards and implementation specifications apply to these programs. In light of the absence of relevant legislative history, we do not consider this Congressional statement strong enough to support a conclusion of implied repeal, where the conflict is one between the HIPAA regulatory standards and implementation specifications and another federal statute. However, it seems strong enough to support an inference that, with respect to these programs, the HIPAA standards and implementation specifications establish the federal policy in the case of a conflict at the regulatory level.

Thus, the first principle that applies where both the HIPAA standards and implementation specifications and the requirements of another federal program apply is that we must seek to reconcile and accommodate any apparently conflicting federal requirements. Two conclusions flow from this principle. First, where one federal statute or regulation permits an activity that another federal statute or regulation requires, and both statutes apply to the entity in question, there is no conflict, because it is possible to comply with both sets of federal requirements.

Second, where one federal statute or regulation permits, but does not require, an activity that another federal statute or regulation prohibits, there is again no conflict, because it is possible to comply with both sets of federal requirements. In each case, the entity has lost some discretion that it would otherwise have had under the more permissive set of requirements, but in neither case has it been required to do something that is illegal under either federal program.

There will, however, also be cases where the privacy or other Administrative Simplification standards and implementation specifications cannot be reconciled with the requirements of another federal program. In such a case the issue of implied repeal is presented. As suggested above, we think that where the conflict is between the privacy or other Administrative simplification regulations and another federal statute, the regulatory requirements would give way, because there is insufficient evidence to support a finding that part C of title XI is intended to repeal other federal laws. For example, if other law prohibits the dissemination of classified or other sensitive information, this rule's requirements for granting individuals' right to copy their own records would give way. Where the conflict is between the Administrative Simplification regulatory requirements and other federal regulatory requirements that are discretionary (not mandated by the other federal law), we think that there is also insufficient evidence to support a finding of implied repeal of the latter regulatory requirements, where the other federal program at issue is not one specifically addressed in section 1171. However, where the other federal program at issue is one of the ones which Congress explicitly intended to have the Administrative Simplification standards and implementation specifications apply to, by including them in the definition of ''health plan'' in section 1171, we think that there is evidence that the Administrative Simplification standards and implementation specifications should prevail over contrary exercises of discretion under those programs.

We considered whether the preemption provision of section 264(c)(2) of Public Law 104–191, discussed in the preceding section, would give effect to State laws that would otherwise be preempted by federal law. For example, we considered whether section 264(c)(2) could be read to make the Medicare program subject to State laws relating to information disclosures that are more stringent than the requirements proposed in this rule, where such laws are presently preempted by the Medicare statute. We also considered whether section 264(c)(2) could be read to apply such State laws to procedures and activities of federal agencies, such as administrative subpoenas and summons, that are prescribed under the authority of federal law. In general, we do not think that section 264(c)(2) would work to apply State law provisions to federal programs or activities with respect to which the State law provisions do not presently apply. Rather, the effect of section 264(c)(2) is to give preemptive effect to State laws that would otherwise be in effect, to the extent they conflict with and are more stringent than the requirements promulgated under the Administrative Simplification authority of HIPAA. Thus, we do not believe that it is the intent of section 264(c)(2) to give an effect to State law that it would not otherwise have in the absence of section 264(c)(2).

We explore some ramifications of these conclusions with respect to specific federal programs below. We note that the summaries below do not identify all possible conflicts or overlaps of the proposed rules with other federal requirements; rather, we have attempted to explain the general nature of the relationship of the different federal programs. We would anticipate issuing more detailed guidance in the future, when the final privacy policies are adopted, and the extent of conflict or overlap can be ascertained. We also invite comment with respect to issues raised by other federal programs.

a. *The Privacy Act.* The Privacy Act of 1974, 5 U.S.C. 552a, is not preempted or amended by part C of title XI. The Privacy Act applies to all federal agencies, and to certain federal contractors who operate Privacy Act protected systems of records on behalf of federal agencies. It does not, however, apply to non-federal entities that are reached by part C. While the proposed rules are applicable to federal and non-federal entities, they are not intended to create any conflict with Privacy Act requirements. In any situation where compliance with the proposed rules would lead a federal entity to a result contrary to the Privacy Act, the Privacy Act controls. In sections of the proposed rules which might otherwise create the appearance of a conflict with Privacy Act requirements, entities subject to the Privacy Act are directed to continue to comply with Privacy Act requirements.

Because the Privacy Act gives federal agencies the authority to promulgate agency-specific implementing regulations, and because the Privacy Act also allows agencies to publish routine uses that have the status of exceptions to the Privacy Act's general rule prohibiting disclosure of Privacy Act protected information to third parties, the issue of possible conflicts between the proposed Administrative Simplification rules and existing Privacy Act rules and routine uses must be addressed. Where the federal program at issue is one of the ones that Congress explicitly intended to have the Administrative Simplification standards and implementation specifications apply to, by including them in the definition of ''health plan'' in section 1171, we think that there is evidence that the Administrative Simplification standards and implementation specifications should prevail over contrary exercises of discretion under those programs. That is, to the extent that a routine use is truly discretionary to an agency which is also a covered entity under section 1172(a), the agency would not have discretion to ignore the Administrative Simplification regulations. It is possible, however, that in some cases there might be underlying federal statutes that call for disclosure of certain types of information, and routine uses could be promulgated as the only way to implement those statutes and still comply with the Privacy Act. If this were to happen or be the case, the routine use should prevail.

b. *The Substance Abuse Confidentiality regulations.* Regulations that are codified at 42 CFR part 2 establish confidentiality requirements for the patient records of substance abuse ''programs'' that are ''federally assisted.'' Substance abuse programs are specialized programs or personnel that provide alcohol and drug abuse treatment, diagnosis, or referral for treatment. 42 CFR 2.11. The term ''federally assisted'' is broadly defined, and includes federal tax exempt status and Medicare certification, among other criteria. 42 CFR 2.12(b). Such programs may not disclose patient identifying information without the written consent of the patient, unless the information is needed to respond to a medical emergency, or such information is disclosed for purposes of research, audit, or evaluation. Disclosures may not be made in response to a subpoena; rather, a court order is required in order for a disclosure of covered records to be lawfully made. Limited disclosures may also be made by such programs to State or local officials under a State law requiring reporting of incidents of suspected child abuse and neglect and

to law enforcement officials regarding a patient's crime on program premises or against program personnel or a threat to commit such a crime. 42 CFR 2.12. Unlike the rules proposed below, the confidentiality protections continue indefinitely after death, although part 2 would permit disclosure of identifying information relating to the cause of death under laws relating to the collection of vital statistics or permitting inquiry into cause of death.

It seems likely that most, if not all, programs covered by the part 2 regulations will also be covered, as health care providers, by the rules proposed below. As can be seen from the above summary, the part 2 regulations would not permit many disclosures that would be permitted under proposed § 164.510 below, such as many disclosures for law enforcement, directory information, governmental health data systems, and judicial and other purposes. In addition, the general permissive disclosure for treatment or payment purposes at proposed § 164.506 below would be inconsistent with the more restrictive requirements at part 2. In such situations, providers (or others) subject to both sets of requirements could not make disclosures prohibited by part 2, even if the same disclosures would be permitted under the rules proposed below.

There are also a number of requirements of the part 2 regulations that parallel the requirements proposed below. For example, the minimum necessary rule, where applicable, would parallel a similar requirement at 42 CFR 2.13(a). Similarly, the notice requirements of part 2, at 42 CFR 2.22 parallel the notice requirements proposed below, although the notice required below would be more detailed and cover more issues. The preemptive effect on State law should be the same under both part 2 and section 264(c)(2). The requirements for disclosures for research proposed below are likewise similar to those in part 2. In such cases, health care providers would have to comply with the more extensive or detailed requirements, but there should be no direct conflict.

Many other provisions of the proposed rules, however, simply have no counterpart in part 2. For example, the part 2 regulations do not require programs to maintain an accounting of uses and disclosures, nor do they provide for a right to request amendment or correction of patient information. Similarly, the part 2 regulations contain no prohibition on conditioning treatment or payment on provision of an individual authorization for disclosure. In such situations, health care providers would be bound by both sets of requirements.

c. *ERISA.* ERISA was enacted in 1974 to regulate pension and welfare employee benefit plans that are established by private sector employers, unions, or both, to provide benefits to their workers and dependents. An employee welfare benefit plan includes plans that provide ''through the purchase of insurance or otherwise * * * medical, surgical, or hospital care or benefits, or benefits in the event of sickness, accident, disability, (or) death.'' 29 U.S.C. 1002(1). In 1996, Public Law 104–191 amended ERISA to require portability, nondiscrimination, and renewability of health benefits provided by group health plans and group health insurance issuers. Numerous, although not all, ERISA plans are covered under the rules proposed below as ''health plans.''

As noted above, section 514(a) of ERISA, 29 U.S.C. 1144(a), preempts all State laws that ''relate to'' any employee benefit plan. However, section 514(b) of ERISA, 29 U.S.C. 1144(b)(2)(A), expressly saves from preemption State laws which regulate insurance. Section of ERISA, 29 U.S.C. 1144(b)(2)(B), provides that an ERISA plan is deemed not to be an insurer for the purpose of regulating the plan under the State insurance laws. Thus, under the deemer clause, States may not treat ERISA plans as insurers subject to direct regulation by State law. Finally, section 514(d) of ERISA, 29 U.S.C. 1144(d), provides that ERISA does not ''alter, amend, modify, invalidate, impair, or supersede any law of the United States.''

We considered whether the preemption provision of section 264(c)(2) of Public Law 104–191, discussed in the preceding section, would give effect to State laws that would otherwise be preempted by section 514(a) of ERISA. Our reading of the statutes together is that the effect of section 264(c)(2) is simply to leave in place State privacy protections that would otherwise apply and which are more stringent than the federal privacy protections. In the case of ERISA plans, however, if those laws are preempted by section 514(a), they would not otherwise apply. We do not think that it is the intent of section 264(c)(2) to give an effect to State law that it would not otherwise have in the absence of section 264(c)(2). Thus, we would not view the preemption provisions below as applying to State laws otherwise preempted by section 514(a) of ERISA.

Many plans covered by the rules proposed below are also subject to ERISA requirements. To date our discussions and consultations have not uncovered any particular ERISA requirements that would conflict with the rules proposed below. However, we invite comment, particularly in the form of specific identification of statutory or regulatory provisions, of requirements under ERISA that would appear to conflict with provisions of the rules proposed below.

d. *Other federally funded health programs.* There are a number of authorities under the Public Health Service Act and other legislation that contain explicit confidentiality requirements either in the enabling legislation or in the implementing regulations. Many of these are so general that there would appear to be no problem of inconsistency, in that nothing in the legislation or regulations would appear to restrict the assisted provider's discretion to comply with the requirements proposed below. There are, however, several authorities under which either the requirements of the enabling legislation or of the program regulations would impose requirements that would differ from the rules proposed below. We have identified several as presenting potential issues in this regard. First, regulations applicable to the substance abuse block grant program funded under section 1943(b) of the Public Health Service Act require compliance with 42 CFR part 2, and thus raise the issues identified in section 2 above. Second, there are a number of federal programs which, either by statute or by regulation, restrict the disclosure of patient information to, with minor exceptions, disclosures ''required by law.'' See, for example, the program of projects for prevention and control of sexually transmitted diseases funded under section 318(e)(5) of the Public Health Service Act (42 CFR 51b.404); the regulations implementing the community health center program funded under section 330 of the Public Health Service Act (42 CFR 51c.110); the regulations implementing the program of grants for family planning services under title X of the Public Health Service Act (42 CFR 59.15); the regulations implementing the program of grants for black lung clinics funded under 30 U.S.C. 437(a) (42 CFR 55a.104); the regulations implementing the program of maternal and child health projects funded under section 501 of the Act (42 CFR 51a.6); the regulations implementing the program of medical examinations of coal miners (42 CFR 37.80(a)). These legal requirements would restrict the grantees or other entities under the programs

involved from making many of the disclosures that proposed § 164.510 would permit. In some cases, permissive disclosures for treatment, payment or health care operations would also be limited. Since proposed § 164.510 is merely permissive, there would not be a conflict between the program requirements, as it would be possible to comply with both. However, it should be recognized that entities subject to both sets of requirements would not have the total range of discretion that the rules proposed below would suggest.

J. Compliance and Enforcement (§ 164.522)

1. Compliance

[*Please label written comments about this section with the subject: ''Compliance.''*]

The rules proposed below at § 164.522 would establish several requirements designed to enable the Secretary to monitor and seek to ensure compliance with the provisions of this subpart. The general philosophy of this section is to provide a cooperative approach to obtaining compliance, including use of technical assistance and informal means to resolve disputes. However, in recognition of the fact that it would not always be possible to achieve compliance through cooperation, the section also would provide the Secretary with tools for carrying out her statutory mandate to achieve compliance.

a. *Principles for achieving compliance.* Proposed § 164.522(a) would establish the principle that the Secretary will seek the cooperation of covered entities in obtaining compliance. Section 164.522(a)(2) provides that the Secretary could provide technical assistance to covered entities to help them come into compliance with this subpart. It is clearly in the interests of both the covered entities and the individuals they serve to minimize the costs of compliance with the privacy standards. To the extent that the Department could facilitate this by providing technical assistance, it would endeavor to do so.

b. *Individual complaints and compliance reviews.* We are proposing in § 164.522(b) that individuals have the right to file a complaint with the Secretary if they believe that a covered plan or provider has failed to comply with the requirements of this subpart. Because individuals would have received notice, pursuant to proposed § 164.512, of the uses and disclosures that the entity could make and of the entity's privacy practices, they would have a basis for making a realistic judgment as to when a particular action or omission would be improper. The notice would also inform individuals how they could find out how to file such complaints. We thus consider the proposed complaint right to be one that could realistically be exercised by individuals, given the regulatory structure proposed.

We are concerned about the burden that handling the potential volume of such complaints would create for this Department, but we recognize that such a complaint mechanism would provide helpful information about the privacy practices of covered plans or providers and could serve to identify particularly troublesome compliance problems on an early basis.

The procedures proposed in this section are modeled on those used by the Department's Office for Civil Rights, although they would be adapted to reflect the requirements of this subpart. We would require complainants to identify the entities and describe the acts or omissions alleged to be out of compliance and would require individuals to file such complaints within 180 days of those acts or omissions. We have tried to keep the requirements for filing complaints as minimal as possible, to facilitate use of this right. The Secretary would also attempt to keep the identity of complainants confidential, if possible. However, we recognize that it could be necessary to disclose the identity of complainants in order to investigate the substance of their complaints, and the rules proposed below would permit such disclosures.

The Secretary could promulgate alternative procedures for complaints based on agency-specific concerns. For example, to protect classified information, we may promulgate rules that would allow an intelligence community agency to create a separate body within that agency to receive complaints.

The Secretary would try to resolve complaints on an informal basis wherever possible. Where a resolution could not be reached, the Secretary could make a formal finding of noncompliance. However, resolution could occur, and an agreement reached with the covered entity, even after a finding that a violation occurred. The Secretary could use the finding as a basis to initiate an action under section 1176 of the Act or to refer the matter to the Department of Justice for prosecution under section 1177 of the Act. It should be recognized that the decision to initiate an action under either section of the law would be a discretionary one, and proposed § 164.522 would not require such prosecutorial action to be taken. Proposed § 164.522(e)(1)(ii) would, however, permit the use of findings made in connection with a complaint, group of complaints, or compliance review to be acted on in this fashion.

The rules proposed below also would provide that the Secretary would inform both the covered plan or provider and the complainant, whenever a decision was made on a complaint.

We are proposing in § 164.522(c) that the Secretary could conduct compliance reviews to determine whether covered entities are in compliance. A compliance review could be based on information indicating a possible violation of this subpart even though a formal complaint has not been filed. As is the case with a complaint investigation, a compliance review may examine the policies, practices or procedures of a covered entity and may result in voluntary compliance or in a violation or no violation finding.

c. *Responsibilities of covered entities.* Proposed § 164.522(d) establishes certain obligations for covered entities that would be necessary to enable the Secretary to carry out her statutory role to determine their compliance with these requirements. Proposed § 164.522(d)(1) would require covered entities to maintain records as directed. Proposed § 164.522(d)(2) would require them to participate as required in compliance reviews. Proposed § 164.522(d)(3) would affirmatively establish their obligation to provide information to the Secretary upon demand. Finally, paragraph (d)(4) would prohibit intimidating, discriminatory or other retaliatory actions by a covered entity against a person who files a complaint with the Secretary; testifies, assists or participates in any manner in an investigation, compliance review, proceeding, or hearing under this Act; or opposes any act or practice made unlawful by this subpart. This language is modeled after the Americans with Disabilities Act and title VII of the Civil Rights Act of 1964. Prohibitions against retaliation are also common throughout Department programs. The experience of the federal government in enforcing civil rights and other laws has been that voluntary compliance with and effective enforcement of such laws depend in large part on the initiative of persons opposed to illegal practices. If retaliation for opposing practices that a person reasonably believes are unlawful were permitted to go unremedied, it would have a chilling effect upon the willingness of persons to speak out and

to participate in administrative processes under this subpart.

Opposition to practices of covered entities refers to a person's communication of his or her good faith belief that a covered entity's activities violate this subpart. Opposition includes, but is not limited to, filing a complaint with the covered entity under § 164.518(d) and making a disclosure as a whistleblower under § 164.518(c)(4). This provision would not protect a person whose manner of opposition is so unreasonable that it interferes with the covered entities' legitimate activities. This provision would cover such situations such as where an employee of a physician is fired in retaliation for confronting the doctor regarding her practice of illegally disclosing individuals' records or where a health plan drops coverage after an enrollee argues to the plan that he has a right to access to his records.

We recognize that under these requirements the covered entity would be disclosing protected health information to representatives of the Department when such information is relevant to a compliance investigation or assessment. We recognize that this would create a mandatory disclosure of protected health information and that such a requirement carries significant privacy concerns. Those concerns must, however, be weighed against the need to obtain compliance by entities with the privacy standards, and to protect against future improper uses and disclosures of protected health information. The proposed rule accordingly attempts to strike a balance between these interests, providing that the Department would not disclose such information, except as may be necessary to enable the Secretary to ascertain compliance with this subpart or in enforcement proceedings or as otherwise required by law.

2. Enforcement

[*Please label written comments about this section with the subject: ''Enforcement.''*]

Congress established a two-pronged approach to enforcement of all of the requirements established under part C of title XI of the Act. First, section 1176 grants the Secretary the authority to impose civil monetary penalties against those covered entities which fail to comply with the requirements established under part C. These penalties are to be imposed according to the procedures established for imposition of civil monetary penalties in section 1128A of the Act. Second, section 1177 establishes criminal penalties for certain wrongful disclosures of individually identifiable health information.

The selection of the civil monetary penalty process at section 1128A of the Act as the enforcement mechanism for the Administrative Simplification standards and requirements indicates the type of process Congress believes is appropriate for civil enforcement of those standards and requirements. The Secretary's Recommendations call for a privacy right of action to permit individuals to enforce their privacy rights. However, the HIPAA does not provide a private right of action, so the Secretary lacks the authority to provide for such a remedy. Accordingly, we would provide that individuals could file complaints with the Secretary and the Secretary could then, when appropriate, investigate. The Secretary may also conduct compliance reviews. See proposed § 164.522(b) and (c).

Under section 1177(a), the offense of ''wrongful disclosure'' is a disclosure that violates the standards or requirements established under part C. These would include any disclosures not otherwise permitted under the privacy standards or the parallel security standards.

As we noted in the Notices of Proposed Rulemaking for the other Administrative Simplification regulations, we will propose regulations in the future to establish these procedures. Because such procedures will not constitute ''standards'' within the meaning of part C, they would not be subject to the delay in effective date provisions that apply to the various Administrative Simplification regulations.

III. Small Business Assistance

This rule is significant because it establishes for the first time a federally required regime of information practices in the medical industry. The length, and at times complexity, of the preamble discussion may impress small businesses as creating overly burdensome and costly requirements. We believe, however, that several features of the rule, combined with initiatives by the Department and professional associations, will make the rule easily administrable for the vast majority of small businesses.

First, a significant portion of the rule addresses the topic of signed individual authorization for disclosure of health information—the information that the authorization would include and when such an authorization would be required. Importantly, no patient written authorization would be required when information is disclosed for purposes of treatment and payment and health care operations, or when disclosure is mandated by law. In other words, doctors who disclose patient health information only to other doctors for treatment purposes, or to insurance companies to process payment, or for operational purposes can continue to do so without any change in current practices under this proposal. Only those covered entities who disclose health information to marketers, reporters, private investigators, researchers, and others for purposes unrelated to treatment, payment, and health care operations are required to get the written consent of the patient in accordance with this rule.

Second, the Department plans to engage in outreach and education programs to ease the implementation of this rule for small businesses. Already, this rule provides model forms for getting patient authorization and provides an example of a notice of information practices (another requirement in the rule, described further below). We also expect that professional associations will develop forms tailored to specific groups' needs. The Department pledges to work with professional associations to provide the greatest possible guidance to small businesses covered by this rule.

Third, in implementing this rule, we will apply the principle of ''scalability,'' so that a particular entity's characteristics—including its size, type of business, and information practices—would be relevant to how that entity adopts procedures to comply with this rule. Take one example—this rule requires the designation of a ''privacy official.'' Large health plans dealing with a vast range of information flows may well consider hiring a full time person to oversee compliance with the rule, to assist in planning systems development, and to draft contracts with business partners, among other tasks. A small doctor's office, on the other hand, may instead determine that an existing office manager could oversee the office's privacy policies. There would be no expectation that this small doctor's office hire a full-time privacy official. In each of these examples, the covered entity would be complying with the rule's requirement that a privacy official be designated—but the ways that each complies would reflect the different circumstances of each entity's practice.

It is important for small businesses to understand what their obligations would be and to implement the necessary procedures to comply, with the help of Department's model forms and other resources from professional associations. While most covered

entities would need to be in compliance within two years of the final publication of the rule, small businesses would have an extra year to come into compliance.

Here, we set out the principal (although not exclusive) requirements for small businesses:

1. Notice to Individuals of Information Practices (§ 164.512)

Each covered entity would have to develop a notice of information practices, which, as described above, could be modeled on the form attached to this proposal or on model forms that we expect professional associations to develop. The notice must accurately reflect the entity's practices and include the elements listed in § 164.512.

Covered *health care providers* would have to provide the notice to individuals at first service after the effective date of the rule. Providers are also required to post a current copy of the notice in a clear and prominent location for individuals to see. Covered health *plans* would have to provide the notice to any individual covered by the plan when this rule becomes effective, at enrollment, and after any material change to the notice or at least once every three years.

2. Access of Individuals to Protected Health Information (§ 164.514)

Covered plans and providers would be required to allow individuals to inspect and copy their protected health information. These plans or providers could charge individuals a reasonable cost-based fee for copying.

3. Accounting for Uses and Disclosures (§ 164.515)

Covered plans and providers would have to be able to provide an accounting for uses and disclosures of protected health information for purposes other than treatment, payment, or health care operations. We expect that this burden will be very low for most small businesses, given the nature of most disclosures by such businesses.

4. Amendment and Correction (§ 164.516)

Covered plans and providers would be required to allow individuals to request amendments or corrections to their protected health information.

5. Designated Privacy Official (§ 164.518(a))

Each covered entity would designate a privacy official. As described above, in a small providers office, the office manager may be the official in charge of making sure that the office is implementing its privacy policies and procedures and taking complaints.

6. Training (§ 164.518(b))

All members of covered entities' workforces who have contact with protected health information would be required to have some sort of privacy training about the entity's policies and procedures and to sign a certificate indicating that they had such training. For a small entity, this could simply mean the privacy official briefly discussing how they handle privacy concerns and going over the entity's notice of information practices.

7. Safeguards (§ 164.518(c))

A covered entity would have to establish administrative, technical, and physical safeguards to protect the privacy of protected health information from unauthorized access or use. For a small provider, this may mean having the ability to securely lock up any record that are not being used and ensuring that records are not kept in an area where anyone who is not authorized could view them.

8. Complaints (§ 164.518(d))

Every covered entity would be required to have policies and procedures in place that allow individuals to file complaints about possible privacy violations. For a small entity, this could mean simply that they keep a specific file for complaints.

9. Sanctions (§ 164.518(e))

Covered entities would be required to develop and apply sanctions when a member of a covered entity's work force or business partner fails to comply with the entity's policies and procedures related to this rule. For a small businesses, these could range from requiring a re-training on privacy, to placing a notation of the violation in an employee's record, to dismissal or ending a contract with a business partner.

10. Documentation of Policies and Procedures (§§ 164.520)

Covered entities would be required to document policies and procedures for use and disclosure of protected health information relating to this regulation, including elements listed in § 164.520, and would need to maintain one copy of each version of its notice of information practices, and authorization forms. See § 164.520(f) for a full list of recordkeeping requirements.

11. Minimum Necessary (§ 164.506(b))

When using or disclosing protected health information for treatment, payment, healthcare operations, and other purposes, an entity would be required to disclose only the amount of protected health information necessary to accomplish the intended purpose of the use or disclosure.

12. Business Partners (§ 164.506(e))

For those small businesses that hire ''business partners'' to assist them in carrying out their operations, this rule would require that they take steps, including having certain terms in a contract, to ensure that their business partners are also protecting the privacy of individually identifiable health information. We expect that model contracts will be developed by potential business partners and others that can be used to fulfill the requirements of this section.

13. Special Disclosures That Do Not Require Authorization—Public Health, Research, etc. (§ 164.510)

This proposed rule would also permit disclosure of patients' health information in special cases and under certain conditions. These disclosures would be optional under this proposed rule but may be mandatory under other laws. The primary examples of such permissible disclosures are for: public health purposes, for health oversight purposes, for judicial and administrative proceedings, to coroners and medical examiners, to law enforcement agencies, to next-of-kin, to governmental health data systems, for research purposes, other disclosures required by law, among others. Each of these disclosures and uses would be subject to specific conditions, described in the proposed rule.

14. Verification (§ 164.518(c)(2))

Entities would be required to have reasonable procedures to verify the identity or authority, as applicable, of persons requesting the disclosure of protected health information if the person making the request is not already known to the entity. In most cases, the covered entity could simply ask for a form of identification like a drivers license.

IV. Preliminary Regulatory Impact Analysis

Section 804(2) of title 5, United States Code (as added by section 251 of Public Law 104–121), specifies that a ''major rule'' is any rule that the Office of Management and Budget finds is likely to result in—

- An annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers, individual industries,

Federal, State, or local government agencies, or geographic regions; or

• Significant adverse effects in competition, employment, investment productivity, innovation, or on the ability of Unites States based enterprises to compete with foreign-based enterprises in domestic and export markets.

We estimate that the impact of this final rule will be over $1 billion in the first year of implementation. Therefore, this rule is a major rule as defined in Title 5, United States Code, section 804(2).

DHHS has examined the impacts of this proposed rule under Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). According to Executive Order 12866, a regulatory action is ''significant'' if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs or if it raises novel legal or policy issues. DHHS finds that this proposed rule is a significant regulatory action as defined by Executive Order 12866. Also in accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

When this proposed rule becomes a final rule, in accordance with the Small Business Regulatory Enforcement and Fairness Act (Pub. L. 104–121), the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget (the Administrator) has determined that this proposed rule would be a major rule for the purpose of congressional review. A major rule for this purpose is defined in 5 U.S.C. 804(2) as one that the Administrator has determined has resulted or is likely to result in an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, federal State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) projects a significant increase in the number of medical transactions that will be conducted or transmitted electronically. HIPAA notes the privacy needs that result when individually identifiable health information can be transmitted quickly through electronic information systems. While there is a compelling need to protect the privacy of health information in today's health care system, the expected growth of electronic systems to aide medical diagnostics, claims processing and research makes it even more critical to improve privacy protections.

A fundamental assumption of this regulation is that the greatest benefits of improved privacy protection will be realized in the future as patients gain increasing trust in health care practitioners' ability to maintain the confidentiality of their health information. Furthermore, our analysis rests on the principle that health information privacy is a right, and as such, cannot be valued solely by market costs. Because it is difficult to measure future benefits based on present data, our estimates of the costs and benefits of this regulation are based on the current business environment and do not include projections beyond five years. As a result, we cannot accurately account for all of the regulation's future costs and benefits, but the Department is confident that future benefits will be higher than those stated in this analysis.

In order to achieve a reasonable level of privacy protection, we have three objectives for the proposed rule: (1) To establish baseline standards for health care privacy protection, (2) to establish protection for all health information maintained or transmitted by covered entities, and (3) to protect the privacy of health information that is maintained in electronic form, as well as health information generated by electronic systems.

Establishing minimum standards for health care privacy protection is an attempt to create a baseline level of privacy protection for patients across States. The Health Privacy Project's report, *The State of Health Privacy: An Uneven Terrain*[6] makes it clear that under the current system of state laws, privacy protection is extremely variable. Our statutory authority under HIPAA allows us to preempt state laws when state law provides less stringent privacy protection than the regulation. Only in cases where state law does not protect the patient's health information as stringently as in this proposed rule, or when state law is more restrictive of a patient's right to access their own health care information, will our rule preempt state law. We discuss preemption in greater detail in other parts of the preamble (see the effects of the rule on state laws, section 2 below).

Our second objective is to establish a uniform base of protection for all health information maintained or transmitted by covered entities. As discussed in the preamble, HIPAA restricts the type of entities covered by the proposed rule to three broad categories: health care providers, health care clearinghouses, and health plans. However, there are similar public and private entities that we do not have the authority to regulate under HIPAA. For example, life insurance companies are not covered by this proposed rule but have access to a large amount of protected health information. State government agencies not directly linked to public health functions or health oversight may also have access to protected health information. Examples of this type of agency include the motor vehicle administration, which frequently maintains individual health information, and welfare agencies that routinely hold health information about their clients.

Our third objective is to protect the privacy of health information that is maintained in electronic form, as well as health information generated by electronic systems. Health information is currently stored and transmitted in multiple forms, including in electronic, paper, and oral formats. In order to provide consistent protection to information that has been electronically transmitted or maintained, we propose that this rule cover all personal, protected health information that has ever been maintained or transmitted electronically. This type of information includes output such as computer printouts, X-rays, magnetic tape, and other information that was originally maintained or transmitted electronically. For example, laboratory tests are often computer generated, printed out on paper, and then stored in a patient's record. Because such lab results were originally maintained electronically, the post-electronic (i.e. printed) output of those lab results would also be covered under the proposed rule.

It is important to note that the use of electronic systems to maintain and transmit health information is growing among health care providers, and health plans. Faulkner and Gray report that provider use of electronically processed

[6] Janlori Goldman, Institute for Health Care Research and Policy, Georgetown University: www.healthprivacy.org/resources.

health transactions grew from 47 percent to 62 percent between 1994 and 1998. Payer use of electronic transactions grew 17 percent between 1996 and 1997. Once all of the HIPAA administrative simplification standards are implemented, we expect the number of electronic transactions processed by payers and providers to grow.

The variation in business practice regarding use of paper records versus electronic media for storing and transmitting health information is captured by comparing the percentage of providers that submit paper claims with those that submit electronic claims. Faulkner & Gray's *Health Data Directory* [1] shows that only 40 percent of non-Medicare physician claims and 16 percent of dental claims were submitted electronically in 1998. In contrast, 88 percent of all pharmacy claims were submitted electronically.

We believe that most physicians either have, or will have in the near future, the capacity to submit claims electronically. Faulkner and Gray reported that 81 percent of physicians with Medicare patients submitted their Medicare claims electronically. The difference in the percent of electronic clams submitted to Medicare suggests that the physicians' decisions to submit claims electronically may be heavily influenced by the administrative requirements of the health plan receiving the claim. Since HIPAA requires all health plans to accept electronic transactions and, in order to compete in the technologically driven health care market, more health plans may require electronic claims submissions, physicians will conduct many more electronic transactions in the near future. Therefore, it is extremely important that adequate privacy protections are implemented now.

A. Relationship of This Analysis to Analyses in Other HIPAA Regulations

Historically, Congress has recognized that privacy standards must accompany the electronic data interchange standards and that the increased ease of transmitting and sharing individually identifiable health information must be accompanied by an increase in the privacy and confidentiality. In fact, the majority of the bulk of the first Administrative Simplification section that was debated on the floor of the Senate in 1994 (as part of the Health Security Act) was made up of privacy provisions. Although the requirement for the issuance of concomitant privacy standards remained a part of the bill passed by the House of Representatives, the requirement for privacy standards was removed in conference. This section was moved from the standard-setting authority of Title XI (section 1173 of the Act) and placed in a separate section of HIPAA, section 264. Subsection (b) of section 264 required the Secretary of HHS to develop and submit to the Congress recommendations for:

(1) The rights that an individual who is a subject of individually identifiable health information should have.

(2) The procedures that should be established for the exercise of such rights.

(3) The uses and disclosures of such information that should be authorized or required.

The Secretary's Recommendations were submitted to the Congress on September 11, 1997, and are summarized below. Section 264(c)(1) provides that:

> If legislation governing standards with respect to the privacy of individually identifiable health information transmitted in connection with the transactions described in section 1173(a) of the Social Security Act (as added by section 262) is not enacted by (August 21, 1999), the Secretary of Health and Human Services shall promulgate final regulations containing such standards not later than (February 21, 2000). Such regulations shall address at least the subjects described in subsection (b).

As the Congress did not enact legislation governing standards with respect to the privacy of individually identifiable health information prior to August 21, 1999, HHS has now, in accordance with this statutory mandate, developed proposed rules setting forth standards to protect the privacy of such information.

These privacy standards have been, and continue to be, an integral part of the suite of Administrative Simplification standards intended to simplify and improve the efficiency of the administration of our health care system.

The proposed rule should be considered along with all of the administrative simplification standards required by HIPAA. We assessed several strategies for determining the impact of this proposed rule. We considered whether it would be accurate to view the impact as a subset of the overall HIPAA standards or whether this privacy component should be viewed as an addition to the earlier impact analyses related to HIPAA. We decided that while this proposed rule is considered one of the HIPAA standards, any related costs or benefits should be viewed as an addition to earlier analyses. The original HIPAA analyses did not incorporate the expected costs and benefits of privacy regulation because, at the time of the original analyses, we did not know whether Congress would enact legislation or whether privacy would need to be addressed by regulation. Therefore, much of our cost analysis is based on the expected incremental costs above those related to other HIPAA regulations.

B. Summary of Costs and Benefits.

The Department has estimated the costs and benefits of the proposed rule based on several caveats. In general, it is difficult to estimate the costs and benefits of improved privacy protection. The ability to measure costs of the proposed regulation is limited because there is very little data currently available on the cost of privacy protection. The Department has not been able to estimate costs for a number of requirements of the proposed regulation that we know will impose some cost to covered entities. For those elements for which there are estimated costs, data and information limitations limit the precision of the Department's estimates; for those reasons we have provided an overall range of costs in addition to point estimates, and welcome further information from the public as part of the comment process. Furthermore, the number of new privacy requirements that the regulation will introduce to the health care industry exacerbates difficulties estimating the benefits of privacy. Benefits are difficult to measure because we conceive of privacy primarily as a right and secondarily as a commodity. As discussed below, the significant benefits of the proposed regulation to individuals and society can be demonstrated by illustrating the serious privacy concerns raised by mental health, substance abuse, cancer screening, and HIV/AIDS patients and the benefits that may be derived from greater privacy.

The estimated cost of compliance with the proposed rule would be at least $3.8 billion over five years. The cost includes estimates for the majority of the requirements of the proposed regulation, but not all. These estimates include costs to federal, State, and local governments. Federal, and State and local costs are therefore a subset of total costs. Based on a plausible range of costs for the key components of the analysis, the cost of the regulation would likely be in the range $1.8 to $6.3 billion over five years (not including those elements of the regulation for

[1] Health Data Directory, Faulkner & Gray; 1999 Edition, pp 22–23.

which we could not make any cost estimates).

The compliance costs are in addition to Administrative Simplification estimates. The cost of complying with the privacy regulation represents about 0.09 percent of projected national health expenditures during the first year following the regulation's enactment. The five-year cost of the proposed regulation also represents 1.0 percent of the increase in health care costs that will occur during the same five-year period.[8]

The largest cost item is the amending and correcting of records, which would represent over one-half of total costs. Provider and plan notices, which we estimate would cost $439 million, is the second largest cost, and inspection and copying of records is estimated to be $405 million. The one-time costs for providers to develop policies and procedures represent somewhat less than 10 percent of the total cost, or $333 million. Plans would bear a substantially smaller cost—approximately $62 million. Other systems changes would cost about $90 million over the period. The cost of administering written authorizations would total approximately $271 million over five years.

The cost estimates include private- and public-sector costs. Many of the public-sector cost elements will be the same as those in the private market. However, privacy notices are likely to represent a smaller fraction of total public-sector costs, while systems compliance costs in the public sector may be higher than in the private sector due to oversight and administrative requirements.

The costs presented in this document are the Department's best estimates of the cost of implementing the proposed regulation based on available information and data. Because of inadequate data, we have not made cost estimates for the following components of the regulation: The principle of minimum necessary disclosure; the requirement that entities monitor business partners with whom they share PHI; creation of de-identified information; internal complaint processes; sanctions; compliance and enforcement; the designation of a privacy official and creation of a privacy board; and additional requirements on research/optional disclosures that will be imposed by the regulation. The cost of these provisions may be significant in some cases, but it would be inaccurate to project costs for these requirements given the fact that several of these concepts are new to the industry, and there is little direct evidence on costs. We solicit comment regarding costs of the regulation that we have not quantified.

The privacy protections established by this regulation will provide major social benefits. Establishing privacy protection as a fundamental right is an important goal and will have significant, non-quantifiable social benefits. A well-designed privacy standard can be expected to build confidence among the public about the confidentiality of their health information. Increased confidence in the privacy of an individual's health information can be expected to increase the likelihood that many people will seek treatment for particular classes of disease, particularly mental health conditions, sexually transmitted diseases such as HIV/AIDS, and earlier screening for certain cancers. The increased utilization of medical services that would result from increased confidence in privacy would lead to improved health for the individuals involved, reduced costs to society associated with delayed treatments, and improved public health attributable to reduced transmission of communicable diseases.

TABLE 1.—THE COST OF COMPLYING WITH THE PROPOSED PRIVACY REGULATION

[In dollars]

Provision	Initial or first year cost (2000)	Annual cost after the first year	Five year (2000–2004) cost
Development of Policies and Procedures—Providers (totaling 871,294)	$333,000,000	.....	$333,000,000
Development of Policies and Procedures—Plans (totaling 18,225)	62,000,000	.....	62,000,000
System Changes—All Entities	90,000,000	.....	90,000,000
Notice Development Cost—All Entities	20,000,000	.....	30,000,000
Notice Issuance—Providers	59,730,000	37,152,000	208,340,000
Notice Issuance—Plans	46,200,000	46,200,000	231,000,000
Inspection/Copying	81,000,000	81,000,000	405,000,000
Amendment/Correction	407,000,000	407,000,000	2,035,000,000
Written Authorization	54,300,000	54,300,000	271,500,000
Paperwork/Training	22,000,000	22,000,000	110,000,000
Other Costs*	**N/E	N/E	N/E
Total	$1,165,230,000	$647,652,000	$3,775,840,000

*Other Costs include: minimum necessary disclosure; monitoring business partners with whom entities share PHI; creation of de-identified information; internal complaint processes; sanctions; compliance and enforcement; the designation of a privacy official and creation of a privacy board; additional requirements on research/optional disclosures that will be imposed by the regulation.

**N/E = ''Not estimated''.

We promote the view that privacy protection is an important personal right, and suggest that the greatest of the benefits of the proposed regulation are impossible to estimate based on the market value of health information alone. However, it is possible to evaluate some of the benefits that may accrue to individuals as a result of proposed regulation, and these benefits, alone, demonstrate that the regulation is warranted.

These benefits are considered both qualitatively and quantitatively. As a framework for the discussion, the cost of the provisions in the regulation that have been quantified is $0.46 per health care encounter. Although the value of privacy cannot be fully calculated, it is worth noting that if individuals would be willing to pay more than $0.46 per health care encounter to improve health information privacy, the benefits of the

[8] Health Care Finance Administration, Office of the Actuary, 1997.

proposed regulation would outweigh the cost.

Several qualitative examples illustrate the benefits of the proposed regulation. In one case, medical privacy concerns may prevent patients from obtaining early testing and screening for certain types of cancer. Of types of cancer for which screening is available, survival rates might increase to 95 percent diagnosed in the early stages [9]. For HIV/AIDS patients, new treatments for patients who are diagnosed with HIV in the early stages may save $23,700 per quality-adjusted year of life saved [10]. Later in this document, the potential to reduce illness and disability associated with sexually transmitted diseases is discussed.

We recognize that many of the costs and benefits of health information privacy are difficult to quantify, but we believe that our estimates represent a reasonable range of the economic costs and benefits associated with the regulation.

C. Need for the Proposed Action.

Privacy is a fundamental right. As such, it has to be viewed differently than any ordinary economic good. Although the costs and benefits of a regulation need to be considered as a means of identifying and weighing options, it is important not to lose sight of the inherent meaning of privacy: it speaks to our individual and collective freedom.

A right to privacy in personal information has historically found expression in American law. All fifty states today recognize in tort law a common law or statutory right to privacy. Many states specifically provide a remedy for public revelation of private facts. Some states, such as California and Tennessee, have a right to privacy as a matter of state constitutional law. The multiple historical sources for legal rights to privacy are traced in many places, including Chapter 13 of Alan Westin's Privacy and Freedom and in Ellen Alderman & Caroline Kennedy, The Right to Privacy (1995).

To take but one example, the Fourth Amendment to the United States Constitution guarantees that ''the right of the people to be secure in their persons, houses, papers and effects, against unreasonable searches and seizures, shall not be violated.'' By referring to the need for security of ''persons'' as well as ''papers and effects'' the Fourth Amendment suggests enduring values in American law that relate to privacy. The need for security of ''persons'' is consistent with getting patient consent before performing invasive medical procedures. The need for security in ''papers and effects'' underscores the importance of protecting information about the person, contained in sources such as personal diaries, medical records, or elsewhere. As is generally true for the right of privacy in information, the right is not absolute. The test instead is what constitutes an ''unreasonable'' search of the papers and effects.

The United States Supreme Court has specifically upheld the constitutional protection of personal health information. In *Whalen* v. *Roe,* 429 U.S. 589 (1977), the Court analyzed a New York statute that created a database of persons who obtained drugs for which there was both a lawful and unlawful market. The Court, in upholding the statute, recognized at least two different kinds of interests within the constitutionally protected ''zone of privacy.'' ''One is the individual interest in avoiding disclosure of personal matters,'' such as this proposed regulation principally addresses. This interest in avoiding disclosure, discussed in *Whalen* in the context of medical information, was found to be distinct from a different line of cases concerning ''the interest in independence in making certain kinds of important decisions.'' In the recent case of *Jaffee* v. *Redmond,* 116 S.Ct. 1923 (1996), the Supreme Court held that statements made to a therapist during a counseling session were protected against civil discovery under the Federal Rules of Evidence. The Court noted that all fifty states have adopted some form of the psychotherapist-patient privilege. In upholding the federal privilege, the Supreme Court stated that it ''serves the public interest by facilitating the appropriate treatment for individuals suffering the effects of a mental or emotional problem. The mental health of our citizenry, no less than its physical health, is a public good of transcendent importance.''

Many writers have urged a philosophical or common-sense right to privacy in one's personal information. Examples include Alan Westin, Privacy and Freedom (1967) and Janna Malamud Smith, Private Matters: In Defense of the Personal Life (1997). These writings emphasize the link between privacy and freedom and privacy and the ''personal life,'' or the ability to develop one's own personality and self-expression. Smith, for instance, states:

> The bottom line is clear. If we continually, gratuitously, reveal other people's privacies, we harm them and ourselves, we undermine the richness of the personal life, and we fuel a social atmosphere of mutual exploitation. Let me put it another way: Little in life is as precious as the freedom to say and do things with people you love that you would not say or do if someone else were present. And few experiences are as fundamental to liberty and autonomy as maintaining control over when, how, to whom, and where you disclose personal material. Id. at 240–241.

Individuals' right to privacy in information about themselves is not absolute. It does not, for instance, prevent reporting of public health information on communicable diseases or stop law enforcement from getting information when due process has been observed. But many people believe that individuals should have some right to control personal and sensitive information about themselves.

Among different sorts of personal information, health information is among the most sensitive. Many people believe that details about their physical self should not generally be put on display for neighbors, employers, and government officials to see. Informed consent laws place limits on the ability of other persons to intrude physically on a person's body. Similar concerns apply to intrusions on information about the person. Moving beyond these facts of physical treatment, there is likely a greater intrusion when the medical records reveal details about a person's mental state, such as during treatment for mental health. If, in Justice Brandeis' words, the ''right to be let alone'' means anything, then it likely applies to having outsiders have access to one's intimate thoughts, words, and emotions.

In addition to these arguments based on the right to privacy in personal information, market failures will arise to the extent that privacy is less well protected than the parties would have agreed to, if they were fully informed and had the ability to monitor and enforce contracts. The chief market failures with respect to privacy concern information, negotiating, and enforcement costs. The information costs arise because of the information asymmetry between the company and the patient—the company typically knows far more than the patient about how the information will be used by that company. A health care provider or plan, for instance, knows many details about how protected health information will be generated, combined with other databases, or sold to third parties.

[9] American Cancer Society. http://www.cancer.org/statistics/97cff/97facts.html

[10] John Hornberger et al, ''Early treatment with highly active anti-retroviral therapy (HAART) is cost-effective compared to delayed treatment,'' 12th World AIDS conference, 1998.

Patients face at least two layers of cost in learning about how their information is used. First, as with many aspects of health care, patients face the challenge of trying to understand technical medical terminology and practices. It will often be difficult for a patient to understand the medical records and the implications of transferring various parts of such records to a third party. Second, especially in the absence of consistent national rules, patients may face significant costs in trying to learn and understand the nature of a company's privacy policies.

The costs of learning about companies' policies are magnified by the difficulty patients face in detecting whether companies in fact are complying with those policies. Patients might try to adopt strategies for monitoring whether companies have complied with their announced policies. For instance, if a person received health care from several providers that promised not to sell her name to third parties, she could report a different middle initial to each provider. She could then identify the provider that broke the agreement by noticing the middle initials that later appeared on an unsolicited marketing letter. These sorts of strategies, however, are both costly (in time and effort) and likely to be ineffective. A company using the patient's name, for instance, could cross-check her address with her real name, and thereby insert the correct middle initial. In addition, modern health care often requires protected health information to flow legitimately among multiple entities for purposes of treatment, payment, health care operations, and other necessary uses. Even if the patient could identify the provider whose data ultimately leaked, the patient could not easily tell which of those multiple entities had impermissibly transferred her information.

The cost and ineffectiveness of monitoring logically leads to less than optimal protection of health information. Consider the incentives facing a company that acquires protected health information. That company gains the full benefit of using the information, including in its own marketing efforts or in the fee it can receive when it sells the information to third parties. The company, however, does not suffer the full losses from disclosure of protected health information. Because of imperfect monitoring, customers often will not learn of, and thus not be able to enforce against, that unauthorized use. They will not be able to discipline the company efficiently in the marketplace for its less-than-optimal privacy practices. Because the company internalizes the gains from using the information, but does not bear a significant share of the cost to patients (in terms of lost privacy), it will have a systematic incentive to over-use protected health information. In market failure terms, companies will have an incentive to use protected health information where the patient would not have freely agreed to such use.

These difficulties in contract enforcement are made worse by the third-party nature of many health insurance and payment systems. Even where individuals would wish to bargain for privacy, they may lack the legal standing to do so. For instance, employers often negotiate the terms of health plans with insurers. The employee may have no voice in the privacy or other terms of the plan, facing a take-it-or-leave-it choice of whether to be covered by insurance. The incentive of employers may be contrary to the wishes of employees—employers may in some cases inappropriately insist on having access to sensitive medical information in order to monitor employees' behavior and health status. In light of these complexities, there are likely significant market failures in the bargaining on privacy protection. Many privacy-protective agreements that patients would wish to make, absent barriers to bargaining, will not be reached. The economic, legal and philosophical arguments become more compelling as the medical system shifts from predominantly paper to predominantly electronic records. From an economic perspective, market failures will arise to the extent that privacy is less well protected than the parties would have agreed to, if they were fully informed and had some equality of bargaining power. The chief market failures with respect to privacy concern information and bargaining costs. The information costs arise because of the information asymmetry between the company and the patient—the company typically knows far more than the patient about how the information will be used by that company. A health care provider or plan, for instance, knows many details about how protected health information will be generated, combined with other databases, or sold to third parties.

Rapid changes in information technology mean that the size of the market failures will likely increase greatly in the markets for personal health information. Improvements in computers and networking mean that the costs of gathering, analyzing, and disseminating electronic data are plunging. Market forces are leading many medical providers and plans to shift from paper to electronic records, due both to lower cost and the increased functionality provided by having information in electronic form. These market changes will be accelerated by the administrative simplification implemented by the other regulations promulgated under HIPAA. A chief goal of administrative simplification, in fact, is to create a more efficient flow of medical information where appropriate. This proposed privacy regulation is an integral part of the overall effort of administrative simplification; it creates a framework for more efficient flows for certain purposes, including treatment and payment, while restricting flows in other circumstances except where appropriate institutional safeguards exist.

If the medical system shifts to predominantly electronic records in the near future, without use of accompanying privacy rules, then one can imagine a near future where clerical and medical workers all over the country may be able to pull up protected health information about individuals—without meaningful patient consent and without effective institutional controls against further dissemination. In terms of the market failure, it will become more difficult for patients to know how their health provider or plan is using their personal health information. It will become more difficult to monitor the subsequent flows of protected health information, as the number of electronic flows and possible points of leakage both increase. Similarly, the costs and difficulties of bargaining to get the patients' desired level of use will likely rise due the greater number and types of entities that receive protected health information.

As the benefits section, below, discusses in more detail, the protection of privacy and correcting the market failure have practical implications. Where patients are concerned about lack of privacy protections, they might fail to get medical treatment that they would otherwise seek. This failure to get treatment may be especially likely for certain conditions, including mental health, substance abuse, and conditions such as HIV. Similarly, patients who are concerned about lack of privacy protections may report inaccurately to their providers when they do seek treatment. For instance, they might decide not to mention that they are taking prescription drugs that indicate that they have an embarrassing condition. These inaccurate reports may lead to mis-diagnosis and less-than-optimal treatment, including

inappropriate additional medications. In short, the lack of privacy safeguards can lead to efficiency losses in the form of foregone or inappropriate treatment.

The shift from paper to electronic records, with the accompanying greater flows of sensitive health information, also strengthens the arguments for giving legal protection to the right to privacy in protected health information. In an earlier period where it was far more expensive to access and use medical records, the risk of harm to individuals was relatively low. In the potential near future, where technology makes it almost free to send lifetime medical records over the Internet, the risks may grow rapidly. It may become cost-effective, for instance, for companies to offer services that allow purchasers to obtain details of a person's physical and mental treatments. In addition to legitimate possible uses for such services, malicious or inquisitive persons may download medical records for purposes ranging from identity theft to embarrassment to prurient interest in the life of a celebrity or neighbor. Of additional concern, such services might extend to providing detailed genetic information about individuals, without their consent. Many persons likely believe that they have a right to live in society without having these details of their lives laid open to unknown and possibly hostile eyes. These technological changes, in short, may provide a reason for institutionalizing privacy protections in situations where the risk of harm did not previously justify writing such protections into law.

States have, to varying degrees, attempted to enhance confidentiality and correct the market problems by establishing laws governing at least some aspects of medical record privacy. This approach, though a step in the right direction, is inadequate. The states themselves have a patch quilt of laws that fail to provide a consistent or comprehensive policy, and there is considerable variation among the states in the scope of the protections provided. Moreover, health data is becoming increasingly ''national''; as more information becomes available in electronic form, it can have value far beyond the immediate community where the patient resides. Neither private action nor state laws provide a sufficiently rigorous legal structure to correct the market failure now or in the future. Hence, a national policy with consistent rules is a vital step toward correcting the market failure that exists.

In summarizing the need for the proposed regulation, the discussion here has emphasized how the proposed regulation would address violations of a right to privacy in the information about oneself, market failures, and the need for a national policy. These arguments become considerably stronger with the shift from predominantly paper to predominantly electronic records. Other arguments could supplement these justifications. As discussed in the benefits section below, the proposed privacy protections may prevent or reduce the risk of unfair treatment or discrimination against vulnerable categories of persons, such as those who are HIV positive, and thereby, foster better health. The proposed regulation may also help educate providers, plans, and the general public about how protected health information is used. This education, in turn, may lead to better information practices in the future.

Clearly, the growing problem of protecting privacy is widely understood and a major public concern. Over 80 percent of persons surveyed in 1999 agreed with the statement that they had ''lost all control over their personal information.'' A Wall Street Journal/NBC poll on September 16, 1999 asked Americans what concerned them most in the coming century. ''Loss of personal privacy'' topped the list, as the first or second concern of 29 percent of respondents. Other issues such as terrorism, world war, and global warming had scores of 23 percent or less. The regulation is a major step toward addressing this public concern.

D. Baseline Privacy Protections

Determining the impact of the rule on covered entities requires us to establish a baseline for current privacy policies. We must first determine current practices and requirements related to protected information—specifically, practices related to disclosure and use, notification of individuals of information practices, inspection and copying, amendment and correction, administrative policies, procedures, and related documentation.

Privacy practices are most often shaped by professional organizations that publish ethical codes of conduct and by State law. On occasion, State laws defer to professional conduct codes. At present, where neither professional organizations nor States have developed guidelines for privacy practices, an entity may implement privacy practices independently.

Professional codes of conduct or ethical behavior generally can be found as opinions and guidelines developed by organizations such as the American Medical Association, the American Hospital Association, and the American Dental Association. These are generally issued though an organization's governing body. The codes do not have the force of law, but providers often recognize them as binding rules.

State laws are another important means of protecting health information. While professional codes of conduct usually only have slight variations, State laws vary dramatically. Some States defer to the professional codes of conduct, others provide general guidelines for privacy protection, and others provide detailed requirements relating to the protection of information relating to specific diseases or to entire classes of information. In cases where neither State law nor professional ethical standards exist, the only privacy protection individuals have is limited to the policies and standards that the health care entity adopts.

Before we can attempt to determine the impact of the proposed rule on covered entities, we must make an effort to establish the present level of privacy protection. Current privacy protection practices are determined by the standards and practices that the professional associations have adopted for their members and by State laws.

1. Professional Codes of Conduct and the Protection of Health Information

We examined statements issued by five major professional groups, one national electronic network association and a leading managed care association. There are a number of common themes that all the organizations appear to subscribe to:

- The need to maintain and protect an individual's health information;
- Development of policies to ensure the confidentiality of protected health information;
- Only the minimum necessary information should be released to accomplish the purpose for which the information is sought.

Beyond these principles, the major associations differ with respect to the methods used to protect health information. One critical area of difference is the extent to which professional organizations should release protected health information. A major mental health association advocates the release of identifiable patient information ''* * * only when de-identified data are inadequate for the purpose at hand.'' A major association of physicians counsels members who use electronically maintained and transmitted data to require that they and their patients know in advance who has access to protected patient data, and the purposes for which the data will be

used. In another document, the association advises physicians not to ''sell'' patient information to data collection companies without fully informing their patients of this practice and receiving authorization in advance to release of the information.

Only two of the five professional groups state that patients have the right to review their medical records. One group declares this as a fundamental patient right, while the second association qualifies their position by stating that the physician has the final word on a patient's access to their health information. This association also recommends that its members respond to requests for access to patient information within 10 days, and recommends that entities allow for an appeal process when patients are denied access. The association further recommends that when a patient contests the accuracy of the information in their record and the entity refuses to accept the patient's change, the patient's statement should be included as a permanent part of the patient's record.

In addition, three of the five professional groups endorse the maintenance of audit trails that can track the history of disclosures of protected health information.

The one set of standards that we reviewed from a health network association advocated the protection of private health information from disclosure without patient authorization and emphasized that encrypting information should be a principal means of protecting patient information. The statements of a leading managed care association, while endorsing the general principles of privacy protection, were vague on the release of information for purposes other than treatment. They suggest allowing the use of protected health information without the patient's authorization for what they term ''health promotion.'' It is possible that the use of protected health information for ''health promotion'' may be construed under the proposed rule as part of marketing activities.

Based on the review of the leading association standards, we believe that the proposed rule embodies all the major principles expressed in the standards. However, there are some major areas of difference between the proposed rule and the professional standards reviewed. These include the subject individual's right of access to health information in the covered entity's possession, relationships between contractors and covered entities, and the requirement that covered entities make their privacy policies and practices available to patients through a notice and the ability to respond to questions related to the notice. Because the proposed regulation would require that (with a few exceptions) patients have access to their health information that a covered entity possesses, large numbers of providers may have to modify their current practices in order to allow patient access, and to establish a review process if they deny a patient access. Also, none of the privacy protection standards reviewed require that providers or plans prepare a formal statement of privacy practices for patients (although the major physician association urges members to inform patients about who would have access to their protected health information and how their health information would be used). Only one HMO association explicitly made reference to information released for legitimate research purposes, and none of the other statements we reviewed discuss release of information for research purposes. The proposed rule allows for the release of protected health information for research purposes without an individual's authorization, but only for research that is supervised by an institutional research board or an equivalent privacy board. This research requirement may cause some groups to revise their disclosure authorization standards.

2. State Laws

The second body of privacy protections is found in a myriad of State laws and requirements. To determine whether or not the proposed rule would preempt a State law, we first identified the relevant laws, and second, determined whether state or federal law provides individuals with greater privacy protection.

Identifying the relevant state statutes: Health privacy statutes can be found in laws applicable to many issues including insurance, worker's compensation, public health, birth and death records, adoptions, education, and welfare. For example, Florida has over 60 laws that apply to protected health information. According to the Georgetown Privacy Project [11], Florida is not unique. Every State has laws and regulations covering some aspect of medical information privacy. In many cases, State laws were enacted to address a specific situation, such as the reporting of HIV/AIDS, or medical conditions that would impair a person's ability to drive a car. Identifying every State statute, regulation, and court case that interprets statutes and regulations dealing with patient medical privacy rights is an important task but cannot be completed in this discussion. For the purpose of this analysis, we simply acknowledge the complexity of State requirements surrounding privacy issues.

Lastly, we recognize that the private sector will need to complete a State-by-State analysis to comply with the notice and administrative procedures portion of this proposed rule. This comparison should be completed in the context of individual markets; therefore it is more efficient for professional associations or individual businesses to complete this task.

Recognizing limits of our ability to effectively summarize State privacy laws and our difficulty in determining preemption at the outset, we discuss conclusions generated by the Georgetown University Privacy Project in Janlori Goldman's report, *The State of Health Privacy: An Uneven Terrain*. We consider Georgetown's report the best and most comprehensive examination of State privacy laws currently published. The report, which was completed in July 1999, is based on a 50-state survey. However, the author is quick to point out that this study is not exhaustive.

The following analysis of State privacy statutes and our attempt to compare State laws to the proposed rule is limited as a result of the large amount of State-specific data available. To facilitate discussion, we have organized the analysis into two sections: access to medical information and disclosure of medical information. Our analysis is intended to suggest areas where the proposed rule appears to preempt various State laws; it is not designed to be a definitive or wholly comprehensive State-by-State comparison.

Access to Subject's Information: In general, State statutes provide individuals with access to their own medical records. However, only a few States allow individuals access to virtually all entities that hold health information. In 33 States, individuals may access their hospital and health facility records. Only 13 States guarantee individuals access to their HMO records, and 16 States provide individuals access to their medical information when it is held by insurers. Seven states have no statutory right of patient access; three States and the District of Columbia have laws that only assure individuals' right to access their mental health records. Only one State permits individuals access to records held by providers, but it excludes pharmacists from the definition of provider. Thirteen States grant individuals statutory right of access to pharmacy records.

[11] *Ibid*, Goldman, p. 6.

The amount that entities are allowed to charge for copying of individuals' records varies widely from State to State. A study conducted by the American Health Information Management Association [12] found considerable variation in the amounts, structure, and combination of fees for search and retrieval, and the copying of the record.

In 35 States, there are laws or regulations that set a basis for charging individuals inspecting and copying fees. Charges vary not only by State, but also by whether the request is related to a worker's compensation case or a patient-initiated request. Charges also vary according to the setting. For example, States differentiate most often between clinics and hospitals. Also, charges vary by the number of pages and whether the request is for X-rays or for standard medical information.

Of the 35 States with laws regulating inspection and copying charges, seven States either do not allow charges for retrieval of records or require that the entity provide the first copy free of charge. Some States may prohibit hospitals from charging patients a retrieval and copying fee, but allow clinics to do so. It is noteworthy that some States that do not permit charges for retrieval sometimes allow entities to charge per-page rates ranging between $0.50 and $0.75. In States that do allow a retrieval charge, the per-page charge is usually $0.25. Eleven states specify only that the record holder may charge ''reasonable/actual costs.''

Of the States that allow entities to charge for record retrieval and copying, charges range from a flat amount of $1.00 to $20.00. Other States allow entities to charge varying rates depending on the amount of material copied. For example, an entity may charge $5.00 for the first five pages and then a fixed amount per page. In those cases, it appears that retrieval and copying costs were actually combined. The remaining States have a variety of cost structures: One State allows $0.25 per page plus postage plus a $15.00 retrieval charge. Another State allows a $1.00 charge per page for the first 25 pages and $0.25 for each page above 25 pages plus a $1.00 annual retrieval charge. A third state allows a $1.00 per page charge for the first 100 pages and $0.25 for each page thereafter.

According to the report by the Georgetown Privacy Project, among States that do grant access to patient records, the most common basis for denying individuals access is concern for the life and safety of the individual or others. This proposed rule considers the question of whether to deny patient access on the basis of concern for the individual's life or safety, concluding that the benefits of patient access most often outweigh harm to the individual. This issue, which is discussed in greater detail in other sections, has been resolved in favor of promoting patient access.

The amount of time an entity is given to supply the individual with his or her record varies widely. Many States allow individuals to amend or correct inaccurate health information, especially information held by insurers. However, few States provide the right to insert a statement in the record challenging the covered entity's information when the individual and entity disagree.[13]

Disclosure of Health Information: State laws vary widely with respect to disclosure of identifiable health information. Generally, States have applied restrictions on the disclosure of health information either to specific entities or to specific health conditions. Just two states place broad limits on disclosure of protected health information without regard for policies and procedures developed by covered entities. Most States require patient authorization before an entity may disclose health information, but as the Georgetown report points out, ''In effect, the authorization may function more as a waiver of consent—the patient may not have an opportunity to object to any disclosures.'' [14]

It is also important to point out that none of the States appear to offer individuals the right to restrict disclosure of their protected health information for treatment. Thus, the provision of the proposed rule that allows patients to restrict disclosure of the their protected information is not currently included in any State law. Because the ability to restrict disclosure currently is not a standard practice, the proposed rule would require entities to add these capabilities to their information systems.

State statutes often have exceptions to requiring authorization before disclosure. The most common exceptions are for purposes of treatment, payment, or auditing and quality assurance functions—which are similar to the definition we have established for health care operations, are therefore not subject to prior authorization requirements under the proposed rule. Restrictions on re-disclosure of protected health information also vary widely from State to State. Some States restrict the re-disclosure of health information, and others do not. The Georgetown report cites State laws that require providers to adhere to professional codes of conduct and ethics with respect to disclosure and re-disclosure of protected health information. What is not clear is the degree to which individual information is improperly released or used in the absence of specific legal sanctions.

Most States have adopted specific measures to provide additional protections with regard to certain conditions or illnesses that have clear social or economic consequences. Although the Georgetown study does not indicate the number of States that have adopted disease-specific measures to protect information related to sensitive conditions and illnesses, the analysis seems to suggest that nearly all States have adopted some form of additional protection. The conditions and illnesses most commonly afforded added privacy protection are:

- Substance abuse;
- Information derived from genetic testing;
- Communicable and sexually-transmitted diseases;
- Mental health; and
- Abuse, neglect, domestic violence, and sexual assault.

We have included a specific discussion of disclosures for research purposes because if an entity decides to disclose information for research purposes, it will incur costs that otherwise would be associated with other disclosures under this rule. Some States place restrictions on releasing condition-specific health information for research purposes, while others allow release of information for research without the patient's authorization. States frequently require that researchers studying genetic diseases, HIV/AIDS, and other sexually transmitted diseases have different authorization and privacy controls than those used for other types of research. Some States require approval from an IRB or agreements that the data will be destroyed or identifiers removed at the earliest possible time. Another approach has been for States to require researchers to obtain sensitive, identifiable information from a State public health department. One State does not allow automatic release of protected health information for research purposes without notifying the subjects that their health information may be used in research and allowing

[12] ''Practice Briefs,'' Journal of AHIMA; Harry Rhodes, Joan C. Larson, Association of Health Information Outsourcing Service; January 1999.

[13] Ibid, Goldman, p.20.

[14] Ibid, Goldman, p. 21.

them opportunity to object to the use of their information.[15]

Comparing State statutes to the proposed rule: A comparison of State privacy laws with the proposed rule highlights several of the proposed rule's key implications:

- No State law requires covered entities to make their privacy and access policies available to patients. Thus, all covered entities that have direct contact with patients will be required to prepare a statement of their privacy protection and access policies. This necessarily assumes that entities have to develop procedures if they do not already have them in place.
- The proposed rule will affect more entities than are affected under many State laws. In the application of the proposed rule to providers, plans, and clearinghouses, the proposed rule will reach nearly all entities involved in delivering and paying for health care. Yet because HIPAA applies only to information that has been stored and transmitted electronically, the extent to which the proposed rule will reach information held by covered entities is unclear.
- State laws have not addressed the form in which health information is stored. We do not know whether covered entities will choose to treat information that never has been maintained or transmitted electronically in the same way that they treat post-electronic information. We also do not know what portion of information held in non-electronic formats has ever been electronically maintained or transmitted. Nevertheless, the proposed rule would establish a more level floor from which States could expand the privacy protections to include both electronic information and non-electronic information.
- Among the three categories of covered entities, it appears that plans will be the most significantly affected by the access provisions of the proposed rule. Based on the Health Insurance Association of America (HIAA) data,[16] there are approximately 94.7 million non-elderly persons who purchase health insurance in the 35 States that do not provide patients a legal right to inspect and copy their records. We do not have information on how many of those people are in plans that grant patients inspection and copying rights although State law does not require them to do so. We discuss these points more fully in the cost analysis section.
- Although the proposed rule would establish a uniform disclosure and re-disclosure requirement for all covered entities, the groups most likely to be affected are health insurers, benefits management administrators, and managed care organizations. These groups have the greatest ability and economic incentives to use protected health information for marketing services to both patients and physicians without individual authorization. Under the proposed rule, covered entities would have to obtain the individual's authorization before they could use or disclose their information for purposes other than treatment, payment, and health care operations—except in the situations explicitly defined as allowable disclosures without authorization.
- While our proposed rule appears to encompass many of the requirements found in current State laws, it also is clear that within State laws, there are many provisions that cover specific cases and health conditions. Certainly, in States that have no research disclosure requirements, the proposed rule will establish a baseline standard. But in States that do place conditions on the disclosure of protected health information, the proposed rule may place additional requirements on covered entities.
- State privacy laws do not always apply to entities covered by the proposed rule. For example, State laws may provide strong privacy protection for hospitals and doctors but not for dentists or HMOs. State laws protecting particular types of genetic testing or conditions may be similarly problematic because they protect some types of sensitive information and not others. In some instances, a patient's right to inspect his or her medical record may be covered under State laws and regulations when a physician has the medical information, but not under State requirements when the information being sought is held by a plan. Thus, the proposed rule would extend privacy requirements already applicable to some entities within a State to other entities that currently are not subject to State privacy requirements.

3. Federal Laws

The Privacy Act of 1974. Federal agencies will be required to comply with both the Privacy Act of 1974 (5 U.S.C. 552a) and the HIPAA regulation. The Privacy Act provides Federal agencies with a framework and scheme for protecting privacy, and the HIPAA regulation will not alter that scheme. Basic organizational and management features, such as the provision of safeguards to protect the privacy of health information and training for employees—which are required by this proposed rule—already are required by the Privacy Act.

The proposed rule has been designed so that individuals will not have fewer rights than they have now under the Privacy Act. It may require that agencies obtain individual authorization for some disclosures that they now make without authorization under routine uses.

Private-sector organizations with contracts to conduct personal data handling activities for the Federal government are subject to the Privacy Act by virtue of performing a function on behalf of a Federal agency. They too will be required to comply with both rules in the same manner as Federal agencies.

Substance Abuse Confidentiality Statute. Organizations that operate specialized substance abuse treatment facilities and that either receive Federal assistance or are regulated by a Federal agency are subject to confidentiality rules established by section 543 of the Public Health Service Act (42 U.S.C. 290dd–2) and implementing regulations at 42 CFR part 2.

These organizations will be subject both to that statute and to the HIPAA regulation. The proposed rule should have little practical effect on the disclosure policies of these organizations, because the patient confidentiality statute governing information about substance abuse is generally more restrictive than this proposed rule. These organizations will continue to be subject to current restrictions on their disclosures. The substance abuse confidentiality statute does not address patient access to records; the proposed privacy rule makes clear that patient access is allowed.

Federal agencies are subject to these requirements, and currently they administer their records under both these requirements and the Privacy Act. The Department of Veterans Affairs is subject to its own substance abuse confidentiality statute, which is identical in substance to the one of more general applicability. It also covers information about HIV infection and sickle cell anemia (38 U.S.C. 7332).

Rules Regarding Protection of Human Subjects. Health care delivered by covered entities conducting clinical trials typically are subject to both the

[15] ''Medical records and privacy: empirical effects of legislation; A memorial to Alice Hersh'; McCarthy, Douglas B; Shatin, Deborah; *et al. Health Service Research:* April 1, 1999; No. 1, Vol. 34; p. 417. The article details the effects of the Minnesota law conditioning disclosure of protected health information on patient authorization.

[16] *Source Book of Health Insurance Data: 1997–1998*, Health Insurance Association of America, 1998. p. 33.

proposed rule and to Federal regulations for protection of human re search subjects (The Federal Policy for the Protection of Human Subjects, codified for the Department of Health and Human Services in Title 45 CFR part 46, and/or the Food and Drug Administration's human subject regulations for research in support of medical product applications to the Food and Drug Administration, or regulated by that agency, at 21 CFR parts 50 and 56).

Current human subjects rules impose no substantive restrictions on disclosure of patient information. Institutional review boards must consider the adequacy of confiden tiality protections for subjects, and researchers must tell subjects to what extent their con fidentiality will be protected. There should be no conflict between these requirements and the proposed rules. The proposed HIPAA regulation will expand on the current human subjects requirements by requiring a more detailed description of intended use of patient information. The proposed HIPAA rule also requires additional criteria for waiver of patient authorization.

Medicaid. States may use information they obtain in the process of administering Medicaid only for the purposes of administering the program, pursuant to a State plan condition in section 1902(a)(7) of the Social Security Act, 42 U.S.C. 1396a(a)(7). The proposed HIPAA rule applies to State Medicaid programs, which under the rule are considered health plans. There will be no conflict in the substantive requirements of current rules and this proposed rule. Medicaid rules regarding disclosure of patient information are stricter than provisions of the proposed rule; therefore, Medicaid agencies simply will continue to follow the Medicaid rules.

ERISA. ERISA (29 U.S.C. 1002) was enacted in 1974 to regulate pension and welfare employee benefit plans that are established by private-sector employers, unions, or both, to provide benefits to their workers and dependents. An employee welfare benefit plan provides benefits—through insurance or otherwise—such as medical, surgical benefits, as well as benefits to cover accidents, disability, death, or unemployment. In 1996, HIPAA amended ERISA to require portability, nondiscrimination, and renewability of health benefits provided by group health plans and group health insurance issuers. Many, although not all, ERISA plans are covered under the proposed rule as health plans. We believe that the proposed rule does not conflict with ERISA. Further discussion of ERISA can be found in the preamble for this proposed rule.

E. Costs

Affected entities will be implementing the privacy proposed rules at the same time many of the administrative simplification standards are being implemented. As described in the overall impact analysis for the administrative simplification standards in the **Federal Register**, Vol. 63, No. 88, May 7, 1998, page 25344, the data handling changes occurring due to the other HIPAA standards will have both costs and benefits. To the extent the changes required for the privacy standards implementations can be made concurrently with the changes required for the other standards, costs for the combined implementation should be only marginally higher than for the administrative simplification standards alone. The extent of this additional cost is uncertain, in the same way that the costs associated with each of the individual administrative simplification standards was uncertain.

The costs associated with implementing the privacy standards will be directly related to the number of affected entities and the number of affected transactions in each entity.[17] We chose to use the SBA data in the RFA because we wanted our analysis to be as consistent to SBA definitions as possible to give the greatest accuracy for the RFA purposes. As described in the overall administrative simplification impact estimates (Tables 1 and 2, page 25344), about 20,000 health plans (excluding non-self administered employer plans)[18] and hundreds of thousands of providers face implementation costs. In the administrative simplification analysis, the costs of provider system upgrades were expected to be $3.6 billion over the period 1998–2002, and plan system cost upgrades were expected to be $2.2 billion. (In the aggregate, this $5.8 billion cost is expected to be more than completely offset by $7.3 billion in savings during the 5 year period analyzed).

The relationship between the HIPAA security and privacy standards is particularly relevant. On August 12, 1998, the Secretary published a proposed rule to implement the HIPAA standards on security and electronic standards. That rule specified the security requirements for covered entities that transmit and store information specified in Part C, Title XI of the Act. In general, that rule would establish the administrative and technical standards for protecting ''* * * any health information pertaining to an individual that is electronically maintained or transmitted.'' (63 FR 43243). The security rule is intended to spell out the system and administrative requirements that a covered entity must meet in order to assure itself and the Secretary that the protected health information is safe from destruction and tampering from people without authorization for its access.

By contrast, the privacy rule describes the policies and procedures that would govern the circumstances under which protected health information may be used and released with and without patient authorization and when a patient may have access to his or her protected medical information. This rule assumes that a covered entity will have in place the appropriate security apparatus to successfully carry out and enforce the provisions contained in the security rule.

Although the vast majority of health care entities are privately owned and operated, Federal, State, and local government providers are reflected in the total costs.[19] Federal, state, and locally funded hospitals represent approximately 26 percent of hospitals in the United States. This is a significant portion of hospitals, but represents a relatively small proportion of all

[17] We have used two different data sources for our estimates of the number of entities. In the regulatory impact analysis (RIA), we chose to use the same number of entities cited in the other Administrative Simplification rules. In the regulatory flexibility analysis (RFA), we used the most recent data available from the Small Business Administration (SBA).

We chose to use the Administrative Simplification estimates in the RIA because we wanted our analysis to be as consistent as possible with those regulations. We also believe that because the Administrative Simplification numbers are higher than those in the SBA data, it was the more conservative data source.

[18] We have not included the 3.9 million ''other'' employer health plans listed in HCFA's administrative simplification regulations because these plans that are administered by a third party. The proposed regulation will not regulate the employer-plans but will regulate the third party administrators of the plans. Because plan administrators have already been included in our analysis, these other employer-sponsored plans will not incur additional costs.

[19] These costs only represent those of public entities serving in the role of provider plan. The federal costs only reflect those incurred by a provider and plan offering Medicaid or Medicare, and hospitals run by the federal government including those run by the Veteran's Administration and the militry. Federal enforcement and other costs are not included. These estimates do not reflect any larger systems changes necessary to running federal programs. Likewise State costs are incorporated to the extent that States serve as providers or plans (including Medicaid).

provider entities. The number of government providers who are employed at locations other than government hospitals is significantly smaller (approximately 2 percent of all providers). Weighting the relative number of government hospital and non-hospital providers by the revenue these types of providers generate, we estimate that health care services provided directly by government entities represent 3.4 percent of total health care services. IHS and Tribal facilities costs are included in the total, since the adjustments made to the original private provider data to reflect federal providers included them. In drafting the proposed rule the Department consulted with States, representatives of the National Congress of American Indians, representatives of the National Indian Health Board, and a representative of the self-governance tribes. During the consultation we discussed issues regarding the application of Title II of HIPAA to the States and Tribes.

Estimating the costs associated with the privacy proposed rule involves, for each provision, consideration of both the degree to which covered entities must modify their records management systems and privacy policies under the proposed rule, and the extent to which there is a change in behavior of both patients and the covered entities as a result of the proposed rule. In the following sections we will examine these provisions as they would apply to the various covered entities as they undertake to comply with the proposed rule. The major costs that covered entities will incur are one time costs associated with implementation of the proposed rules, and ongoing costs that result from changes in behavior that both the covered entities and patients would make in response to the new proposed rules.

We have quantified the costs imposed by the proposed regulation to the extent that we had adequate data. In some areas, however, there was too little data to support quantitative estimates. As a result, the RIA does not include cost estimates for all of the requirements of the regulation. The areas for which explicit cost estimates have not be made are: The principle of minimum necessary disclosure; the requirement that entities monitor business partners with whom they share PHI; creation of de-identified information; internal complaint processes; sanctions; compliance and enforcement; the designation of a privacy official and creation of a privacy board; and additional requirements on research/optional disclosures that will be imposed by the regulation. The cost of some of these provisions may be significant, but it would be inaccurate to project costs for these requirements given the fact that several of these concepts are new to the industry.

The one time costs are primarily in the area of development and codification of procedures. Specific activities include: (1) Analysis of the significance of the federal regulations on covered entity operation; (2) development and documentation of policies and procedures (including new ones or modification of existing ones); (3) dissemination of such policies and procedures both inside and outside the organization; (4) changing existing records management systems or developing new systems; and (5) training personnel on the new policies and system changes.

Covered entities will also incur ongoing costs. These are likely to be the result of: (1) Increased numbers of patient requests for access and copying of their own records; (2) the need for covered entities to obtain patient authorization for uses of protected information that had not previously required an authorization; (3) increased patient interest in limiting payer and provider access to their records; (4) dissemination and implementation both internally and externally of changes in privacy policies, procedures, and system changes; and (5) training on the changes.

Compliance with the proposed rule will cost $3.8 billion over five years. These costs are in addition to the administrative simplification estimates. The cost of complying with the regulation represents 0.09 percent of projected national health expenditures the first year the regulation is enacted. The five year costs of the proposed regulation also represents 1.0 percent of the increase in health care costs experienced over the same five-year period.[20] Because of the uncertainty of the data currently available, the Department has made estimates on ''low'' and ''high'' range assumptions of the key variables. These estimates show a range of $1.8 to $6.3 billion over five years. It is important to note that these estimates do not include the areas for which we have made no cost estimates (discussed above).

Initial Costs

Privacy Policies and Procedures

With respect to the initial costs for covered entities, the expectation that most of the required HIPAA procedures will be implemented as a package suggests that additional costs for the privacy standards should be small. Since the requirements for developing formal processes and documentation of procedures mirror what will already have been required under the security regulations, the additional costs should be small. The expectation is that national and state associations will develop guidelines or general sets of processes and procedures and that these will generally be adopted by individual member entities. Relatively few providers or entities are expected to develop their own procedures independently or to modify significantly those developed by their associations. Our estimates are based on assumed costs for providers ranging from $300 to $3000, with the weighted average being about $375. The range correlates to the size and complexity of the provider, and is a reasonable estimate of the cost of coordinating the policies and procedures outlined in the proposed regulation. With fewer than 1 million provider entities, the aggregate cost would be on the order of $300 million.

For plans, our estimate assumes that the legal review and development of written policies will be more costly because of the scope of their operations. They are often dealing with a large number of different providers and may be dealing with requirements from multiple states. Again, we expect associations to do much of the basic legal analysis but plans are more likely to make individual adaptations. We believe this cost will range from $300 for smaller plans and $15,000 for the largest plans. Because there are very few large plans in relation to the number of small plans, the weighted average implementation costs will be about $3050.

The total cost of development of policies and procedures for providers and plans is estimated to be $395 million over five years.

System Compliance Costs

With respect to revisions to electronic data systems, the specific refinements needed to fulfill the privacy obligations ought to be closely tied to the refinements needed for security obligations. The overall administrative simplification system upgrades (procedures, systems, and training) of $5.8 billion would certainly be disproportionately associated with the security standard, relative to the other 11 elements. If in privacy it constitutes 15 percent, then the security standard would represent about $900 million system cost. If the marginal cost of the privacy elements is another 10 percent,

[20] Health Care Finance Administration, Office of the Actuary, 1997.

then the addition cost would be $90 million.

Ongoing Costs

The recurrent costs may be more closely related to total numbers of persons with claims than to the number of covered entities. The number of individuals served by an entity will vary greatly. The number of persons with claims will give a closer approximation of how many people entities will have to interact with for various provisions.

Notice of Privacy Practices

No State laws or professional associations currently require entities to provide patients ''notice'' of their privacy policies. Thus, we expect that all entities will incur costs developing and disseminating privacy policy notices. Each entity will have a notice cost associated with each person to whom they provide services. Data from the 1996 Medical Expenditure Panel Survey shows that there are approximately 200 million ambulatory care encounters per year, nearly 20 million persons with a hospital episode, 7 million with home-health episodes, and over 170 million with prescription drug use (350 million total). For the remaining four years of the five year period, we have estimated that, on average, a quarter of the remaining population will enter the system, and thus receive a notice. If we account for growth in the number of people who may enter the health care system over the five year period of our analysis, we estimate that approximately 543 million patients will be seen at least once by one or more types of providers.

The development cost for notices is estimated to cost $30 million over five years, though most of this is likely to occur the first year. The first year cost of providing notices to patients, customers and plan enrollees would be $106 million. The total five year cost of providing new and subsequent copies to all provider patients and customers would be approximately $209 million.

The notice obligations of insurers apply on initial enrollment, with updated notices at least every 3 years. However, given enrollment changes and the sophistication of automation, we believe many plans would find it cheaper and more efficient to provide annual notices.

The 1998 National Health Interview Survey (NHIS) from the Census Bureau shows about 174.1 million persons are covered by private health insurance, on an unduplicated basis. NHIS calculates that persons who are privately insured hold approximately 1.3 policies per person. Based on information provided by several plans, we believe most plans would provide an independent mailing the first year, but in subsequent years would provide notices as an inclusion in other mailings. The cost for this would be $0.75 over five years. If we account for these duplicate policies and assume that the cost of sending the notices to a policyholder is $0.75, the total cost to plans would be $231 million over five years. This includes both public and private plans.

We request comments regarding our cost estimates for development and distribution of notices.

The costs for more careful internal operation of covered entities to execute their formal privacy procedures are highly dependent on the extent to which current practice tracks the future procedures. Entities that already have strict data sharing and confidentiality procedures will incur minimal costs, since their activities need not change much. Entities that have not developed explicit health information privacy policies may be compelled to obtain patient authorization in situations where they did not previously. These changes will generate ongoing costs as well as initial costs. We solicit comment with respect to the way current costs differ from those projected by the requirements of the proposed privacy rule. An example of such an area is ''the minimum necessary disclosure principle''—because of differing current practices, we do not have data that reliably indicate how much this provision will cost.

Inspection and Copying

The Georgetown report on State privacy laws indicates that 33 states currently give patients some right to access medical information. The most common right of access granted by State law is the right to inspect personal information held by physicians and hospitals. In the process of developing estimates for the cost of providing access and copying, we assumed that most providers currently have procedures for allowing patients to inspect and copying their own record. Thus, we expect that the economic impact of requiring entities to allow individuals to access and copy their records should be relatively small. Copying costs, including labor, should be a fraction of a dollar per page. We expect the cost to be passed on to the consumer.

There are few studies that address the cost of providing medical records to patients. The most recent was a study in 1998 by the Tennessee Comtroller of the Treasury. It found an average cost of $9.96 per request, with an average of 31 pages per request. The total cost per page of providing copies was $0.32 per page. This study was performed on hospitals only. The cost per request may be lower for other types of providers, since those seeking hospital records are more likely to be sick and have more complicated records than those in a primary care or other type of office. An earlier report showed much higher costs than the Tennessee study. In 1992, Rose Dunn published a report based on her experience as a manager of medical records. She estimated a 10 page request would cost $5.32 in labor costs only, equaling labor cost per page of $0.53. However, this estimate appears to reflect costs before computerization. The expected time spent per search was 30.6 minutes; 85 percent of this time could be significantly reduced with computerization (this includes time taken for file retrieval, photocopying, and re-filing; file retrieval is the only time cost that would remain under computerization.) For subsequent estimates, we will use the Tennessee experience.

The proposed regulation states that entities may charge patients a reasonable fee to inspect and copy their health information. For this reason, we expect the cost of inspecting and copying an individual medical record to be passed on to consumers who request the service. Nonetheless, it is important to provide an estimate of the potential costs associated with inspection and copying. We assume that 1.5 percent of patients will request access to inspect and copy their medical record, and that the cost of accessing and copying a record is approximately $10 (as cited in the Tennessee study). The cost of inspection and copying is $81 million a year, or $405 million over five years. This cost is likely to be borne entirely by the consumer.

Amendment and Correction

We have assumed that many providers make provisions to help patients expedite amendment and correction of their medical record where appropriate. However, as with inspection and copying, the right to request amendment and correction of an individual's medical record is not guaranteed by all States. Based on these assumptions and our cost analysis, we conclude that the principal economic effect of the proposed rule would be to expand the right to request amendment and correction to plans and providers that are not covered by state laws or codes of conduct. In addition, we expect that the proposed rule may draw additional attention to the issue of record inaccuracies and stimulate

patient demand for access, amendment, and correction of medical records.

Our cost calculations assume that persons who request an opportunity to amend or correct their record have already obtained a copy of their medical record. Therefore, the administrative cost of amending and correcting the patient's record is completely separate from inspection and copying costs. In this section we have only addressed the cost of disputing a factual statement within the patient record, and do not calculate the cost of appeals or third party review.

Administrative review of factual statements contained within a patient's record may be expensive. Most errors may be of a nature that a clerk or nurse can correct (e.g., the date of a procedure is incorrect) but some may require physician review. Thus, we have estimated that the average cost of amending and correcting a patient record may be $75 per instance.

If amendment and correction requests are associated with two-thirds of requests for inspection and copying, and the cost of correcting (or noting the patient's request for correction) is $75, the total cost of amending and correcting patient records will be $407 million annually, or $2 billion over five years. Comments on our estimate of amendment and correction costs would be helpful, particularly if they speak to current amendment and correction costs or frequency in the health care industry.

Reconstructing a History of Disclosures (Other Than for Treatment and Payment)

To our knowledge, no current State law or professional code requires providers and plans to maintain the capability to reconstruct a patient's health information history. Therefore, the requirement in this rule to be able to reconstruct the disclosure history of protected health information is completely new. Although it is likely that some providers and plans have already developed this capability, we assume that all providers and plans would be required to invest in developing the capacity to generate disclosure histories.

With respect to reconstruction of disclosure history, two sets of costs would exist. On electronic records, fields for disclosure reason, information recipient, and date would have to be built into the data system. The fixed cost of the designing the system to include this would be a component of the $90 million additional costs discussed earlier. The ongoing cost would be the data entry time, which should be at de minimis levels. Comments would again be especially useful with respect to the extent to which recording the additional information goes beyond current practice.

Authorizations

Although many States have laws that require entities to obtain patient authorization before releasing individually identified health information to payers and other third parties, many of the authorization requirements either allow for blanket authorizations that deprive the patient of meaningful control over the release of their health information, or the authorization statutes are less stringent than the provisions of the proposed rule. Therefore, for purposes of estimating the economic impact of the NPRM, we are assuming that all providers and plans will have to develop new procedures to conform to the proposed rule.

Written patient authorization requirements will generate costs, to the extent covered entities are currently releasing information in the targeted circumstances without specific authority. Collecting such authorization should have costs on the order of those associated with providing access to records (not on a per page basis). The frequency of such collections is unknown. Since the requirement does not apply to treatment and payment, assuming 1 percent of the 543 million encounters over five years might be reasonable. At a cost of about $10 each, the aggregate cost would be about $54 million annually, or $271 million over five years. Comments would be especially useful from entities currently following such procedures.

Training

The ongoing costs associated with paperwork and training are likely to be minimal. Because training happens as a regular business practice, and employee certification connected to this training is also the norm, we estimate that the marginal cost of paperwork and training is likely to be small. We assume a cost of approximately $20 per provider office, and approximately $60–100 for health plans and hospitals. Thus, we estimate that the total cost of paperwork and training will be $22 million a year.

Conclusion

Overall, the five-year costs beyond those already shown in the administrative simplification estimates would be about $3.8 billion over five years, with an estimated range of $1.8 to $6.3 billion. Table 2 shows the components described above. The largest cost item is for amendment and correction, which is over half of the estimated total cost of the regulation. Inspection and copying, at $405 million over five years, and issuance of notices by providers and plans, at $439 million over five years, are the second biggest components. The one-time costs of development of policies and procedures by providers would represent approximately 10 percent of the total cost, or $333 million. Plans and clearinghouses would have a substantially smaller cost, about $62 million. Other systems changes are expected to cost about $90 million over the period. Finally, the estimates do not consider all of the costs imposed by the regulation.

TABLE 2.—THE COST OF COMPLYING WITH THE PROPOSED PRIVACY REGULATION

[In Dollars]

Provision	Initial or first year cost (2000)	Annual cost after the first year	Five year (2000–2004) cost
Development of Policies and Procedures—Providers (totaling 871,294)	$333,000,000	.....	$333,000,000
Development of Policies and Procedures—Plans (totaling 18,225)	62,000,000	.....	62,000,000
System Changes—All Entities	90,000,000	.....	90,000,000
Notice Development Cost—all entities	20,000,000	.....	30,000,000
Notice Issuance—Providers	59,730,000	37,152,000	208,340,000
Notice Issuance—Plans	46,200,000	46,200,000	231,000,000
Inspection/Copying	81,000,000	81,000,000	405,000,000
Amendment/Correction	407,000,000	407,000,000	2,035,000,000
Written Authorization	54,300,000	54,300,000	271,500,000

TABLE 2.—THE COST OF COMPLYING WITH THE PROPOSED PRIVACY REGULATION—Continued

[In Dollars]

Provision	Initial or first year cost (2000)	Annual cost after the first year	Five year (2000–2004) cost
Paperwork/Training	22,000,000	22,000,000	110,000,000
Other Costs*	**N/E	N/E	N/E
Total	1,165,230,000	647,652,000	3,775,840,000

*Other Costs include: minimum necessary disclosure; monitoring business partners with whom entities share PHI; creation of de-identified information; internal complaint processes; sanctions; compliance and enforcement; the designation of a privacy official and creation of a privacy board; additional requirements on research/optional disclosures that will be imposed by the regulation.

**N/E = ''Not estimated''.

Costs to the Federal Government

The proposed rule will have a cost impact on various federal agencies that administer programs that require the use of individual health information. Federal agencies or programs clearly affected by the rule are those that meet the definition of a covered entity. The costs when government entities are serving as providers are included in the total cost estimates. However, non-covered agencies or programs that handle medical information, either under permissible exceptions to the disclosure rules or through an individual's expressed authorization, will likely incur some costs complying with provisions of this rule. A sample of federal agencies encompassed by the broad scope of this rule include the: Department of Health and Human Services, Department of Defense, Department of Veterans Affairs, Department of State, and the Social Security Administration.

The federal costs of complying with the regulation are included in the estimates of total costs. The greatest cost and administrative burden on the federal government will fall to agencies and programs that act as covered entities, by virtue of being either a health plan or provider. Examples include the Medicare, Medicaid, Children's Health Insurance and Indian Health Service programs at the Department of Health and Human Services; the CHAMPVA health program at the Department of Veterans Affairs; and the TRICARE health program at the Department of Defense. These and other health insurance or provider programs operated by the federal government are subject to requirements placed on covered entities under this proposed rule, including, but not limited to, those outlined in Section D of the impact analysis. While many of these federal programs already afford privacy protections for individual health information through the Privacy Act, this rule is expected to create additional requirements beyond those covered by existing Privacy Act rule. Further, we anticipate that most federal health programs will, to some extent, need to modify their existing Privacy Act practices to fully comply with this rule.

The cost to federal programs that function as health plans will be generally the same as those for the private sector. The primary difference is the expectation that systems compliance costs may be higher due to the additional burden of compliance and oversight costs.

A unique cost to the federal government will be in the area of enforcement. The Office of Civil Rights (OCR), located at the Department of Health and Human Services, has the primary responsibility to monitor and audit covered entities. OCR will monitor and audit covered entities in both the private and government sectors, will ensure compliance with requirements of this rule, and will investigate complaints from individuals alleging violations of their privacy rights. In addition, OCR will be required to recommend penalties and other remedies as part of their enforcement activities. These responsibilities represent an expanded role for OCR. Beyond OCR, the enforcement provisions of this rule will have additional costs to the federal government through increased litigation, appeals, and inspector general oversight.

Examples of other unique costs to the federal government include such activities as public health surveillance at the Centers for Disease Control and Prevention, health research projects at the Agency for Health Care Policy and Research, clinical trials at the National Institutes of Health, and law enforcement investigations and prosecutions by the Federal Bureau of Investigations. For these and other activities, federal agencies will incur some costs to ensure that protected health information is handled and tracked in ways that comply with the requirements of this title. A preliminary analysis of these activities suggests that the federal cost will be on the order of $31 million. We are currently in the process of refining these estimates and will include better information on them in the final rule.

Costs to State Governments

The proposed rule will also have a cost effect on various state agencies that administer programs that require the use of individual health information. State agencies or programs clearly affected by the rule are those that meet the definition of a covered entity. The costs when government entities are serving as providers are included in the total cost estimates. However, non-covered agencies or programs that handle medical information, either under permissible exceptions to the disclosure rules or through an individual's expressed authorization, will likely incur some costs complying with provisions of this rule. Samples of state agencies encompassed by the broad scope of this rule include the: Medicaid, Children's Health Insurance program at the Department of Health and Human Services.

We have included state costs in the estimation of total costs. The greatest cost and administrative burden on the state government will fall to agencies and programs that act as covered entities, by virtue of being either a health plan or provider. Examples include the Medicaid, Children's Health Insurance program at the Department of Health and Human Services. These and other health insurance or provider programs operated by state government are subject to requirements placed on covered entities under this proposed rule, including, but not limited to, those outlined in Section D of the impact analysis. While many of these state programs already afford privacy protections for individual health information through the Privacy Act, this rule is expected to create additional requirements beyond those covered by

existing Privacy Act rule. Further, we anticipate that most state health programs will, to some extent, need to modify their existing Privacy Act practices to fully comply with this rule.

The cost to state programs that function as health plans will be different than the private sector, much as the federal costs vary from private plans. A preliminary analysis suggests that state costs will be on the order of $90 million over five years. We will refine the estimates for the state government costs for enforcement, research and other distinct state government functions in the final rule. We welcome comment by state and local governments which will help the Department improve its analysis on these state costs.

F. Benefits

As we have discussed in the preamble, there are important societal benefits associated with improving health information privacy. Confidentiality is a key component of trust between patients and providers, and some studies indicate that a lack of privacy may deter patients from obtaining preventive care and treatment.[21] For these reasons, traditional approaches to estimating the value of a commodity cannot fully capture the value of personal privacy. It may be difficult for individuals to assign value to privacy protection because most individuals view personal privacy as a right. Because we promote the view that privacy protection is an important personal right, the benefits of the proposed regulation are impossible to estimate based on the market value of health information alone. However, it is possible to evaluate some of the benefits that may accrue to individuals as a result of proposed regulation, and these benefits, alone, suggest that the regulation is warranted. Added to these benefits is the intangible value of privacy, the personal security that we may feel when our records are confidential, which is very real and very significant but for which there is no economic value or proxy.

There are a number of ways to discuss the expected benefits of this proposed regulation. The first option is to discuss the benefits qualitatively. We believe that this is necessary to give the reader a basic understanding of how this proposed regulation will benefit society. The second option that we have used is to quantify the benefits of the proposed rule as they would apply to a few illness categories that may be particularly responsive to privacy concerns. This quantitative discussion is meant to be illustrative of the benefits rather than a comprehensive accounting of all of the benefits of the proposed rule. The combination of the two approaches clearly illustrates that the benefits of the regulation are significant in relation to the economic costs.

Before beginning our discussion of the benefits, it is important to create a framework for how the costs and benefits may be viewed in terms of individuals rather than societal aggregates. We have estimated the value an insured individual would need to place on increased privacy to make the proposed Privacy regulation a net benefit to those who receive health insurance. Our estimates are derived from data produced by the 1998 Current Population Survey from the Census Bureau, and report that 220 million persons are covered by either private or public health insurance. Joining the Census Bureau data with cost assumptions calculated in Section E, we have estimated the cost of the proposed regulation is $3.41 per insured individual. If we assume that individuals who use the health care system will be willing to pay more than $3.41 per year (or approximately $0.28 per month) to improve health information privacy, the benefits of the proposed regulation will outweigh the cost.

This is a conservative estimate of the number of people who will benefit from the regulation because it assumes that only those individuals who have health insurance will use medical services or benefit from the provisions of the proposed regulation. Currently, there are 44 million Americans who do not have any form of health care insurance. In addition, the estimates do not include those who pay for medical care directly, without any insurance or government support. By lowering the number of users in the system, we have inflated our estimate of the per-person cost of the regulation, therefore, we assume that our estimate represents the highest cost to an individual.

An alternative approach to determining how people would have to value increased privacy for this regulation to be beneficial is to look at the costs divided by the number of encounters with health care professionals annually. Data from the Medical Expenditure Panel Survey (MEPS) produced by the Agency for Health Care Policy Research (AHCPR) report approximately 1.62 billion health care visits, or encounters annually (e.g., office visits, hospital and nursing home stays, etc.). As with our calculation of average annual cost per insured patient, we have divided the total cost of complying with the regulation ($751 million per year) by the total annual number of health care encounters. The cost of instituting requirements of the proposed regulation is $0.46 per health care encounter. If we assume that individuals would be willing to pay more than $0.46 per health care encounter to improve health information privacy, the benefits of the proposed regulation will outweigh the cost.

Qualitative Discussion

A well designed privacy standard can be expected to build confidence among the public about the confidentiality of their medical records. The seriousness of public concerns about privacy in general are shown in the 1994 Equifax-Harris Consumer Privacy Survey, where ''84 percent of Americans are either very or somewhat concerned about threats to their personal privacy.''[22] A 1999 report, ''Promoting Health and Protecting Privacy'' notes ''* * * many people fear their personal health information will be used against them: to deny insurance, employment, and housing, or to expose them to unwanted judgements and scrutiny.''[23] These concerns would be partly allayed by the privacy standard. Further, increased confidence will increase the likelihood of some people seeking treatment for particular classes of disease. It will also change the dynamic of current payments. Insured patients currently paying out-of-pocket for confidentiality reasons will be more likely to file with their insurer. The increased utilization that would result from increased confidence in privacy could be beneficial under many circumstances. For many medical conditions, early treatment can lead to lower costs.

Fear of disclosure of treatment is an impediment to health care for many Americans. In the 1993 Harris-Equifax Health Information Privacy Survey, 7 percent of respondents said they or a member of their immediate family had chosen not to seek medical services due to fear of harm to job prospects or other life opportunities. About 2 percent reported having chosen not to file an insurance claim because of concerns with privacy or confidentiality.[24] Increased confidence on the part of patients that their privacy would be protected would lead to increased

[21] Equifax-Harris Consumer Privacy Survey, 1994.

[22] *Consumer Privacy Survey*, Harris-Equifax, 1994, p. vi.

[23] *Promoting Health: Protecting Privacy*, California Health Care Foundation and Consumers Union, January 1999, p. 12.

[24] *Health Information Privacy Survey*, Harris-Equifax, 1993, pp. 49–50.

treatment among people who delay or never begin care, as well as among people who receive treatment but pay directly (to the extent that the ability to use their insurance benefits will reduce cost barriers to more complete treatment).

The following are four examples of areas where increased confidence in privacy would have significant benefits. They were chosen both because they are representative of widespread and serious health problems, and because they are areas where reliable and relatively complete data are available for this kind of analysis. The logic of the analysis, however, applies to any health condition. Even for relatively minor conditions, an individual still might be concerned with maintaining privacy, and even a person with no significant health problems is going to value privacy because of the possibility at some time they will have a condition that they want to keep private.

Cancer. The societal burden of disease imposed by cancer is indisputable. Cancer is the second leading cause of death in the US,[25] exceeded only by heart disease. In 1999, 1.38 million new cancer cases will be diagnosed, as well as 900,000 new basal and squamous skin cell cancers.[26] The National Cancer Institute estimates that the overall cost of cancer is $104 billion; $35 billion in direct medical cost, $12 billion for morbidity costs (cost of lost productivity) and $57 billion for mortality costs.[27]

Among the most important elements in the fight against cancer are screening, early detection and treatment of the disease. However, however, many patients are concerned that some screening procedures will make them vulnerable to discrimination by insurers or employers. These privacy concerns have been cited as a reason patients do not seek early treatment for diseases such as cancer. As a result of forgoing early screening, cancer patients may ultimately face a more severe illness. For example, half of new diagnoses occur among types of cancer for which screening is available. Based on this research, studies show that if Americans participated in regular cancer screening, the rate of survival among patients who have screening-accessible cancers could increase to 95 percent.[28]

Approximately 184,300 women will be diagnosed with breast cancer this year,[29] and 25,000 women will be diagnosed with ovarian cancer.[30] In the same year, almost 44,000 women will die of breast cancer,[31] and 14,500 will die from ovarian cancer.[32] Early detection of these cancers could have a significant impact on reducing loss due to disability and death. For example, only 24 percent of ovarian cancers are diagnosed in the early stages. Of these, approximately 90 percent of patients survive treatment. The survival rate of women who detect breast cancer early is similarly high; more than 90 percent of women who detect and treat breast cancer in its early stages will survive.[33]

Researchers have developed screening techniques to identify breast, ovarian, and colon cancers, and tests have been developed to identify the presence or absence of cellular abnormalities that may lead to cancer. Despite these technological advances, the principle of patient autonomy requires that patients must decide for themselves if they will submit to screening procedures. Many individuals fear that employers and insurers will use cancer screening to discriminate against them. Several studies illustrate that persons with and without cancer fear discrimination. Thus, despite the potential benefits that early identification of cancer may yield, many researchers find that patient concerns regarding the confidentiality of cancer screening may prevent them from requesting the test, and result in disability or loss of life.

HIV/AIDS. Early detection is essential for the health and survival of an HIV (Human Immunodeficiency Virus) positive person. Concerns about the confidentiality of HIV status may prevent some people from getting tested. For this reason, each state has passed some sort of legislation regarding the confidentiality of HIV status. However, HIV status can be revealed indirectly through disclosure of HAART (Highly Active Anti-Retroviral Therapy) or similar HIV treatment drug use. In addition, since HIV/AIDS (Acquired Immune Deficiency Syndrome) is often the only specially protected condition, ''blacked out'' information on medical charts could indicate HIV positive status.[34] Strengthening privacy protections beyond this disease could increase confidence in privacy regarding HIV as well. Drug therapy for HIV positive persons has proven to be a life-extending, cost-effective tool.[35] A 1998 study showed that beginning treatment with HAART in the early asymptomatic stage is more cost-effective than beginning it late. After five years, only 15 percent of patients with early treatment are estimated to develop an ADE (AIDS-defining event), whereas 29 percent would if treatment began later. Early treatment with HAART prolongs survival (adjusted for quality of life) by 6.2 percent. The overall cost-effectiveness of early HAART treatment is estimated at $23,700 per quality-adjusted year of life saved.[36]

Other Sexually Transmitted Diseases. It is difficult to know how many people are avoiding testing for STDs despite having a sexually transmitted disease. A 1998 study by the Kaiser Family Foundation found that the incidence of disease was 15.3 million in 1996, though there is great uncertainty due to under-reporting.[37] For a potentially embarrassing disease such as an STD, seeking treatment requires trust in both the provider and the health care system for confidentiality. Greater trust should lead to more testing and greater levels of treatment. Earlier treatment for curable STDs can mean a decrease in morbidity and the costs associated with complications. These include expensive fertility problems, fetal blindness, ectopic pregnancies, and other reproductive complications.[38] In addition, there could be greater overall savings if earlier treatment translates into reduced spread of infections.

Substance Abuse and Mental Health Treatment. When individuals have a better understanding of the privacy practices that we are requiring in this proposed rule, some will be less reluctant to seek substance abuse and mental health treatment. One way that individuals will receive this information is through the notice requirement.

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[25] American Cancer Society. http://4a2z.com/cgi/rfr.cgi?4CANCER-2-http://www.cancer.org/frames.html

[26] American Cancer Society. http://www.cancer.org/statistics/97cff/97facts.html

[27] American Cancer Society. http://www.cancer.org/statistics/97cff/97facts.html

[28] American Cancer Society. http://www.cancer.org/statistics/97cff/97facts.html

[29] Avon's Breast Cancer Crusade. http://www.pmedia.com/Avon/library/faq.html

[30] Ovarian Cancer National Alliance. http://www.ovariancancer.org/index.shtml

[31] Cancer Statistics, 1999, Landis, Murray, Bolden and Wingo. CA: A Cancer Journal for Clinicians, Jan/Feb, 1999, Vol. 49, No. 1

[32] Ovarian Cancer National Alliance. http://www.ovariancancer.org/index.shtml

[33] Breast Cancer Information Service. http://trfn.clpgh.org/bcis/FAQ/facts2.html

[34] *Promoting Health: Protecting Privacy,* California Health Care Foundation and Consumers Union, January 1999, p. 13.

[35] For example, Roger Detels, M.D., et al., in ''Effectiveness of Potent Anti-Retroviral Therapy * * * ''JAMA, 1998; 280: 1497–1503 note the impact of therapy on HIV persons with respect to lengthening the time to development of AIDS, not just delaying death in persons who already have AIDS.

[36] John Hornberger *et al,* ''Early treatment with Highly Active Anti-Retroviral Therapy (HAART) is cost-effective compared to delayed treatment,'' 12th World AIDS conference, 1998.

[37] *Sexually Transmitted Diseases in America,* Kaiser Family Foundation, 1998. p. 12.

[38] Standard Medical information; see *http://www.mayohealth.org* for examples.

Increased use of mental health services would be expected to be beneficial to the persons receiving the care, to their families, and to society at large. The individual direct benefit from treatment would include an improved quality of life, reduced disability associated with the mental conditions, and a reduced mortality rate. The benefit to families would include quality of life improvements and reduced medical costs for other family members associated with abusive behavior by the treated individual. The benefit to society would include reduced costs of crime and reduced future public program treatment costs.

The 1998 Substance Abuse and Mental Health Statistics Source Book from SAMHSA reports cost-of-disease estimates from a range of studies, suggesting several hundred billion dollars of non-treatment costs associated with alcohol, drug, and mental (ADM) disorders. As an example of the magnitude of costs associated with mental health treatment, a 1997 National Institutes of Health report suggests that the total economic cost of mental health disorders such as anxiety, depressive (mood) disorders, eating disorders, and schizophrenia is approximately $115.5 billion annually.[39] Evidence suggests that appropriate treatment of mental health disorders can result in 50–80 percent of individuals experiencing improvements in these types of conditions. Improvements in patient functioning and reduced hospital stays could result in hundreds of million of dollars in cost savings annually.

The potential additional economic benefits associated with improving patient confidentiality and thus encouraging some unknown portion of individuals to either seek initial mental health treatment or increase service use are difficult to quantify well. Nevertheless, one can lay out a range of possible benefit levels to illustrate the possibility of cost savings associated with an expansion of mental health treatment to individuals who, due to protections offered by the privacy regulation, might seek mental health treatment that they otherwise would not have absent this regulation. This can be illustrated by drawing upon existing data on both the economic costs of mental illness and the treatment effectiveness of mental health interventions.

Although figures on the number of individuals who avoid mental health treatment due to privacy concerns do not exist, some indirect evidence is available. A 1993 Harris-Equifax Health Information Privacy Survey (noted earlier) found that 7 percent of respondents reported that they or a member of their immediate family had chosen not to seek services for a physical or mental health condition due to fear of harm to job prospects or other life opportunities. It should be noted that this survey is somewhat dated and represents only one estimate. Moreover, given the wording of the question, there are other reasons aside from privacy concerns that led these individuals to respond positively.

For the purpose of an illustration, however, assumptions can be made about what proportion of the 7 percent responding affirmatively to this question may have avoided seeking mental health services due to privacy concerns. Given the proportion of mental health services that compromise total health care services in this country, a reasonable upper limit of the number of individuals avoiding mental health treatment due to privacy concerns might be 1.8 percent (*i.e.*, 25% of 7%), while a reasonable lower limit might be 0.36 percent (*i.e.*, 5% of 7%). Taking these figures as upper and lower limits, it is possible to estimate potential benefits by multiplying these figures by the annual economic cost reductions associated with treatment effectiveness rates. For example, using the upper limit of 1.8 percent, multiplying this by the annual economic costs of mental illness ($115.5 billion) and a treatment effectiveness rate of 80 percent, yields an estimate of potential annual benefits of $1,663,200,000. Similarly, using the upper limit of 1.8 percent coupled with a treatment effectiveness rate of 50 percent yields an estimate of potential annual benefits of $1,039,500,000. Assuming a lower limit of 0.36 percent more individuals seeking mental health treatment due to enhance privacy protections, coupled with a treatment effectiveness rate of 80% yields an estimate of potential annual benefits of $332,640,000. Similarly, using the lower limit of 0.36 percent coupled with a treatment effectiveness rate of 50 percent yields an estimate of potential annual benefits of $207,900,000. Therefore, given the existing data on the annual economic costs of mental illness and the rates of treatment effectiveness for these disorders, coupled with assumptions regarding the percentage of individuals who might seek mental health treatment under conditions of greater privacy protections, the potential additional economic benefit in this one treatment area could range from approximately $208 million to $1.67 billion annually.

TABLE 3.—POTENTIAL BENEFITS OF THE PROPOSED PRIVACY REGULATION FROM COST SAVINGS DUE TO EARLY TREATMENT OF MENTAL HEALTH DISORDERS

Illness	Total annual economic cost of illness (in billions)	Percent net cost reduction if additional care is received
Mental Health—Anxiety Disorders	$46.6	70–90
Mental Health—Depressive (Mood) Disorders	30.4	60–80
Mental Health—Eating Disorders	6.0	40–60
Mental Health—Schizophrenia	32.5	60–85
Total	115.5	N/A

[39] *Disease-Specific Estimates of Direct and Indirect Costs of Illness and NIH Support; 1997 Update,* 1997.

G. Examination of Alternative Approaches

1. Creation of De-identified Information (164.506(d))

We considered defining ''individually identifiable health information'' as any information that is not anonymous, that is, for which there is any possibility of identifying the subject. We rejected this option, for several reasons. First, the statute suggests a different approach. The term ''individually identifiable health information'' is defined in HIPAA as health information that:

> * * * identifies the individual, or with respect to which there is a reasonable basis to believe that the information can be used to identify the individual.

By including the modifier ''reasonable basis,'' Congress appears to reject the absolute approach to defining ''identifiable.'' Covered entities would not always have the statistical sophistication to know with certainty when sufficient identifying information has been removed so that the record is no longer identifiable. We believe that covered entities need more concrete guidance as to when information will and will not be ''identifiable'' for purposes of this regulation.

Defining non-identifiable to mean anonymous would require covered entities to comply with the terms of this regulation with respect to information for which the probability of identification of the subject is very low. We want to encourage covered entities and others to remove obvious identifiers or encrypt them whenever possible; use of the absolute definition of ''identifiable'' would not promote this salutary result.

For these reasons, we propose at § 164.506(d)(2)(ii) that there be a presumption that, if specified identifying information is removed and if the holder has no reason to believe that the remaining information can be used by the reasonably anticipated recipients alone or in combination with other information to identify an individual, then the covered entity would be presumed to have created de-identified information.

At the same time, in proposed § 164.506(d)(2)(iii), we are leaving leeway for more sophisticated data users to take a different approach. We are including a ''reasonableness'' standard so that entities with sufficient statistical experience and expertise could remove or code a different combination of information, so long as the result is still a low probability of identification. With this approach, our intent is to provide certainty for most covered entities, while not limiting the options of more sophisticated data users.

In this rule we are proposing that covered entities and their business partners be permitted to use protected health information to create de-identified health information. Covered entities would be permitted to further use and disclose such de-identified information in any way, provided that they do not disclose the key or other mechanism that would enable the information to be re-identified, and provided that they reasonably believe that such use or disclosure of de-identified information will not result in the use or disclosure of protected health information. See proposed § 164.506(d)(1). This means that a covered entity could not disclose de-identified information to a person if the covered entity reasonably believes that the person would be able to re-identify some or all of that information, unless disclosure of protected health information to such person would be permitted under this proposed rule. In addition, a covered entity could not use or disclose the key to coded identifiers if this rule would not permit the use or disclosure of the identified information to which the key pertains. If a covered entity re-identifies the de-identified information, it may only use or disclose the re-identified information consistent with these proposed rules, as if it were the original protected health information.

We invite comment on the approach that we are proposing and on whether alternative approaches to standards for entities determining when health information can reasonably be considered no longer individually identifiable should be considered.

2. General Rules (§ 164.506)

As a general rule, we are proposing that protected health information not be used or disclosed by covered entities except as authorized by the individual who is the subject of such information or as explicitly provided this rule. Under this proposal, most uses and disclosures of an individual's protected health information would not require explicit authorization by the individual, but would be restricted by the provisions of the rule. Covered entities would be able to use or disclose an individual's protected health information without authorization for treatment, payment and health care operations. See proposed § 164.506(a)(1)(i). Covered entities also would be permitted to use or disclose an individual's protected health information for specified public and public policy-related purposes, including public health, research, health oversight, law enforcement, and use by coroners. Covered entities would be *permitted* by this rule to use and disclose protected health information when required to do so by other law, such as a mandatory reporting requirement under State law or pursuant to a search warrant. See proposed § 164.510. Covered entities would be *required* by this rule to disclose protected health information for only two purposes: to permit individuals to inspect and copy protected health information about them (see proposed § 164.514) and for enforcement of this rule (see proposed § 164.522(d)).

Covered entities of all types and sizes would be required to comply with the proposed privacy standards outlined below. The proposed standards would not impose particular mechanisms or procedures that covered entities must adopt to implement the standards. Instead, we would require that each affected entity assess its own needs and devise, implement, and maintain appropriate privacy policies, procedures, and documentation to address its business requirements. How each privacy standard would be satisfied would be a business decision that each entity would have to make. This permits the privacy standards to establish a stable baseline, yet remain flexible enough to take advantage of developments and methods for protecting privacy that will evolve over time.

Because the privacy standards would need to be implemented by all covered entities, from the smallest provider to the largest, multi-state health plan, a single approach to implementing these standards would be neither economically feasible nor effective in safeguarding health information privacy. For example, in a small physician practice the office manager might be designated to serve as the privacy official as one of many duties (see proposed § 164.518(a)) whereas at a large health plan, the privacy official may constitute a full time position and have the regular support and advice of a privacy staff or board.

In taking this approach, we intend to strike a balance between the need to maintain the confidentiality of protected health information and the economic cost of doing so. Health care entities must consider both aspects in devising their solutions. This approach is similar to the approach we proposed in the Notice of Proposed Rulemaking for the administrative simplification security and electronic signature standards.

3. Use and Disclosure for Treatment, Payment, and Health Care Operations (§ 164.506(a))

We are proposing that, subject to limited exceptions for psychotherapy notes and research information unrelated to treatment discussed below, a covered entity be permitted to use or disclose protected health information without individual authorization for treatment, payment or health care operations.

We are not proposing to require individual authorizations of uses and disclosures for health care and related purposes, although such authorizations are routinely gathered today as a condition of obtaining health care or enrolling in a health plan. Although many current disclosures of health information are made pursuant to individual authorizations, these authorizations provide individuals with little actual control over their health information. When an individual is required to sign a blanket authorization at the point of receiving care or enrolling for coverage, that consent is often not voluntary because the individual must sign the form as a condition of treatment or payment for treatment. Individuals are also often asked to sign broad authorizations but are provided little or no information about how their health information would be or will in fact be used. Individuals cannot make a truly informed decision without knowing all the possible uses, disclosures and re-disclosures to which their information will be subject. In addition, since the authorization usually precedes creation of the record, the individual cannot predict all the information the record could contain and therefore cannot make an informed decision as to what would be released.

Our proposal is intended to make the exchange of protected health information relatively easy for health care purposes and more difficult for purposes other than health care. For individuals, health care treatment and payment are the core functions of the health care system. This is what they expect their health information will be used for when they seek medical care and present their proof of insurance to the provider. Consistent with this expectation, we considered requiring a separate individual authorization for every use or disclosure of information but rejected such an approach because it would not be realistic in an increasingly integrated health care system. For example, a requirement for separate patient authorization for each routine referral could impair care, by delaying consultation and referral as well as payment.

We therefore propose that covered entities be permitted to use and disclose protected health information without individual authorization for treatment and payment purposes, and for related purposes that we have defined as health care operations. For example, providers could maintain and refer to a medical record, disclose information to other providers or persons as necessary for consultation about diagnosis or treatment, and disclose information as part of referrals to other providers. Providers also could use a patient's protected health information for payment purposes such as submitting a claim to a payer. In addition, providers could use a patient's protected health information for health care operations, such as use for an internal quality oversight review. We would note that, in the case of an individual where the provider has agreed to restrictions on use or disclosure of the patient's protected health information, the provider would be bound by such restrictions as provided in § 164.506(c).

We also propose to prohibit covered entities from seeking individual authorization for uses and disclosures for treatment, payment and health care operations unless required by State or other applicable law. As discussed above in section II.C, such authorizations could not provide meaningful privacy protections or individual control and could in fact cultivate in individuals erroneous understandings of their rights and protections.

The general approach that we are proposing is not new. Some existing State health confidentiality laws permit disclosures without individual authorization to other health care providers treating the individual, and the Uniform Health-Care Information Act permits disclosure ''to a person who is providing health-care to the patient'' (9 Part I, U.L.A. 475, 2–104 (1988 and Supp. 1998)). We believe that this approach would be the most realistic way to protect individual confidentiality in an increasingly data-driven, electronic and integrated health care system. We recognize, however, that particularly given the limited scope of the authority that we have under this proposed rule to reach some significant actors in the health care system, that other approaches could be of interest. We invite comments on whether other approaches to protecting individuals' health information would be more effective.

4. Minimum Necessary Use and Disclosure (§ 164.506(b))

We propose that, except as discussed below, a covered entity must make all reasonable efforts not to use or disclose more than the minimum amount of protected health information necessary to accomplish the intended purpose of the use or disclosure, taking into consideration technological limitations.

Under this proposal, covered entities generally would be required to establish policies and procedures to limit the amount of protected health care information used or disclosed to the minimum amount necessary to meet the purpose of the use or disclosure, and to limit access to protected health information only to those people who need access to the information to accomplish the use or disclosure. With respect to use, if an entity consists of several different components, the entity would be required to create barriers between components so that information is not used inappropriately. The same principle applies to disclosures.

A ''minimum necessary'' determination would need to be consistent with and directly related to the purpose of the use or disclosure and take into consideration the ability of a covered entity to delimit the amount of information used or disclosed and the relative burden imposed on the entity. The proposed minimum necessary requirement is based on a reasonableness standard: covered entities would be required to make reasonable efforts and to incur reasonable expense to limit the use and disclosure of protected health information as provided in this section.

In our discussions of the minimum necessary requirement, we considered whether or not this should apply to all entities and whether or not it should be applied to all protected health information. We decided that the principle of minimum necessary disclosure is critical to the protection of privacy and that because small entities represent 83 percent of the health care industry, we would not exempt them from this provision without undermining its effectiveness.

We understand that the requirements outlined in this section do not create a bright line test for determining the minimum necessary amount of protected health information appropriate for most uses or disclosures. Because of this lack of precision, we considered eliminating the requirement altogether. We also considered merely requiring covered entities to address the concept within their internal privacy

procedures, with no further guidance as to how each covered entity would address the issue. These approaches were rejected because minimizing both the amount of protected health information used and disclosed within the health care system and the number of persons who have access to such information is vital if we are to successfully enhance the confidentiality of people's personal health information. We invite comments on the approach that we have adopted and on alternative methods of implementing the minimum necessary principle.

5. Right To Restrict Uses and Disclosures (§ 164.506(c))

We propose to permit in § 164.506(c) that individuals be able to request that a covered entity restrict further uses and disclosures of protected health information for treatment, payment, or health care operations, and if the covered entity agrees to the requested restrictions, the covered entity could not make uses or disclosures for treatment, payment or health care operations that are inconsistent with such restrictions, unless such uses or disclosures are mandated by law. This provision would not apply to health care provided to an individual on an emergency basis.

We should note that there is nothing in this proposed rule that would require a covered entity to agree to a request to restrict, or to treat or provide coverage to an individual requesting a restriction under this provision. Covered entities who do not wish to, or due to contractual obligations cannot, restrict further use or disclosure are not obligated to agree to a request under this provision.

We considered providing individuals substantially more control over their protected health information by requiring all covered entities to attempt to accommodate any restrictions on use and disclosure requested by patients. We rejected this option as unworkable. While industry groups have developed principles for requiring patient authorizations, we have not found widely accepted standards for implementing patient restrictions on uses or disclosures. Restrictions on information use or disclosure contained in patient consent forms are sometimes ignored because they may not be read or are lost in files. Thus, it seems unlikely that a requested restriction could successfully follow a patient's information through the health care system—from treatment to payment, through numerous operations, and potentially through certain permissible disclosures. Instead we would limit the provision to restrictions that have been agreed to by the covered entity.

We recognize that the approach that we are proposing could be difficult because of the systems limitations described above. However, we believe that the limited right for patients proposed in this proposed rule can be implemented because it only applies in instances in which the covered entity agrees to the restrictions. We assume that covered entities would not agree to restrictions that they are unable to implement.

We considered limiting the rights under this provision to patients who pay for their own health care (or for whom no payment was made by a health plan). Individuals and providers that engage in self-pay transactions have minimal effect on the rights or responsibilities or payers or other providers, and so there would be few instances when a restriction agreed to in such a situation would have negative implications for the interests of other health care actors. Limiting the right to restrict to self-pay patients also would reduce the number of requests that would be made under this provision. We rejected this approach, however, because the desire to restrict further uses and disclosures arises in many instances other than self-pay situations. For example, a patient could not want his or her records shared with a particular physician because that physician is a family friend. Or an individual could be seeking a second opinion and may not want his or her treating physician consulted. Individuals have a legitimate interest in restricting disclosures in these situations. We solicit comment on the appropriateness of limiting this provision to instances in which no health plan payment is made on behalf of the individual.

6. Application to Business Partners (§ 164.506(e))

In § 164.506(e), we propose to require covered entities to take specific steps to ensure that protected health information disclosed to a business partner remains protected. We intend these provisions to allow customary business relationships in the health care industry to continue while providing privacy protections to the information shared in these relationships. Business partners would not be permitted to use or disclose protected health information in ways that would not be permitted of the covered entity itself under these rules.

Other than for purposes of consultation or referral for treatment, we would allow covered entities to disclose protected health information to business partners only pursuant to a written contract that would, among other specified provisions, limit the business partner's uses and disclosures of protected health information to those permitted by the contract, and would impose certain security, inspection and reporting requirements on the business partner. We would hold the covered entity responsible for certain violations of this proposed rule made by their business partners, and require assignment of responsibilities when a covered entity acts as a business partner of another covered entity.

Under this proposed rule, a business partner would be acting on behalf of a covered entity, and we propose that its use or disclosure of protected health information be limited to the same extent that the covered entity for whom they are acting would be limited. Thus, a business partner could have no more authority to use or disclose protected health information than that possessed by the covered entity from which the business partner received the information. We would note that a business partner's authority to use and disclose protected health information could be further restricted by its contract with a covered entity, as described below.

We are not proposing to require the business partners of covered entities to develop and distribute a notice of information practices, as provided in proposed § 164.512. A business partner would, however, be bound by the terms of the notice of the covered entity from which it obtains protected health information. See proposed § 164.506(e). We are proposing this approach so that individuals could rely on the notices that they receive from the covered entities to which they disclose protected health information. If the business partners of a covered entity were able to make wider use or make more disclosures than the covered entity, the patients or enrollees of the covered entity would have difficulty knowing how their information was being used and to whom it was being disclosed.

We are also proposing that a business partner's use and disclosure of protected health information be limited by the terms of the business partner's contractual agreement with the covered entity. We propose that a contract between a covered entity and a business partner could not grant the business partner authority to make uses or disclosures of protected health information that the covered entity itself would not have the authority to make. The contract between a covered entity and a business partner could further limit the business partner's authority to

use or disclose protected health information as agreed to by the parties. Further, the business partner would have to apply the same limitations to its subcontractors (or persons with similar arrangements) who assist with or carry out the business partner's activities.

To help ensure that the uses and disclosures of business partners are limited to those recognized as appropriate by the covered entities from whom they receive protected health information, subject to the exception discussed below, we are proposing that covered entities be prohibited from disclosing protected health information to a business partner unless the covered entity has entered into a written contract with the business partner that meets the requirements of this subsection. See proposed § 164.506(e)(2)(i).

The contract requirement that we are proposing would permit covered entities to exercise control over their business partners' activities and provides documentation of the relationship between the parties, particularly the scope of the uses and disclosures of protected health information that business partners could make. The presence of a contract also would formalize the relationship, better assuring that key questions such as security, scope of use and disclosure, and access by subject individuals are adequately addressed and that the roles of the respective parties are clarified. Finally, a contract can bind the business partner to return any protected health information from the covered entity when the relationship is terminated.

In lieu of a contracting requirement, we considered imposing only affirmative duties on covered entities to ensure that their relationships with business partners conformed to the standards discussed in the previous paragraph. Such an approach could be considered less burdensome and restrictive, because we would be leaving it to the parties to determine how to make the standards effective. We rejected this approach primarily because we believe that in the vast majority of cases, the only way that the parties could establish a relationship with these terms would be through contract. We also determined that the value of making the terms explicit through a written contract would better enable the parties to know their roles and responsibilities, as well as better enable the Secretary to exercise her oversight role. In addition, we understand that most covered entities already enter into contracts in these situations and therefore this proposal would not disturb general business practice. We invite comment on whether there are other contractual or non-contractual approaches that would afford an adequate level of protection to individuals' protected health information. We also invite comment on the specific provisions and terms of the proposed approach.

We are proposing one exception to the contracting requirement: when a covered entity consults with or makes a referral to another covered entity for the treatment of an individual, we would propose that the sharing of protected health information pursuant to that consultation or referral not be subject to the contracting requirement described above. See proposed § 164.506(e)(1)(i). Unlike most business partner relationships, which involve the systematic sharing of protected health information under a business relationship, consultation and referrals for treatment occur on a more informal basis among peers, and are specific to a particular individual. Such exchanges of information for treatment also appear to be less likely to raise concerns about further impermissible use or disclosure, because providers receiving such information are unlikely to have a commercial or other interest in using or disclosing the information. We invite comment on the appropriateness of this exception, and whether there are additional exceptions that should be included in the final regulation.

We note that covered health care providers receiving protected health information for consultation or referral purposes would still be subject to this rule, and could not use or disclose such protected health information for a purpose other than the purpose for which it was received (i.e., the consultation or referral). Further, we note that providers making disclosures for consultations or referrals should be careful to inform the receiving provider of any special limitations or conditions to which the disclosing provider has agreed to impose (e.g., the disclosing provider has provided notice to its patients that it will not make disclosures for research).

We are proposing that covered entities be accountable for the uses and disclosures of protected health information by their business partners. A covered entity would be in violation of this rule if the covered entity knew or reasonably should have known of a material breach of the contract by a business partner and it failed to take reasonable steps to cure the breach or terminate the contract. See proposed § 164.506(e)(2)(iii). A covered entity that is aware of impermissible uses and disclosures by a business partner would be responsible for taking such steps as are necessary to prevent further improper use or disclosures and, to the extent practicable, for mitigating any harm caused by such violations. This would include, for example, requiring the business partner to retrieve inappropriately disclosed information (even if the business partner must pay for it) as a condition of continuing to do business with the covered entity. A covered entity that knows or should know of impermissible use of protected health information by its business partner and fails to take reasonable steps to end the breach would be in violation of this rule.

We considered requiring covered entities to terminate relationships with business partners if the business partner committed a serious breach of contact terms required by this subpart or if the business partner exhibited a pattern or practice of behavior that resulted in repeated breaches of such terms. We rejected that approach because of the substantial disruptions in business relationships and customer service when terminations occur. We instead require the covered entity to take reasonable steps to end the breach and mitigate its effects. We would expect covered entities to terminate the arrangement if it becomes clear that a business partner cannot be relied upon to maintain the privacy of protected health information provided to it. We invite comments on our approach here and whether requiring automatic termination of business partner contracts would be warranted in any circumstances.

We also considered imposing more strict liability on covered entities for the actions of their business partners, just as principals are strictly liable for the actions of their agents under common law. We decided, however, that this could impose too great a burden on covered entities, particularly small providers. We are aware that, in some cases, the business partner will be larger and more sophisticated with respect to information handling than the covered entity. Therefore we instead opted to propose that covered entities monitor use of protected health information by business partners, and be held responsible only when they knew or should have known of improper use of protected health information.

Our intention in this section is to recognize the myriad of business relationships that currently exist and to ensure that when they involve the exchange of protected health information, the roles and responsibilities of the different parties with respect to the protected health

information are clear. We do not propose to fundamentally alter the types of business relationships that exist in the health care industry or the manner in which they function. We request comments on the extent to which our proposal would disturb existing contractual or other arrangements among covered entities and business partners.

7. Application to Information About Deceased Persons (§ 164.506(f))

We are proposing that information otherwise protected by these regulations retain that protection for two years after the death of the subject of the information. The only exception that we are proposing is for uses and disclosures for research purposes.

HIPAA includes no temporal limitations on the application of the privacy protections. Although we have the authority to protect individually identifiable health information maintained by a covered entity indefinitely, we are proposing that the requirements of this rule generally apply for only a limited period, as discussed below. In traditional privacy law, privacy interests, in the sense of the right to control use or disclosure of information about oneself, cease at death. However, good arguments exist in favor both of protecting and not protecting information about the deceased. Considering that one of the underlying purposes of health information confidentiality is to encourage a person seeking treatment to be frank in the interest of obtaining care, there is good reason for protecting information even after death. Federal agencies and others sometimes withhold sensitive information, such as health information, to protect the privacy of surviving family members. At the same time, perpetual confidentiality has serious drawbacks. If information is needed for legitimate purposes, the consent of a living person legally authorized to grant such consent must be obtained, and the further from the date of death, the more difficult it may be to identify the person. The administrative burden of perpetual protection may eventually outweigh the privacy interests served.

While various State laws have been passed specifically addressing privacy of genetic information, there is currently no federal legislation that deals with these issues. We considered extending the two-year period for genetic and hereditary information, but were unable to construct criteria for protecting the possible privacy interests of living children without creating extensive burden for information holders and hampering health research. We invite comments on whether further action is needed in this area and what types of practical provisions may be appropriate to protect genetic and hereditary health information.

8. Uses and Disclosures With Individual Authorization (§ 164.508)

Covered entities would be required to obtain individual authorization to use individually identifiable health information for purposes other than those allowed under the rule. Activities requiring authorization include, for example, marketing. Costs will be ongoing for staffing and administrative activities related to obtaining authorization from individuals.

Our proposal is based on the precept that a combination of strict limits on how covered entities can use and disclose protected health information, adequate notice to individuals about how their information will be used, and guaranteeing individuals' rights to inspect, copy and amend their health records will provide patients with better privacy protection and more effective control over their information than alternative approaches to privacy protection.

This section addresses the requirements that we are proposing when protected health information is disclosed pursuant to the individual's explicit authorization. The regulation would require that covered entities have authorization from individuals before using or disclosing their protected health information for any purpose not otherwise recognized by this regulation. Circumstances where an individual's protected health information could be used or disclosed without authorization are discussed in connection with proposed §§ 164.510 and 164.522 below.

This section proposes different conditions governing such authorizations in two situations in which individuals commonly authorize covered entities to disclose information:

- Where the individual initiates the authorization because he or she wants a covered entity to disclose his or her record, and
- Where a covered entity asks an individual to authorize it to disclose or use information for purposes other than treatment, payment or health care operations.

The requirements proposed in this section are not intended to interfere with normal uses and disclosures of information in the health care delivery or payment process, but only to allow control of uses extraneous to health care. The restrictions on disclosure that the regulation would apply to covered entities may mean that some existing uses and disclosures of information could take place only if the individual explicitly authorized them under this section.

We considered requiring a uniform set of requirements for all authorizations, but concluded that it would be appropriate to treat authorizations initiated by the individual differently from authorizations sought by covered entities. There are fundamental differences, in the uses of information and in the relationships and understandings among the parties, in these two situations. When individuals initiate authorizations, they are more likely to understand the purpose of the release and to benefit themselves from the use or disclosure. When a covered entity asks the individual to authorize disclosure, we believe the entity should make clear what the information will be used for, what the individual's rights are, and how the covered entity would benefit from the requested disclosure.

We are proposing several requirements that would have to be met in the authorization process when the individual has initiated the authorization. We understand that the requirements that we are imposing here would make it quite unlikely that an individual could actually initiate a completed authorization, because few individuals would know to include all of these elements in a request for information. In most instances, individuals authorize a use or disclosure by completing a form provided by a third party, either the ultimate recipient of the information (who may have a form authorizing them to obtain the records from the record holders) or a health care provider or health plan holding the records (who may have a form that documents a request for the release of records to a third party). For this reason, we do not believe that our proposal would create substantial new burdens on individuals or covered entities in cases when an individual is initiating an authorized release of information. We invite comment on whether we are placing new burdens on individuals or covered entities. We also invite comment on whether the approach that we have proposed provides sufficient protection to individuals who seek to have their protected health information used or disclosed.

We are proposing that when covered entities initiate the authorization by asking individuals to authorize disclosure, the authorization be required to include all of the items required above as well as several additional items. We are proposing additional

requirements when covered entities initiate the request for authorization, because in many cases it could be the covered entity, and not the individual, that achieves the primary benefit of the disclosure. We considered permitting covered entities to request authorizations with only the basic features proposed for authorizations initiated by the individual, for the sake of simplicity and consistency. However, we believe that additional protections are merited when the entity that provides or pays for health care requests authorizations to avert possible coercion.

We also acknowledge that there will be costs related to moving away from a blanket authorization system. These costs will be discussed more explicitly in the sections on allowable disclosures (both with and without authorization).

Covered entities and third parties that wish to have information disclosed to them will prepare forms for individuals to use to authorize use or disclosure. A model authorization form is displayed in Appendix A to this proposed rule. We considered presenting separate model forms for the two different types of authorizations (initiated by the individual and not initiated by the individual). However, this approach could be subject to misuse and be confusing to covered entities and individuals, who may be unclear as to which form is appropriate in specific situations. The model in the appendix accordingly is a unitary model, which includes all of the requirements for both types of authorization. By following such a model, covered entities, particularly small entities, could avoid the legal and administrative expenses that would be necessary to develop an authorization form that complies with the rule's requirements. The proposed rule does not prevent entities from developing or modifying their own authorization forms. The alternative to providing this model was to simply state that an authorization would be required and allow entities to develop the authorization independently. While we would specify some information required in the authorization in this alternative, we would not give an actual form. This was considered to be an unnecessary burden for entities.

Finally, we are proposing that an individual be permitted to revoke an authorization at any time except to the extent that action has been taken in reliance on the authorization. See proposed § 164.508(e).

9. Uses and Disclosures Permitted Without Individual Authorization (§ 164.510)

This section describes uses and disclosures of protected health information that covered entities could make for purposes other than treatment, payment, and health care operations without individual authorization, and the conditions under which such uses and disclosures could be made. We propose to allow covered entities to use or disclose protected health information without individual authorization for such purposes if the use or disclosure would comply with the applicable requirements of this section.

Covered entities could need to reevaluate and modify their operating procedures to comply with the proposed rule's prohibition on disclosing individually identifiable health information without patient authorization for any purpose other than treatment, payment, health care operations, or those situations explicitly identified as permissible disclosures under this proposed rule. Many entities could already do this. Entities that do not do this would need to alter information management systems and implement administrative policies and procedures to prevent inappropriate disclosures. Entities would also have to determine whether or not an authorization is necessary for each disclosure beyond treatment, payment, and health care operations that is not explicitly defined as a permissible disclosure under this proposed rule. It should be noted that the minimum necessary principle is an important component of the costs related to any disclosure. We expect that there would be significant initial and ongoing costs.

If an entity chooses to disclose protected health information without authorization from individuals, there would be a number of new provisions that it would have to comply with. For example, if a disclosure is to researchers outside of the organization, the entity must obtain written documentation indicating that the research has been approved by an institutional review board (IRB) or equivalent process by a privacy board. This requirement is associated with ongoing administrative costs. We note that any such costs are optional unless other requirements (state laws, mandatory reporting systems, etc.) mandate these disclosures. In order to minimize the burden of these costs for mandatory disclosures, we have tried to apply as few business partner requirements as possible in areas where these mandatory disclosures are possible. However, in cases where the disclosure is optional, entities would have higher costs if they choose to use these disclosures. We expect that entities would consider these costs before making any such disclosure and determine if the benefits to their business of disclosure are greater than the costs related to making the disclosure. Additionally, other than the new requirements for disclosures for research, most of the disclosures are simply recognizing current practices and would not require large new costs.

We considered permitting uses and disclosures only where law affirmatively requires the covered entity to use or disclose protected health information. However, because the activities described below are so important to the population as a whole, we decided to permit a covered entity to use or disclose information to promote those activities even when such activities are not legally mandated. In some cases, however, we would permit a use or disclosure only when such use or disclosure is authorized by other law. The requirements for verification of legal authority are discussed in section II.G.3.

Disclosures that are required by current law would only require minimal additional costs to entities. The only cost directly attributable to this proposed requirement would be the additional cost of noting these disclosures on the accounting of uses and disclosures.

However, disclosures required by this proposed regulation should be considered new costs. These mandatory disclosures would be extremely rare. For example, we expect that the Department would limit the number of compliance audits conducted. In these cases, some of the more expensive activities, including the minimum necessary principle and determining whether or not to make the disclosure, would not be applicable.

We would restrict the discussion of discretionary disclosures to the general principles behind such disclosures rather than a detailed description of each allowable disclosure. More elaborate discussion of options for individual classes of disclosures can be found in the preamble. These disclosures are optional disclosures and therefore, any costs related to making these disclosures would incur optional costs. We do not have a complete understanding of how often these disclosures are currently made, nor do we understand what procedures are currently in place. We also do not understand how often these disclosures would be made given the new costs associated with such disclosures. Note

that the degree of new costs imposed if an entity opts to use a disclosure varies dramatically depending on the type of disclosure. For example, a disclosure of directory information in a hospital would probably not involve significant additional costs, while research that is not subject to the common could would have significant new costs involved. These disclosures, and thus these costs, are optional under this proposed rule. While they may be mandated under other law, such mandated disclosures are already being made, so there would be no additional costs. In this case there are only marginal new costs related to these disclosures.

10. Clearinghouses and the Rights of Individuals

The rights described below would apply with respect to protected health information held by health care providers and health plans. We are proposing that clearinghouses not be subject to all of these requirements. We believe that as business partners of covered plans and providers, clearinghouses would not usually initiate or maintain direct relationships with individuals. The contractual relationship between a clearinghouse (as a business partner) and a covered plan or provider would bind the clearinghouse to the notice of information practices developed by the plan or provider and it would include specific provisions regarding inspection, copying, amendment and correction. Therefore, we do not believe that clearinghouses should be required to provide a notice or provide access for inspection, copying, amendment or correction. We would require clearinghouses to provide an accounting of any disclosures for purposes other than treatment, payment and health care operations to individuals upon request. See proposed § 164.515. It is our understanding that the vast majority of the clearinghouse function falls within the scope of treatment, payment, and health care operations and therefore we do not believe providing this important right to individuals would impose a significant burden on the industry. We invite comment on whether or not we should require clearinghouses to comply with all of the provisions of the individual rights section.

11. Rights and Procedures for a Written Notice of Information Practices (§ 164.512)

We are proposing that individuals have a right to an adequate notice of the information practices of covered plans and providers. The notice would be intended to inform individuals about what is done with their protected health information and about any rights they may have with respect to that information. Federal agencies must adhere to a similar notice requirement pursuant to the Privacy Act of 1974 (5 U.S.C. 552a(e)(3)).

We are not proposing that business partners (including health care clearinghouses) be required to develop a notice of information practices because, under this proposed rule, they would be bound by the information practices of the health plan or health care provider with whom they are contracting.

The rule requires covered entities to prepare and make available a notice that informs patients about their privacy rights and the entity's actions to protect privacy. Entities that do not already comply with the rule's requirements would incur one-time legal and administrative costs in preparing and making the notice available. In addition, plans would incur ongoing costs related to the dissemination of the notice at least once every three years, and all covered entities would have ongoing costs related to preparation of new notices as disclosure practices change, dissemination to new individuals who receive services, and requests for copies of the notice. Entities would also incur ongoing costs related to answering questions stemming from the notice. In addition to requiring a basic notice, we considered requiring a longer more detailed notice, that would be available to individuals on request. However, we decided that making information available on request, and letting the covered entity decide how best to provide such information, is a more balanced approach. We felt that it would be overly burdensome to all entities, especially small entities, to require two notices.

We considered requiring covered plans or providers to obtain a signed copy of the notice form (or some other signed indication of receipt) when they give the form to individuals. There are advantages to including such a requirement. A signed acknowledgment would provide evidence that the notice form has been provided to the individual. Further, the request to the individual to formally acknowledge receipt would highlight the importance of the notice, providing additional encouragement for the individual to read it and ask questions about its content.

We are concerned, however, that requiring a signed acknowledgment would significantly increase the administrative and paperwork burden of this provision. We also are unsure of the best way for health plans to obtain a signed acknowledgment because plans often do not have face-to-face contact with enrollees. It may be possible to collect an acknowledgment at initial enrollment, for example by adding an additional acknowledgment to the enrollment form, but it is less clear how to obtain it when the form is revised. We solicit comment on whether we should require a signed acknowledgment. Comments that address the relative advantages and burdens of such a provision would be most useful. We also solicit comment on the best way to obtain signed acknowledgments from health plans if such a provision is included in the final rule. We also solicit comments on other strategies, not involving signed acknowledgments, to ensure that individuals are effectively informed about the information practices of covered plans or providers.

We believe that the proposed rule appropriately balances a patient's need for information and assurances regarding privacy with the covered entities' need for flexibility in describing their operations and procedures to protect patient privacy. Instead of a model notice, we have included a sample notice to guide the development of notices. We felt that this would be an appropriate way to reduce the burden on all entities including those classified as small.

In § 164.512, we propose the categories of information that would be required in each notice of information practices, the specific types of information that would have to be included in each category, and general guidance as to the presentation of written materials. A sample notice is provided at Appendix A of this preamble.

In a separate section of this proposed rule, we would require covered plans or providers to develop and document policies and procedures relating to use, disclosure, and access to protected health information. See proposed § 164.520. We intend for the documentation of policies and procedures to be a tool for educating the entity's personnel about its policies and procedures. In addition, the documentation would be the primary source of information for the notice of information practices. We intend for the notice to be a tool for educating individuals served by the covered plan or provider about the information practices of that entity. The information contained in the notice would not be as comprehensive as the documentation, but rather would provide a clear and concise summary of relevant policies and procedures.

We considered prescribing specific language that each covered plan or provider would include in its notice. The advantages of this approach would be that the recipient would get exactly the same information from each covered plan or provider in the same format, and that it would be convenient for covered plans or providers to use a uniform model notice.

There are, however, several disadvantages to this approach. First, and most important, no model notice could fully capture the information practices of every covered plan or provider. Large entities would have different information practices than small entities. Some health care providers, for example academic teaching hospitals, may routinely disclose identifiable health information for research purposes. Other health care providers may rarely or never make such disclosures. To be useful to individuals, each entity's notice of information practices should reflect its unique privacy practices.

Another disadvantage of prescribing specific language is that it would limit each covered plan or provider's ability to distinguish itself in the area of privacy protections. We believe that if information on privacy protections were readily available, individuals might compare and select plans or providers based on their information practices. In addition, a uniform model notice could easily become outdated. As new communication methods or technologies are introduced, the content of the notices might need to reflect those changes.

In proposed § 164.512, we would require each covered plan and provider to include in the notice an explanation of how it uses and discloses protected health information. The explanation must be provided in sufficient detail as to put the individual on notice of the uses and disclosures expected to be made of his or her protected health information. As explained above in section II.C.7, covered plans and providers may only use and disclose protected health information for purposes stated in this notice.

We considered requiring the notice to include not only a discussion of the actual disclosure practices of the covered entity, but also a listing or discussion of all additional disclosures that are authorized by law. We considered this approach because, under this proposed rule, covered plans or providers would be permitted to change their information practices at any time, and therefore individuals would not be able to rely on the entity's current policies alone to understand how their protected health information may be used in the future. We recognize that in order to be fully informed, individuals need to understand when their information could be disclosed.

We rejected this approach because we were concerned that a notice with such a large amount of information could be burdensome to both the individuals receiving the notices and the entities required to prepare and distribute them. There are a substantial number of required and permitted disclosures under State or other applicable law, and this rule generally would permit them to be made.

Alternatively, we considered requiring that the notice include all of the types of permissible disclosures under this rule (*e.g.*, public health, research, next-of-kin). We rejected that approach for two reasons. First, we felt that providing people with notice of the intended or likely disclosures of their protected health information was more useful than describing all of the potential types of disclosures. Second, in many States and localities, different laws may affect the permissible disclosures that an entity may make, in which case a notice only discussing permissible disclosures under the federal rule would be misleading. While it would be possible to require covered plans or providers to develop notices that discuss or list disclosures that would be permissible under this rule and other law, we were concerned that such a notice may be very complicated because of the need to discuss the interplay of federal, State or other law for each type of permissible disclosure. We invite comments on the best approach to provide most useful information to the individuals without overburdening either covered plans or providers or the recipients of the notices.

In § 164.520, we are proposing to require all covered entities to develop and document policies and procedures for the use of protected health information. The notice would simply summarize those documented policies and procedures and therefore would entail little additional burden.

It is critical to the effectiveness of this proposed rule that individuals be given the notice often enough to remind them of their rights, but without overburdening covered plans or providers. We propose that all covered plans and providers would be required to make their notice available to any individual upon request, regardless of whether the requestor is already a patient or enrollee. We believe that broad availability would encourage individuals or organizations to compare the privacy practices of plans or providers to assist in making enrollment or treatment choices. We also propose additional distribution requirements for updating notices, which would be different for health plans and health care providers. The requirements for health plans and health care providers are different because we recognize that they have contact with individuals at different points in time in the health care system.

We considered a variety of combinations of distribution practices for health plans and are proposing what we believe is the most reasonable approach. We would require health plans to distribute the notice by the effective date of the final rule, at enrollment, within 60 days of a material change to the plan's information practices, and at least once every three years.

We considered requiring health plans to post the notice either in addition to or instead of distribution. Because most individuals rarely visit the office of their health plan, we do not believe that this would be an effective means of communication. We also considered either requiring distribution of the notice more or less frequently than every three years. As compared to most health care providers, we believe that health plans often are larger and have existing administrative systems to cost effectively provide notification to individuals. Three years was chosen as a compromise between the importance of reminding individuals of their plans' information practices and the need to keep the burden on health plans to the minimum necessary to achieve this objective. We are soliciting comment on whether requiring a notice every three years is reasonable for health plans.

We propose to require that covered health care providers provide a copy of the notice to every individual served at the time of first service delivery, that they post the notice in a clear and prominent location where it is reasonable to expect individuals seeking service from the provider to be able to read the notice, and that copies be available on-site for individuals to take with them. In addition, we propose to require that covered health care providers provide a copy of the notice to individuals they are currently serving at their first instances of service delivery within a year of the effective date of the final rule.

We would not require providers to mail or otherwise disseminate their notices after giving the notice to individuals at the time of the first service delivery. Providers' patient lists may include individuals they have not

served in decades. It would be difficult for providers to distinguish between ''active'' patients, those who are seen rarely, and those who have moved to different providers. While some individuals would continue to be concerned with the information practices of providers who treated them in the distant past, overall the burden of an active distribution requirement would not be outweighed by improved individual control and privacy protection.

If a provider wishes to make a material change in the information practices addressed in the notice, it would be required to revise its notice in advance. After making the revision, the provider would be required to post the new notice promptly. We believe that this approach creates the minimum burden for providers consistent with giving individuals a clear source of accurate information.

12. Rights and Procedures for Access for Inspection and Copying (§ 164.514)

In § 164.514, we are proposing that, with very limited exceptions, individuals have a right to inspect and copy protected health information about them maintained by a covered health plan or health care provider in a designated record set. Individuals would also have a right of access to protected health information in a designated record set that is maintained by a business partner of a covered plan or provider when such information is not a duplicate of the information held by the plan or provider, including when the business partner is the only holder of the information or when the business partner has materially altered the protected health information that has been provided to it.

In § 164.506(e), we are proposing that covered plans and providers include specific terms in their contract with each business partner. One of the required terms would be that the business partner must provide for inspection and copying of protected health information as provided in this section. Because our authority is limited by HIPAA to the covered entities, we must rely upon covered plans and providers to ensure that all of the necessary protected health information provided by the individual to the plan or provider is available for inspection and copying. We would require covered plans and providers to provide access to information held in the custody of a business partner when it is different from information maintained by the covered plan or provider. We identified two instances where this seemed appropriate: when the protected health information is only in the custody of a business partner and not in the custody of the covered plan or provider; and when protected health information has been materially altered by a business partner. We are soliciting comment on whether there are other instances where access should be provided to protected health information in the custody of a business partner.

Other than in their capacity as business partners, we are not proposing to require clearinghouses to provide access for inspection and copying. As explained above in section II.C.5, clearinghouses would usually be business partners under this proposed rule and therefore they would be bound by the contract with the covered plan or provider. See proposed § 164.506(e). We carefully considered whether to require clearinghouses to provide access for inspection and copying above and beyond their obligations as a business partner, but determined that the typical clearinghouse activities of translating record formats and batching transmissions do not involve setting up designated record sets on individuals. Although the data maintained by the clearinghouse is protected health information, it is normally not accessed by individual identifier and an individual's records could not be found except at great expense. In addition, although clearinghouses process protected health information and discover errors, they do not create the data and make no changes in the original data. They, instead, refer the errors back to the source for correction. Thus, individual access to clearinghouse records provides no new information to the individual but could impose a significant burden on the industry.

We are proposing that covered plans and providers be required to provide access for as long as the entity maintains the protected health information. We considered requiring covered plans and providers to provide access for a specific period or defining a specific retention period. We rejected that approach because many laws and professional standards already designate specific retention periods and we did not want to create unnecessary confusion. In addition, we concluded that individuals should be permitted to have access for as long as the information is maintained by the covered plan or provider. We are soliciting comments on whether we should include a specific duration requirement in this proposed rule.

Proposed § 164.514 would permit denial of inspection and copying under very limited circumstances. The categories of denials would not be mandatory; the entity could always elect to provide all of the requested health information to the individual. For each request by an individual, the entity could provide all of the information requested or it could evaluate the requested information, consider the circumstances surrounding the individual's request, and make a determination as to whether that request should be granted or denied. We intend to create narrow exceptions to the stated rule of open access and we would expect covered plans and providers to employ these exceptions rarely, if at all.

We considered whether entities should be permitted to deny access to information based on a number of factors. For more specific discussion of access denials, please refer to earlier preamble text. For the purposes of the economic impacts, it is important to note that these denials are optional and, therefore, any costs associated with utilizing these denials are optional.

In § 164.514(c) and (d), we are proposing that covered plans and providers be required to have procedures that enable individuals to exercise their rights to inspect and obtain a copy of protected health information as explained above.

We considered whether this proposed rule should include detailed procedures governing a individual's request for inspection and copying. Because this proposed rule would affect such a wide range of entities, we concluded that it should only provide general guidelines and that each entity should have the discretion to develop procedures consistent with its own size, systems, and operations.

In § 164.514(d)(2), we are proposing that the covered plans and providers would take action upon the request as soon as possible but not later than 30 days following receipt of the request. We considered the possibility of not including a time limitation but rather imposing a ''reasonableness'' requirement on the covered plans or providers. We concluded that the individual is entitled to know when to expect a response. This is particularly important in the context of health information, where an individual could need access to his or her information in order to make decisions about care. Therefore, in order to determine what would be ''reasonable,'' we examined the time limitations provided in the Privacy Act, the Freedom of Information Act (FOIA), and several State laws.

The Privacy Act requires that upon receipt of a request for amendment (not access), the agency would send an acknowledgment to the individual

within 10 working days. (5 U.S.C. 552a (d)(2)). We considered several options that included such an acknowledgment requirement. An acknowledgment would be valuable because it would assure the individual that their request was received. Despite the potential value of requiring an acknowledgment, we concluded that it could impose a significant administrative burden on some of the covered plans and providers. This proposed rule would cover a wide range of entities with varying capacities and therefore, we are reluctant to create requirements that would overwhelm smaller entities or interfere too much with procedures already in place. We would encourage plans and providers to have an acknowledgment procedure in place, but would not require it at this point. We are soliciting comment on whether this proposed rule should require such an acknowledgment.

We also considered whether to include specific procedures governing ''urgent'' or ''emergency'' requests. Such procedures would require covered plans and providers to respond in a shorter time frame. We recognize that circumstances could arise where an individual would request inspection and copying on an expedited basis and we encourage covered plans or providers to have procedures in place for handling such requests. We are not proposing additional regulatory time limitations to govern in those circumstances. The 30-day time limitation is intended to be an outside deadline, rather than an expectation. Rather, we would expect a plan or provider to always be attentive to the circumstances surrounding each request and respond in an appropriate time frame, not to exceed 30 days.

Finally, we considered including a section governing when and how an entity could have an extension for responding to a request for inspection and copying. For example, the FOIA provides that an agency could request additional time to respond to a request if the agency needs to search for and collect the requested records from facilities that are separate from the office processing the request; to search for, collect, and appropriately examine a voluminous amount of separate and distinct records; and to consult with another entity or component having a substantial interest in the determination of the request. We determined that the criteria established in the FOIA are tailored to government information systems and therefore could not be appropriate for plans and providers covered by this proposed rule. Furthermore, we determined that the 30-day time period would be sufficient for responding to requests for inspection and copying and that extensions should not be necessary. We are soliciting comments on whether a structured extension procedure should be included in this proposed rule.

In § 164.514(d)(3), we are proposing that covered plans or providers be required to notify the individual of the decision to provide access and of any steps necessary to fulfill the request. In addition we propose that the entity provide the information requested in the form or format requested if it is readily producible in such form or format. Finally, if the covered plan or provider accepts an individual's request, it would be required to facilitate the process of inspection and copying.

In proposed § 164.514(d)(3)(iv), we would permit a covered plan or provider to charge a reasonable, cost-based fee for copying health information provided pursuant to this section. We considered whether we should follow the practice in the FOIA and include a structured fee schedule. We concluded that the FOIA was developed to reflect the relatively uniform government costs and that this proposed rule would apply to a broader range of entities. Depending on the size of the entity, copying costs could vary significantly. Therefore, we propose that the entity simply charge a reasonable, cost-based fee.

In § 164.514(d)(4), we propose that a covered plan or provider that denies an individual's request for inspection and copying in whole or in part be required to provide the individual with a written statement in plain language explaining the reason for the denial. The statement could include a direct reference to the section of the regulation relied upon for the denial, but the regulatory citation alone would not sufficiently explain the reason for the denial. The statement would need to include the name and number of the contact person or office within the entity who is responsible for receiving complaints. In addition, the statement would need to include information regarding the submission of a complaint with the Department pursuant to § 164.522(b).

We considered proposing that covered plans and providers provide a mechanism for appealing a denial of inspection and copying. We believe, however, that the requirement proposed in § 164.518(d) that covered plans and providers have complaint procedures to address patient and enrollee privacy issues generally would allow the individual to raise the issue of a denial with the covered plan or provider. We would expect the complaint procedures to be scalable; for example, a large plan might develop a standard complaint process in each location where it operates whereas, a small practice might simply refer the original request and denial to the clinician in charge for review. We would encourage covered plans and providers to institute a system of appeals, but would not require it by regulation. In addition, the individual would be permitted to file a complaint with the Department pursuant to § 164.522(b).

13. Rights and Procedures With Respect to an Accounting of Disclosures (§ 164.515)

In this proposed rule, we propose that individuals have a right to receive an accounting of all instances where protected health information about them is disclosed by a covered entity for purposes other than treatment, payment, and health care operations, subject to certain time-limited exceptions for disclosures to law enforcement and oversight agencies as discussed below. Providing such an accounting would allow individuals to understand how their health information is shared beyond the basic purposes of treatment, payment and health care operations.

We considered whether to require covered entities to account for all disclosures, including those for treatment, payment and health care operations. We rejected this approach because it would be burdensome and because it would not focus on the disclosures of most interest to individuals. Upon entering the health care system, individuals are generally aware that their information would be used and shared for the purpose of treatment, payment and health care operations. They have the greatest interest in an accounting of circumstances where the information was disclosed for other purposes that are less easy to anticipate. For example, an individual might not anticipate that his or her information would be shared with a university for a research project, or would be requested by a law enforcement agency.

We are not proposing that covered entities include uses and disclosures for treatment, payment and health care operations in the accounting. We believe that it is appropriate for covered entities to monitor all uses and disclosures for treatment, payment and health care operations, and they would be required to do so for electronically maintained information by the Security Standard. However, we do not believe that covered entities should be required to provide an accounting of the uses and disclosures for treatment payment and health care operations.

This proposed rule would not specify a particular form or format for the accounting. In order to satisfy the accounting requirement, a covered entity could elect to maintain a systematic log of disclosures or it could elect to rely upon detailed record keeping that would permit the entity to readily reconstruct the history when it receives a request from an individual. We would require that covered entities be able to respond to a request for accounting within a reasonable time period. In developing the form or format of the accounting, covered entities should adopt policies and procedures that would permit them to respond to requests within the 30-day time period in this proposed rule.

We also considered whether or not the disclosure history should be a formal document that is constantly maintained or whether we should give more flexibility to entities in this regard. We decided that since our ultimate goal is that individuals have access to a disclosure history of their records upon request, it would be reasonable to require only that they be able to do this. We are not prescribing how they fulfill the requirement. We also believe that it is less burdensome to require that they be able to create a disclosure history than to require that they have a specific format for maintaining a disclosure history.

We are proposing that the accounting include all disclosures for purposes other than treatment, payment, and health care operations, subject to certain exceptions for disclosures to law enforcement and oversight agencies, discussed below. This would also include disclosures that are authorized by the individual. The accounting would include the date of each disclosure; the name and address of the organization or person who received the protected health information; and a brief description of the information disclosed. For all disclosures that are authorized by the individual, we are proposing that the covered entity maintain a copy of the authorization form and make it available to the individual with the accounting.

We considered whether the accounting of disclosures should include the name of the person who authorized the disclosure of information. The proposed Security Standard would require covered entities to have an audit mechanism in place to monitor access by employees. We concluded that it would be unnecessary and inappropriate to require the covered entity to include this additional information in the accounting. If the individual identifies an improper disclosure by an entity, he or she should hold the entity not the employee of the entity accountable. It is the responsibility of the entity to train its workforce about its policies and procedures for the disclosure of protected health information and to impose sanctions if such policies and procedures are violated.

14. Rights and Procedures for Amendment and Correction (§ 164.516)

This proposed rule would provide an individual with the right to request a covered plan or provider to amend or correct protected health information relating to the individual. A covered plan or provider would be required to accommodate requests with respect to any information that the covered plan or provider determines to be erroneous or incomplete, that was created by the plan or provider, and that would be available for inspection and copying under proposed § 164.514.

We are concerned about the burden that requests for amendment or correction could place on covered plans and providers and have tried to limit the process to those situations where amendment or correction would appear to be most important. We invite comment on whether our approach reasonably balances burden with adequately protecting individual interests.

We propose to require a covered plan or provider to accommodate a request for amendment or correction if the plan or provider created the information in dispute. We considered requiring covered plans and providers to amend or correct any erroneous or incomplete information it maintains, regardless of whether it created the information. Under this approach, if the plan or provider did not create the information, then it would have been required to trace the information back to the original source to determine accuracy and completeness. We rejected this option because we concluded that it would not be appropriate to require the plan or provider that receives a request to be responsible for verifying the accuracy or completeness of information that it did not create. We also were concerned about the burden that would be imposed on covered plans and providers if they were required to trace the source of any erroneous or incomplete information transmitted to them.

We would rely on a combination of three other requirements to ensure that protected health information remains as accurate as possible as it travels through the health care system. First, we are proposing that a covered plan or provider that makes an amendment or correction be required to notify any relevant persons, organizations, or other entities of the change or addition. Second, we are proposing that other covered plans or providers that receive such a notification be required to incorporate the necessary amendment or correction. Finally, we are proposing that covered plans or providers require their business partners who receive such notifications to incorporate any necessary amendments or corrections. See the discussion in section II.F.4. We are soliciting comments whether this approach would effectively ensure that amendments and corrections are communicated appropriately.

We are proposing that covered plans and providers be required to accommodate requests for amendment or correction for as long as the entity maintains the protected health information. We considered requiring covered plans and providers to accommodate requests for a specific period or defining a specific retention period. We rejected that approach because many laws and professional standards already designate specific retention periods and we did not want to create confusion. In addition, we concluded that individuals should be permitted to request amendments or corrections for as long as the information is maintained by the covered plan or provider. We are soliciting comments on whether we should include a specific duration requirement in this proposed rule.

In § 164.516, we are proposing that covered plans and providers be required to have procedures that enable individuals to exercise their rights to request amendment or correction, including a means by which individuals could request amendment or correction of protected health information about them. We considered whether this proposed rule should include detailed procedures governing an individual's request. But as with the procedures for requesting inspection and copying, we are only providing a general requirement and permitting each plan or provider to develop procedures in accordance with its needs. Once the procedures are developed, the plan or provider would document them in accordance with section § 164.520 and include a brief explanation in the notice that is provided to individuals pursuant to section § 164.512.

We are proposing that the covered plan or provider would take action on a request for amendment or correction as quickly as the circumstances require, but not later than 60 days following the

request. The justification for establishing a time limitation for amendment and correction is virtually identical to that provided for the time limitation for inspection and copying. We concluded that the entity should be provided with some additional flexibility in this context. Depending on the nature of the request, an amendment or correction could require significantly more time than a request for inspection and copying. If a covered plan or provider needed more than 30 days to make a decision, we would encourage, but not require, it to send an acknowledgment of receipt to the individual including an explanation of the reasons for the delay and a date when the individual could expect a final decision.

In § 164.516(c)(3), we are proposing that, upon accepting an amendment or correction, the covered plan or provider would be required to make reasonable efforts to notify relevant persons, organizations, or other entities of the change or addition. An entity would be required to notify such persons that the individual identifies, or that the covered plan or provider identifies as (1) a recipient of the erroneous or incomplete information, and (2) a person who:

- Has relied upon that information to the detriment of the individual; or
- Is a person who could foreseeably rely on such erroneous or incomplete information to the detriment of the individual.

We are concerned about the potential burden that this notification requirement would impose on covered plans and providers. We do not, however, anticipate that a significant number of requests would be submitted to any entity and therefore the need for such notifications would be rare. In addition, we determined that because health information can travel so quickly and efficiently in the modern health care system, the need for notification outweighed the potential burden. It is important to note that a reasonableness standard should be applied to the notification process—if the recipient has not relied upon the erroneous or incomplete information to the detriment of the individual or if it is not foreseeable that the recipient would do so, then it would not be reasonable for the covered plan or provider to incur the time and expense of notification. If, however, if the incorrect information is reasonably likely to be used to the detriment of the individual, the entity should make every effort to notify the recipients of the information of the changes as quickly as possible.

We discussed a number of options regarding the notification of other entities. We considered only requiring that the entity provide the individual with a listing of who else could have received the information. This would place the burden of notification in the hands of the individual rather than the entity. Because individuals would not have the same contacts and relationship with other entities as the original covered entity, we decided that placing the burden on individuals would be more cumbersome for both individuals and the secondary entities receiving the requests. We also considered not including a notification requirement. However, this would mean that individuals would need to both figure out where the information had gone to and make separate requests for amendment or correction to every entity. This also appeared to be overly difficult. We believe that the option we are proposing is fair to both individuals and covered entities.

In proposed § 164.516(c)(4), we would require a covered plan or provider to provide the individual with a written statement in plain language of the reason for the denial and permit the individual to file a written statement of disagreement with the decision to deny the request.

If the individual chooses to file a statement of disagreement, then the covered plan or provider must retain a copy of the statement with the protected health information in dispute. The covered plan or provider could require that the statement be a reasonable length, provided that the individual has reasonable opportunity to state the nature of the disagreement and offer his or her version of accurate and complete information. In all subsequent disclosures of the information requested to be amended or corrected, the covered plan or provider would be required to include a copy of its statement of the basis for denial and, if provided by the individual, a copy of his or her statement of disagreement. If the statement submitted by the individual is unreasonably long, the covered plan or provider could include a summary in subsequent disclosures which reasonably explains the basis of the individual's position. The covered plan or provider would also be permitted to provide a rebuttal to the individual's statement of disagreement and include the rebuttal statement in any subsequent disclosures.

We considered requiring the covered plan or provider to provide a mechanism for appealing denials of amendment or correction but concluded that it would be too burdensome. We are soliciting comment on whether the approach we have adopted reasonably balances the burdens on covered plans or providers with the rights of individuals.

If a covered plan or provider receives a notification of erroneous or incomplete protected health information as provided in proposed § 164.516(d), we are proposing that the covered plan or provider or be required to make the necessary amendment or correction to protected health information in its custody that would be available for inspection and copying. This affirmative duty to incorporate amendments and corrections would be necessary to ensure that individuals' protected health information is as accurate and complete as possible as it travels through the health care system.

15. Administrative Requirements (§ 164.518)

We propose that covered entities be required to implement five basic administrative requirements to safeguard protected health information: Designation of a privacy official, the provision of privacy training, establishment of safeguards, a complaint process, and establishment of sanctions. Implementation of these requirements would vary depending on a variety of different factors such as type of entity (e.g., provider or plan), size of entity (e.g., number of employees, number of patients), the level of automation within the entity (e.g., electronic medical records), and organization of the entity (e.g., existence of an office of information systems, affiliation with a medical school).

a. Designation of a Privacy Official (§ 164.518(a))

In proposed § 164.518(a), we would require covered entities to designate an employee or other person to serve as the official responsible for the development of policies and procedures for the use and disclosure of protected health information. The designation of an official would focus the responsibility for development of privacy policy.

We considered whether covered entities should be required to designate a single official or an entire board. We concluded that a single official would better serve the purposes of focusing the responsibility and providing accountability within the entity. The implementation of this requirement would depend on the size of the entity. For example, a small physician's practice might designate the office manager as the privacy official, and he or she would assume this as one of his or her broader administrative responsibilities. A large entity might appoint a person whose sole

responsibility is privacy policy, and he or she might choose to convene a committee representing several different components of the entity to develop and implement privacy policy.

b. Training (§ 164.518(b))

In proposed § 164.518(b), we would require covered entities to provide training on the entities policies and procedures with respect to protected health information. Each entity would be required to provide initial training by the date on which this proposed rule becomes applicable. After that date, each covered entity would have to provide training to new members of the workforce within a reasonable time period after joining the entity. In addition, we are proposing that when a covered entity makes material changes in its privacy policies or procedures, it would be required to retrain those members of the workforce whose duties are directly affected by the change within a reasonable time of making the change.

The entities would be required to train all members of the workforce (*e.g.,* all employees, volunteers, trainees, and other persons under the direct control of all persons working on behalf of the covered entity on an unpaid basis who are not business partners) who are likely to have contact with protected health information.

Upon completion of the training, the person would be required to sign a statement certifying that he or she received the privacy training and would honor all of the entity's privacy policies and procedures. Entities would determine the most effective means of communicating with their workforce. For example, in a small physician practice, the training requirement could be satisfied by providing each new member of the workforce with a copy of the practice's information policies and requiring members of the workforce to acknowledge that they have reviewed the policies. A large health plan could provide for a training program with live instruction, video presentations or interactive software programs. The small physician practice's solution would not protect the large plan's data, and the plan's solution would be neither economically feasible nor necessary for the small physician practice.

At least once every three years after the initial training, covered entities would be required to have each member of the workforce sign a new statement certifying that he or she would honor all of the entity's privacy policies and procedures. The initial certification would be intended to make members of the workforce aware of their duty to adhere to the entity's policies and procedures. By requiring a recertification every three years, they would be reminded of this duty.

We considered several different options for recertification. We considered proposing that members of the workforce be required to recertify every six months, but concluded that such a requirement would be too burdensome. We considered proposing that recertification be required annually consistent with the recommendations of The American Health Information Management Association (Brandt, Mary D., Release and Disclosure: Guidelines Regarding Maintenance and Disclosure of Health Information, 1997). We concluded that annual recertification could also impose a significant burden on covered entities.

We also considered requiring that the covered entity provide ''refresher'' training every three years in addition to the recertification. We concluded that our goals could be achieved by only requiring recertification once every three years, and retraining in the event of material changes in policy. We are soliciting comment on this approach.

c. Safeguards (§ 164.518(c))

In proposed § 164.518(c), we would require covered entities to put in place administrative, technical, and physical safeguards to protect against any reasonably anticipated threats or hazards to the privacy of the information, and unauthorized uses or disclosures of the information. We proposed similar requirements for certain electronic information in the Notice of Proposed Rulemaking entitled the Security and Electronic Signature Standards (HCFA–0049–P), which can be found at 63 FR 43241. We are proposing parallel and consistent requirements for safeguarding the privacy of protected health information.

i. *Verification procedures.*

As noted in section II.E., for many permitted disclosures the covered entity would be responding to a request for disclosure of protected health information. For most categories of permitted disclosures, when the request for disclosure of protected health information is from a person with whom the covered entity does not routinely do business, we would require the covered entity to verify the identity of the requestor. In addition, for certain categories of disclosures, covered entities would also be required to verify the requestor's legal authority to make the request.

Under § 164.514, a covered entity would be required to give individuals access to protected health information about them (under most circumstances). The covered entity would also be required to take reasonable steps to verify the identity of the individual making the request for access. We do not propose to mandate particular identification requirements (*e.g.,* drivers licence, photo ID, etc), but rather would leave this to the discretion of the covered entity.

We considered specifying the type of documentation or proof that would be acceptable, but decided that the burden of such specific regulatory requirements on covered entities would be unnecessary. Therefore, we propose only a general requirement for reasonable verification of identity and legal authority.

d. Internal Complaint Process (§ 164.518(d))

In proposed § 164.518(d), we would require covered plans and providers to have some mechanism for receiving complaints from individuals regarding the covered plan's or provider's compliance with the requirements of this proposed rule. The covered plan or provider would be required to accept complaints about any aspect of their practices regarding protected health information. We would not require that the entity develop a formal appeals mechanism, nor that ''due process'' or any similar standard be applied. We would not require that covered entities respond in any particular manner or time frame. We are proposing two basic requirements for the complaint process. First, the covered plan or provider would be required to identify a contact person or office in the notice of information practices for receiving complaints. This person or office could either be responsible for handling the complaints or could put the individual in touch with the appropriate person within the entity to handle the particular complaint. See proposed § 164.512. This person could, but would not have to be, the entity's privacy official. See proposed § 164.518(a)(2). Second, the covered plan or provider would be required to maintain a record of the complaints that are filed and a brief explanation of the resolution, if any.

We considered requiring covered plans and providers to provide a formal internal appeal mechanism, but rejected that option as too costly and burdensome for some entities. We also considered eliminating this requirement entirely, but rejected that option because a complaint process would give covered plans or providers a way to learn about potential problems with privacy policies or practices, or training

issues. We also hope that providing an avenue for covered plans or providers to address complaints would lead to increased consumer satisfaction. We believe this approach strikes a reasonable balance between allowing covered plans or providers flexibility and accomplishing the goal of promoting attention to improvement in privacy practices. If an individual and a covered plan or provider are able to resolve the individual's complaint, there could be no need for the individual to file a complaint with the Secretary under proposed § 164.522(b). However, an individual has the right to file a complaint with the Secretary at any time. An individual could file a complaint with the Secretary before, during, after, or concurrent with filing a complaint with the covered plan or provider or without filing a complaint with the covered plan or provider.

We are considering whether modifications of these complaint procedures for intelligence community agencies could be necessary to address the handling of classified information and solicit comment on the issue.

e. Sanctions (§ 164.518(e))

In proposed § 164.518(e), we would require all covered entities to develop and apply when appropriate sanctions for failure to comply with policies or procedures of the covered entity or with the requirements of this proposed rule. All members of the workforce who have regular contact with protected health information should be subject to sanctions, as would the entity's business partners. Covered entities would be required to develop and impose sanctions appropriate to the nature of the issue. The type of sanction applied would vary depending on factors such as the severity of the violation, whether the violation was intentional or unintentional, and whether the violation indicates a pattern or practice of improper use or disclosure of protected health information. Sanctions could range from a warning to termination.

We considered specifying particular sanctions for particular kinds of violations of privacy policy, but rejected this approach for several reasons. First, the appropriate sanction would vary with the entity's particular policies. Because we cannot anticipate every kind of privacy policy in advance, we cannot predict the response that would be appropriate when that policy is violated. In addition, it is important to allow covered entities to develop the sanctions policies appropriate to their business and operations.

We expect that sanctions would be more formally described and consistently carried out in larger, more sophisticated entities. Smaller, less sophisticated entities would be given more latitude and flexibility. For such smaller entities and less sophisticated entities, we would not expect a prescribed sanctions policy, but would expect that actions be taken if repeated instances of violations occur.

f. Sanctions (§ 164.518(f))

We propose in § 164.518(f) that covered entities be required to have procedures for mitigating, to the extent practicable, any deleterious effect of a use or disclosure of protected health information by their members of their workforce or business partners. With respect to business partners, we also propose that covered entities have an affirmative duty to take reasonable steps in response to breaches of contract terms.

16. Development and Documentation of Policies and Procedures (§ 164.520)

In proposed § 164.520, we would require covered entities to develop and document their policies and procedures for implementing the requirements of this proposed rule. This requirement is intended as a tool to facilitate covered entities' efforts to develop appropriate policies to implement this proposed rule, to ensure that the members of its workforce and business partners understand and carry out expected privacy practices, and to assist covered entities in developing a notice of information practices.

The scale of the policies developed should be consistent with the size of the covered entity. For example, a smaller employer could develop policies restricting access to health plan information to one designated employee, empowering that employee to deny release of the information to corporate executives and managers unless required for health plan administration. Larger employers could have policies that include using contractors for any function that requires access to protected health information or requiring all reports they receive for plan administration to be de-identified unless individual authorization is obtained.

We are proposing general guidelines for covered entities to develop and document their own policies and procedures. We considered a more uniform, prescriptive approach but concluded that a single approach would be neither effective in safeguarding protected health information nor appropriate given the vast differences among covered entities in size, business practices and level of sophistication. It is important that each covered entity's internal policies and procedures for implementing the requirements of this regulation are tailored to the nature and number of its business arrangements, the size of its patient population, its physical plant and computer system, the size and characteristics of its workforce, whether it has one or many locations, and similar factors. The internal policies and procedures appropriate for a clearinghouse would not be appropriate for a physician practice; the internal policies and procedures appropriate for a large, multi-state health plan would not be appropriate for a smaller, local health plan.

After evaluating the requirements of federal, State, or other applicable laws, covered entities should develop policies and procedures that are appropriate for their size, type, structure, and business arrangements. Once a covered plan or provider has developed and documented all of the policies and procedures as required in this section, it would have compiled all of the information needed to develop the notice of information practices required in § 164.512. The notice is intended to include a clear and concise summary of many of the policies and procedures discussed in this section. Further, if an individual has any questions about the entity's privacy policies that are not addressed by the notice, a representative of the entity could easily refer to the documented policies and procedures for additional information.

Before making a material change in a policy or procedure, the covered entity would, in most instances, be required to make the appropriate changes to the documentation required by this section before implementing the change. In addition, covered plans and providers would be required to revise their notice of information practices in advance. Where the covered entity determines that a compelling reason exists to take an action that is inconsistent with its documentation or notice before making the necessary changes, it could take such action if it documents the reasons supporting the action and makes the necessary changes within 30 days of taking such action.

In an attempt to ensure that large entities develop coordinated and comprehensive policies and procedures as required by this section, we considered proposing that entities with annual receipts greater than $5

million [40] be required to have a privacy board review and approve the documentation of policies and procedures. As originally conceived, the privacy board would only serve to review research protocols as described in § 164.510(j). We believe that such a board could also serve as ''privacy experts'' for the covered entity and could review the entity's documented policies and procedures. In this capacity, the overriding objective of the board would be to foster development of up-to-date, individualized policies that enable the organization to protect health information without unnecessarily interfering with the treatment and payment functions or business needs. This type of review is particularly important for large entities who would have to coordinate policies and procedures among a large staff, but smaller organizations would be encouraged, but not required, to take a similar approach (*i.e.*, have a widely representative group participate in the development and/or review of the organization's internal privacy policies and the documentation thereof). We solicit comment on this proposal.

We also considered requiring the covered entity to make its documentation available to persons outside the entity upon request. We rejected this approach because covered entities should not be required to share their operating procedures with the public, or with their competitors.

We recognize that the documentation requirement in this proposed rule would impose some paperwork burden on covered plans and providers. However, we believe that it is necessary to ensure that covered plans and providers establish privacy policies and procedures in advance of any requests for disclosure, authorization, or subject access. It is also necessary to ensure that covered entities and members of their workforce have a clear understanding of the permissible uses and disclosures of protected health information and their duty to protect the privacy of such information under specific circumstances.

17. Compliance and Enforcement

The rules proposed below at § 164.522 would establish several requirements designed to enable the Secretary to monitor and seek to ensure compliance with the provisions of this subpart. The general philosophy of this section is to provide a cooperative approach to obtaining compliance, including use of technical assistance and informal means to resolve disputes. However, in recognition of the fact that it would not always be possible to achieve compliance through cooperation, the section also would provide the Secretary with tools for carrying out her statutory mandate to achieve compliance.

Proposed § 164.522(a) would establish the principle that the Secretary would seek the cooperation of covered entities in obtaining compliance. Section 164.522(a)(2) provides that the Secretary could provide technical assistance to covered entities to help them come into compliance with this subpart. It is clearly in the interests of both the covered entities and the individuals they serve to minimize the costs of compliance with the privacy standards. To the extent that the Department could facilitate this by providing technical assistance, it would endeavor to do so.

V. Initial Regulatory Flexibility Analysis

A. Introduction

Pursuant to the Regulatory Flexibility Act 5 U.S.C. 601 *et. seq.*, HHS must prepare a regulatory flexibility analysis if the Secretary certifies that a proposed rule would have a significant economic impact on a substantial number of small entities.

This analysis addresses six issues: (1) Reasons for promulgating the rule; (2) the proposed rule's objectives and legal basis; (3) the number and types of small entities affected by the proposed rule; (4) the specific activities and costs associated with compliance; (5) options that HHS considered to minimize the rule's economic burdens or increase its benefits for small entities; and (6) the relevant Federal rules that could duplicate, overlap, or conflict with the proposed rule. The following sections provide details on each of these issues.

Reasons for Promulgating the Rule

This proposed rule is being promulgated primarily because we have been statutorily mandated to do so under section 264 of Public Law 104–191. Additional information on the reasons for promulgating the rule can be found in earlier preamble discussions (section I.).

Objectives and Legal Basis

This information can be found in earlier preamble discussions (section I.).

Relevant Federal Provisions

This information can be found in earlier preamble discussions (section I.B.)

B. Economic Effects on Small Entities

1. Number and Types of Small Entities Affected

The Small Business Administration defines small entities in the health care sector as those organizations with less than $5 million in annual revenues. [41] Nonprofit organizations are also considered small entities; however, individuals and States are not included in the definition of a small entity. Similarly, small government jurisdictions with a population of less than 50,000 are considered small entities.

Small health entities affected include: Nonprofit health plans, hospitals, and skilled nursing facilities (SNFs); small businesses providing health coverage; small physician practices; pharmacies; laboratories; and durable medical equipment (DME) suppliers; health care clearinghouses; billing companies; and vendors that supply software applications to health care entities.

The U.S. Small Business Administration reports that as of 1996, there were 1,078,020 small health care establishments [42] classified within the SIC codes we have designated (Table A).

[40] The Small Business Administration defines small businesses in the health care field as those generating less than $5 million annually. Small businesses represent approximately 85% of health care entities.

[41] We have used two different data sources for our estimates of the number of entities. In the regulatory impact analysis (RIA), we chose to use the same numbers as we used in other Administrative Simplification rules. In the regulatory flexibility analysis (RFA), we used the most recent data available from the Small Business Administration (SBA).

We chose to use the Administrative Simplification estimates in the RIA because we wanted our analysis to be as consistent as possible with those regulations and also believe that because it is higher than the more recent SBA data, it was the more conservative data source.

We chose to use the SBA data in the RFA because we wanted our analysis to be as consistent to SBA definitions as possible to give the greatest accuracy for the RFA purposes.

[42] Establishments are the physical location where an enterprise conducts business. An entrprise may conduct business in more than one establishment.

TABLE A.—NUMBER OF HEALTH CARE ENTITIES THAT MEET SBA SIZE STANDARDS, 1996 [1]

Standard Industrial Code (SIC)	Industry	Total Number of Health Care Entities	Number of Entities that Meet SBA Size Standards [2]	Percent of Entities that Meet SBA Size Standards [2]
5910	Drug Stores & Proprietary Stores	44,062	23,771	53.9
6320	Accident & Health Insurance & Medical Service Plans (Accident & Health Insurance and Hospital & Medical Service Plans).	3,346	428	12.8
8010	Offices & Clinics of Doctors of Medicine	188,508	171,750	91.1
8020	Offices & Clinics of Dentists	113,965	113,141	99.3
8030	Offices & Clinics of Doctors of Osteopathy	9,168	9,000	98.2
8040	Offices & Clinics of Other Health Practitioners	85,326	83,563	97.9
8050	Nursing & Personal Care Facilities	24,246	11,736	48.4
8060	Hospitals	7,284	837	11.5
8070	Medical & Dental Laboratories	15,354	12,322	80.3
8080	Home Health Care Services	16,218	9,238	57.0
8090	Miscellaneous Health & Allied Services	20,986	12,712	60.6
N/A	Total	528,463	448,498	84.9

[1] Source: Office of Advocacy, U.S. Small Business Administration, from data provided by the Bureau of the Census, Statistics of U.S. Businesses, 1996.
[2] Less than $5,000,000 in annual revenue.

These small businesses represent 83.8% of all health care entities we have examined.[43] Small businesses represent a significant portion of the total number of health care entities but a small portion of the revenue stream for all health care entities. In 1996, the small businesses represented generated approximately $235 million in annual receipts, or 22.2% of the total revenue generated by small health care entities (Table B).[44] The following sections provide estimates of the number of small health care entities that will be required to comply with the rule. We should note, however, that the SBA's published annual receipts of health care industries differs substantially from the National health expenditure data that the Health Care Finance Administration (HCFA) maintains. HCFA's data are generally considered more accurate because the data are validated by several sources.

TABLE B.—ANNUAL RECEIPTS OF HEALTH CARE ENTITIES, 1996 [1]

Standard Industrial Code (SIC)	Industry	Total revenue	Revenue generated by small entities [2]	Percent of total revenue generated by small entities
5910	Drug Stores & Proprietary Stores	$91,701,331	$23,762,195	25.9
6320	Accident & Health Insurance & Medical Service Plans (Accident & Health Insurance and Hospital & Medical Service Plans).	225,866,321	657,074	0.3
8010	Offices & Clinics of Doctors of Medicine	186,598,097	102,355,549	54.9
8020	Offices & Clinics of Dentists	46,131,244	44,811,866	97.1
8030	Offices & Clinics of Doctors Of Osteopathy	4,582,835	3,992,558	87.1
8040	Offices & Clinics of Other Health Practitioners	25,053,745	21,891,338	*87.4*
	Other Health Practitioners (8030 and 8040)	29,636,580	25,883,896	87.3
8050	Nursing & Personal Care Facilities	63,625,522	14,672,710	23.1
8060	Hospitals	343,314,509	2,021,845	0.6
8070	Medical & Dental Laboratories	16,543,625	4,976,094	30.1
8080	Home Health Care Services	27,690,537	7,960,035	28.7
8090	Miscellaneous Health & Allied Services	26,036,633	7,697,264	29.6

[43] Office of Advocacy, U.S. Small Business Administration, from data provided by the Bureau of the Census, Statistics of U.S. Businesses, 1996.

[44] Op. cit. 1996

[45] Office of Advocacy, U.S. Small Business Administration, from data provided by the Bureau of the Census, Statistics of U.S. Businesses, 1996.

[46] Op.cit., 1996

TABLE B.—ANNUAL RECEIPTS OF HEALTH CARE ENTITIES, 1996 [1]—Continued

Standard Industrial Code (SIC)	Industry	Total revenue	Revenue generated by small entities [2]	Percent of total revenue generated by small entities
	Other Health Care Services (8070,8080,8090)	70,270,795	20,633,393	*29.4*
N/A	Total Receipts	1,057,144,399	234,798,528	22.2

[1] Source: Office of Advocacy, U.S. Small Business Administration, from data provided by the Bureau of the Census, Statistics of U.S. Businesses, 1996.

[2] The SBA defines a small business as those businesses with less than $5,000,000 in annual revenue. For consistency with the Regulation, we employ the term ''entity'' in place of ''business''.

The Small Business Administration reports that approximately 80 percent of the 15,000 medical laboratories and dental laboratories in the U.S. are small entities.[45] Furthermore, based on HCFA data, we estimate that 98 percent of the 160,000 durable medical equipment suppliers in the U.S. are small entities. Over 90 percent of health practitioner offices are small businesses.[46] Doctor offices (91%), dentist offices (99%), osteopathy (98%) and other health practitioner offices (98%) are primarily considered small businesses.

There are also a small number of hospitals, home health agencies, non-profit nursing facilities, and skilled nursing facilities that will be affected by the proposed rule. According to the American Hospital Association, there are approximately 3,131 nonprofit hospitals nationwide. Additionally, there are 2,788 nonprofit home health agencies in the U.S. The Health Care Finance Administration reports that there are 591 nonprofit nursing facilities and 4,280 nonprofit skilled nursing facilities.[47]

While it is difficult to calculate the number of clearinghouses that meet the definition of a small business, we believe that a significant portion of the 80 health care clearinghouses that process health care claims in the U.S. have annual revenues of less than $5 million annually.[48] We believe that all of the 4,500 billing companies [49] that provide administrative and billing services for physicians' offices have annual revenues below $5 million per year.

Some contractors that work with health care entities will be required to adopt policies and procedures to protect information. We do not expect that the additional burden placed on contractors will be significant. We have not estimated the effect of the proposed rule on these entities because we cannot reasonably anticipate the number or type of contracts affected by the proposed rule. We also do not know the extent to which contractors would be required to modify their policy practices as a result of the rule's implementation.

2. Activities and Costs Associated with Compliance

For a summary of the basic activities that a small entity would need to do to comply with this rule, please refer to section III of the preamble. This discussion summarizes some of the specific activities that covered entities must undertake to comply with the proposed rule's provisions and options considered that would reduce the burden to small entities. In developing this proposed rule, we considered a variety of alternatives for minimizing the economic burden that it will create for small entities. We could not exempt small businesses from the entire proposed rule because they represent such a large and critical proportion of the health care industry (84 percent).

The guiding principle in our considerations of how to address the burden on small entities has been to make provisions scalable. To the extent possible, we have allowed for entities to determine how extensively they will address certain issues. This ability to adapt provisions to minimize burden has been addressed in earlier preamble language and will be briefly discussed again in the following section.

Before discussing specific provisions, it is important to note some of the broader questions that were addressed in formulating this proposed rule. We considered extending the compliance period for small entities but decided that because they represent such a large portion of the health care market, such an extension would be inappropriate. However, HIPAA does create an extended compliance time of 36 months for small plans. For all other time limit questions, we also considered giving small entities the same sort of extensions. For example, entities are required to either approve or deny a request to inspect and copy information within 20 days. We considered allowing small entities a longer response time. Rather than giving small entities extensions, we decided to establish time limits that we believe are reasonable for affected entities of all sizes, with the understanding that larger entities may not need as much time as they have been allocated in certain situations.

While we considered the needs of small entities during our discussions of provisions for this proposed rule, we are highlighting the most significant discussions in the following sections:

a. *Scalability.* Covered entities of all types and sizes would be required to comply with the proposed privacy standards outlined below. The proposed standards would not impose particular mechanisms or procedures that covered entities must adopt to implement the standards. Instead, we would require that each affected entity assess its own needs and devise, implement, and maintain appropriate privacy policies, procedures, and documentation to address its business requirements. How each privacy standard would be satisfied would be business decisions that each entity would have to make. This allows the privacy standards to establish a stable baseline, yet remain flexible enough to take advantage of developments and methods for protecting privacy that will evolve over time.

Because the privacy standards would need to be implemented by all covered entities, from the smallest provider to the largest, multi-state health plan, a single approach to implementing these standards would be neither economically feasible nor effective in safeguarding health information privacy. For example, in a small physician practice the office manager might be designated to serve as the privacy official as one of many duties (see proposed § 164.518(a)) whereas at a large health plan, the privacy official may constitute a full time position and

[45] Office of Advocacy, U.S. Small Business Administration, from data provided by the Bureau of the Census, Statistics of U.S. Businesses, 1996.

[46] Op.cit., 1996

[47] Health Care Finance Administration, OSCAR

[48] Faulkner & Gray's *Health Data Directory,* 1999

[49] International Billing Association, 1999

have the regular support and advice of a privacy staff or board.

In taking this approach, we intend to strike a balance between the need to maintain the confidentiality of protected health information and the economic cost of doing so. Health care entities must consider both aspects in devising their solutions. This approach is similar to the approach we proposed in the Notice of Proposed Rulemaking for the administrative simplification security and electronic signature standards.

We decided to use this scaled approach to minimize the burden on all entities with an emphasis on small entities.

b. *Minimum necessary use and disclosure.* The decisions called for in determining what would be the minimum necessary information to accomplish an allowable purpose should include both a respect for the privacy rights of the subjects of the medical record and the reasonable ability of covered entities to delimit the amount of individually identifiable health information in otherwise permitted uses and disclosures. For example, a large enterprise that makes frequent electronic disclosures of similar data would be expected to remove identifiers or to limit the data fields that are disclosed to fit the purpose of the disclosure. An individual physician's office would not be expected to have the same capabilities to limit the amount of information disclosed, although, in the cases of disclosures involving a small number of records, such an office could be expected to hide identifiers or to limit disclosures to certain pages of the medical record that are relevant to the purpose of the disclosure.

We understand that the requirements outlined in this section do not create a bright line test for determining the minimum necessary amount of protected health information appropriate for most uses or disclosures. Because of this lack of precision, we considered eliminating the requirement altogether. We also considered merely requiring covered entities to address the concept within their internal privacy procedures, with no further guidance as to how each covered entity would address the issue. These approaches were rejected because minimizing both the amount of protected health information used and disclosed within the health care system and the number of persons who have access to such information is vital if we are to successfully enhance the confidentiality of people's personal health information. We invite comments on the approach that we have adopted and on alternative methods of implementing the minimum necessary principle.

c. *Right to restrict.* We propose to permit in § 164.506(c) that individuals be able to request that a covered entity restrict further uses and disclosures of protected health information for treatment, payment, or health care operations, and if the covered entity agrees to the requested restrictions, the covered entity may not make uses or disclosures for treatment, payment or health care operations that are inconsistent with such restrictions, unless such uses or disclosures are mandated by law. This provision would not apply to health care provided to an individual on an emergency basis.

It should be noted that there is nothing in this proposed rule that requires a health care provider to agree to a request to restrict uses or disclosures for treatment, payment, or health care operations. Providers who do not wish to, or due to contractual obligations cannot, restrict further use or disclosure are not obligated to treat an individual making a request under this provision.

If small entities view this proposed provision as overly burdensome, they would not have to provide treatment to individuals requesting restrictions. We considered requiring that providers conform to requests to restrict use or disclosures. We rejected this approach due to the potential ethical conflicts these restrictions could pose to health care professionals and the possible burden to providers. Providers comprise a large proportion of the small businesses covered under this proposed regulation.

d. *Creation of de-identified information.* In this rule we are proposing that covered entities and their business partners be permitted to use protected health information to create de-identified health information. Covered entities would be permitted to further use and disclose such de-identified information in any way, provided that they do not disclose the key or other mechanism that would enable the information to be re-identified, and provided that they reasonably believe that such use or disclosure of de-identified information will not result in the use or disclosure of protected health information. This means that a covered entity could not disclose de-identified information to a person if the covered entity reasonably believes that the person would be able to re-identify some or all of that information, unless disclosure of protected health information to such person would be permitted under this proposed rule. In addition, a covered entity could not use or disclose the key to coded identifiers if this rule would not permit the use or disclosure of the identified information to which the key pertains. If a covered entity re-identifies the de-identified information, it may only use or disclose the re-identified information consistent with these proposed rules, as if it were the original protected health information. See proposed § 164.506(d)(1).

As with other components of this proposed rule, removal of identifiers from data could be scaled. Small entities without the resources to determine at what point information is truly de-identified could remove the full list of possible identifiers listed in this regulation. Unless they have reason to believe that the information could still be linked to an individual, this proposed requirement would be fulfilled. However, larger, more sophisticated entities, could choose to determine independently what information needs to be removed.

Furthermore, efforts to remove identifiers from information would be optional. If an entity believes that removing identifiers would be excessively burdensome, it could choose not to release the information or to obtain an authorization from individuals before releasing any information.

e. *Uses and disclosures with individual authorization.* Covered entities must obtain individual authorization to use protected health information for purposes other than those allowed under the proposed rule. Activities requiring authorization would include, for example, marketing and eligibility determinations for health coverage or employment. Costs would be ongoing for staffing and administrative activities related to obtaining authorization from individuals.

In establishing the requirement for covered entities to obtain patient authorization to use individually identifiable health information for purposes other than those allowed under the proposed rule, we decided to include in the proposed rule a model ''request for authorization.'' By following such a model, covered entities, particularly small entities, could avoid the legal and administrative expenses that would be necessary to develop an authorization form that complies with the proposed rule's standards. The proposed rule would not prevent entities from developing their own patient authorization forms or from modifying existing forms in a manner consistent with the model.

The alternative to providing this model would be to state that an authorization would be required and allow entities to develop the authorization. We believe that providing no guidance in this area would have caused unnecessary difficulties and burdens for small entities.

f. *Uses and disclosures permitted without authorization.* This proposed rule would not require any uses or authorizations other than to the subject individual and to the Secretary for compliance. If small entities believe that the costs of making such discretionary disclosures are considered too high, they could choose not to make such disclosures. We would allow all covered entities, but particularly small entities, to base their decisions about these disclosures on any criteria that they believe to be important. We expect that the additional costs related to these disclosures would be factored into their decisions.

In cases where uses or disclosures without authorization are required by other law, we would attempt to minimize costs by not requiring application of the minimum necessary principle.

g. *Notice to individuals of rights and procedures.* The proposed rule would require covered entities to prepare and make available a notice that informs patients about their privacy rights and the entity's actions to protect privacy. Entities that do not already comply with the proposed rule's requirements would incur one-time legal and administrative costs. In addition, plans would incur ongoing costs related to the dissemination of the notice at least once every three years, and all covered entities would have ongoing costs related to dissemination to new individuals requesting services and requests for copies of the notice. Entities would also incur ongoing costs related to answering questions that are associated with the notice.

In discussing the requirement for covered entities to prepare and make available a notice regarding patient privacy rights and the entity's privacy practices, we considered exempting small businesses. Because this would exempt 84 percent of firms, we decided not to create this exemption. The second option would be to exempt extremely small entities. One discussion defined small entities as those with fewer than 10 employees. We decided that informing consumers of their privacy rights and of the activities of covered entities with which they conduct business was too important to exempt any entities.

In addition to requiring a basic notice, we considered requiring a longer more detailed notice that would be available to individuals on request. However, we decided that making information available on request and allowing the covered entity to decide how best to provide such information represents a more balanced approach. We believe that it would be overly burdensome to all entities, especially small entities, to require two notices.

We considered prescribing specific language that each covered plan or provider would include in its notice. The advantages of this approach would be that the recipient would receive exactly the same information from each covered plan or provider in the same format and that it would be convenient for covered entities to use a uniform model notice.

There are, however, several disadvantages to this approach. First, and most importantly, no model notice could fully capture the information practices of every covered plan or provider. Large entities will have information practices different from those of small entities. Some health care providers, for example, academic teaching hospitals, might routinely disclose identifiable health information for research purposes. Other health care providers might rarely or never make such disclosures. To be useful to individuals, each entity's notice of information practices should reflect its unique privacy practices.

Another disadvantage of prescribing specific language is that it would limit each covered plan or provider's ability to distinguish itself in the area of privacy protections. We believe that if information on privacy protections becomes readily available, individuals might compare and select plans or providers based on their information practices. In addition, a uniform model notice could easily become outdated. As new communication methods or technologies are introduced, the content of the notices might need to reflect those changes.

We believe that the proposed rule appropriately balances a patient's need for information and assurances regarding privacy with the covered entities' need for flexibility in describing their operations and procedures to protect patient privacy. Instead of a model notice, we have included a sample notice to guide the development of notices. We believe that this is an appropriate way to reduce the burden on all entities including those classified as small.

h. *Administrative requirements for covered entities.* We propose that covered entities be required to implement five basic administrative requirements to safeguard protected health information: designation of a privacy official, the provision of privacy training, establishment of safeguards, a complaint process, and establishment of sanctions. Implementation of these requirements would vary depending on a variety of different factors such as type of entity (*e.g.*, provider or plan), size of entity (*e.g.*, number of employees, number of patients), the level of automation within the entity (*e.g.*, electronic medical records), and organization of the entity (*e.g.*, existence of an office of information systems, affiliation with a medical school).

In proposed § 164.518(a), we would require covered plans and providers to designate a privacy official to be responsible for the development of policies for the use and disclosure of protected health information and for the supervision of personnel with respect to use and disclosure of protected health information. The designation of a privacy official would focus the responsibility for development of privacy policy.

The implementation of this requirement would depend on the size of the entity. For example, a small physician's practice might designate the office manager as the privacy official, and he or she would assume this as one of his or her broader administrative responsibilities. A large entity might appoint an individual whose sole responsibility is privacy policy, and that individual could choose to convene a committee representing several different components of the entity to develop and implement privacy policy.

In proposed § 164.518(b), we would require covered entities to provide training on the their policies and procedures with respect to protected health information. Entities would determine the most effective means of communicating with their workforce. For example, in a small physician practice, the training requirement could be satisfied by providing each new member of the workforce with a copy of the practice's information policies and requiring members of the workforce to acknowledge that they have reviewed the policies. A large health plan could provide for a training program with live instruction, video presentations or interactive software programs. The small physician practice's solution would not protect the large plan's data, and the plan's solution would be neither economically feasible nor necessary for the small physician practice.

In proposed § 164.518(c), we would require covered entities to put in place

administrative, technical, and physical safeguards to protect against any reasonably anticipated threats or hazards to the privacy of the information, and unauthorized uses or disclosures of the information.

In proposed § 164.518(d), we would require covered plans and providers to have some mechanism for receiving complaints from individuals regarding the covered plan's or provider's compliance with the requirements of this proposed rule. We considered requiring covered plans and providers to provide a formal internal appeal mechanism, but rejected that option as too costly and burdensome for some entities. We also considered eliminating this requirement entirely, but rejected that option because a complaint process would give covered plans or providers a way to learn about potential problems with privacy policies or practices, or training issues. We also hope that providing an avenue for covered plans or providers to address complaints would lead to increased consumer satisfaction. We believe this approach strikes a reasonable balance between allowing covered plans or providers flexibility and accomplishing the goal of promoting attention to improvement in privacy practices.

We expect that sanctions would be more formally described and consistently carried out in larger, more sophisticated entities. Smaller, less sophisticated entities would be given more latitude and flexibility. For such smaller entities and less sophisticated entities, we would not expect a prescribed sanctions policy, but would expect that actions be taken if repeated instances of violations occur. In proposed § 164.518(e), we would require all covered entities to develop and apply when appropriate sanctions for failure to comply with policies or procedures of the covered entity or with the requirements of this proposed rule.

i. *Documentation requirements for covered entities.* We are proposing that covered entities be required to document policies and procedures in several important areas. These areas would include use within the entity; informing business partners; disclosures with and without authorization; limitations on use and disclosure for self-pay; inspection and copying; amendment or correction; accounting for uses and disclosures; notice development, maintenance, and dissemination; sanctions; and complaint procedures. We considered whether formal documentation of these policies would be necessary. A key factor in making this decision was determining the burden on entities, particularly the burden on small entities. We also considered whether it would be reasonable to exempt very small entities from this provision. For example, entities with fewer than ten employees could be able to effectively communicate policies and procedures verbally. We decided that we needed to include all entities in the provision because these documentation requirements are intended as tools to educate the management, employees, and business partners about the consideration that should be given to protecting the privacy of health information.

3. The Burden on a Typical Small Business.

We expect that small entities will face a cost burden as a result of complying with the proposed regulation. We estimate that the burden of developing privacy policies and procedures is lower in dollar terms for small businesses than for large businesses, but we recognize that the cost of implementing privacy provisions will be a larger burden to small entities as a proportion of total revenue. Due to these concerns, we rely on the principle of scalability stated in the proposed rule, and have based our cost estimates on the expectation that small entities will develop less expensive and less complex privacy measures than large entities.

In many cases, we have specifically considered the impact that the proposed rule may have on solo practitioners or rural providers. Where these providers do not have large technical systems, it is possible that the regulation may not apply to small providers, or that small providers will not be required to change their business practices other than adhering to the basic requirements that they state their privacy policies and notify patients of their privacy rights. For both activities, the proposed regulation accounts for the activities and size of the practice. Scalability implies that in developing policies and procedures to comply with the proposed regulation, businesses should consider their basic functions and the amount of health information exchanged electronically. All covered entities must take appropriate steps to address privacy concerns, and in determining the scope and extent of their compliance activities, businesses should weigh the costs and benefits of alternative approaches and should scale their compliance activities to their structure, functions, and capabilities.

Our analysis of the costs to small businesses is divided into three sections: (1) Initial start-up costs associated with development of privacy policy; (2) initial start-up costs associated with system change; and (3) ongoing costs, including notification of privacy policies.

Overall, our analysis suggests that the average start-up cost of complying with the proposed rule is $396 per entity. This includes the cost of developing privacy policies and systems compliance changes (Table C). The ongoing costs of privacy compliance are approximately $337 per entity in the first year and $343 every year thereafter (Table D). The total cost of implementing initial and ongoing costs of the proposed regulation in the first year is $733 per entity. After the first year, the total compliance cost to the entity is $343 per year. We estimate that the relative average cost of initial compliance is approximately 0.12 percent of a small entity's annual expenditures in the first year. The relative average cost of ongoing privacy compliance is approximately 0.05 percent of a small entity's annual expenditures.

Our cost calculations are based on several assumptions. The cost of developing privacy policies is based on figures from the regulatory impact analysis that accompanied the HIPAA National Provider Identifier (63 FR 25320). The cost of initial systems compliance is based on current assumptions about market behavior; including the assumption that a relatively small proportion of the total cost of system compliance (20%) will be absorbed by small covered entities. We evaluated the ongoing costs of an entity's privacy protection by calculating that privacy protection costs should be proportional to the number of patients served by the business. For example, the cost of notifying patients of privacy practices will be directly proportional to the number of patients served. We then multiplied the proportion of small entities by the total ongoing costs of privacy compliance.

Initial Costs

Table C shows the results of our calculations of the cost of initial compliance. We calculated initial privacy policy costs separate from initial system compliance costs because we made different assumptions about the cost of each. To calculate initial privacy policy costs per small entity, we multiplied the estimated cost of developing privacy policies (per entity) by the number of establishments. We then averaged these costs and computed that the average cost of developing privacy policies is $334.31 per small entity. The average cost of implementing privacy policies is greater

than the $300 cost we assume most health care provider offices will pay, because we assume that small health plans, hospitals, and nursing and patient care services will spend between $500–$1,000 to implement privacy policies. Calculating the cost of system compliance per entity required us to estimate the percent of total system costs that each type of entity would incur. We used the $90 million figure (cited in the RIA) as the basis for distributing system compliance costs across various types of entities affected by the proposed rule. We estimated how this cost would be divided between small and large entities, and among plans, providers and clearinghouses.

TABLE C.—ANNUAL COST OF IMPLEMENTING PROVISIONS OF THE PROPOSED PRIVACY REGULATION IN THE FIRST YEAR

Industry	Initial costs				Ongoing costs			Total costs	
	Initial privacy policy costs incurred by small entities, per entity	Initial system compliance cost incurred by small entities [1], per entity	Notice development cost, per small entity	Total initial compliance cost, per small entity [2]	First year notice issuance costs for small entities, per small entity	Annual amendment and correction cost to small entities, per small entity	Annual written authorization cost to small entities, per small entity	Total annual ongoing cost in the first year, per small entity	Total annual initial and ongoing cost in the first year, per small entity
Drug Stores & Proprietary Stores [3]	$300	$131.19	$59.40	$490.58	$118.26	$768.64	$102.55	$989.45	$1,480.03
Accident & Health Insurance & Medical Service Plans [3] (Accident & Health Insurance and Hospital & Medical Service Plans)	1,000	1,939.86	203.91	3,143.77	314.02	127.60	17.02	458.65	3,602.41
Offices & Clinics Of Doctors Of Medicine	300	21.04	21.20	342.24	42.21	260.93	34.81	337.96	680.20
Offices & Clinics Of Dentists	300	7.43	13.25	320.68	26.39	163.11	21.76	211.26	531.94
Offices & Clinics Of Other Health Practitioners	300	11.10	17.82	328.92	35.47	219.29	29.26	284.02	612.94
Nursing & Personal Care Facilities	1,500	117.15	49.63	1,666.79	98.82	610.88	81.50	791.20	2,457.99
Hospitals	1,500	7,362.22	79.65	8,941.87	158.59	980.36	130.80	1,269.75	10,211.62
Home Health Care Services	300	58.06	30.66	388.72	61.05	377.38	50.35	488.77	877.49
Other Health Care Services including Lab Services	300	19.83	10.84	330.68	21.59	133.47	17.81	172.87	503.55
Average Cost	334.31	40.13	21.17	395.61	42.05	260.23	34.72	337.00	732.61

[1] The SBA defines small health care entities as those with annual revenue under $5,000,000.
[2] Total Initial Compliance Cost includes policy implementation and systems compliance costs.
[3] Includes some entities not covered by this regulation. Pharmacies are the only component of Drug Stores and Proprietary Stores covered by the regulation. Accident and workers compensation insurance are not covered by the regulation.

TABLE D.—ANNUAL COST OF IMPLEMENTING PROVISIONS OF THE PROPOSED PRIVACY REGULATION, AFTER THE FIRST YEAR

Industry	Ongoing Costs				
	Annual notice issuance costs after the first year, per small entity	Annual amendment and correction cost to small entities, per small entity	Annual written authorization cost to small entities, per small entity	Annual ongoing costs for paperwork and training, per small entity	Total annual ongoing cost after the first year, per small entity
Drug Stores & Proprietary Stores [1]	73.26	768.64	102.55	20	964.45
Accident & Health Insurance & Medical Service Plans [2] (Accident & Health Insurance and Hospital & Medical Service Plans)	314.02	127.60	17.02	60	518.65
Offices & Clinics Of Doctors Of Medicine	26.15	260.93	34.81	20	341.90
Offices & Clinics Of Dentists	16.35	163.11	21.76	20	221.22
Offices & Clinics Of Other Health Practitioners	21.97	219.29	29.26	20	290.52
Nursing & Personal Care Facilities	61.22	610.88	81.50	100	853.59
Hospitals	98.24	980.36	130.80	100	1,309.40
Home Health Care Services	37.82	377.38	50.35	20	485.54
Other Health Care Services including Lab Services	13.38	133.47	17.81	20	184.65
Average Cost	26.16	260.23	34.72	22.28	343.39

[1] The SBA defines small health care entities as those with annual revenue under $5,000,000.
[2] Includes some entities not covered by this regulation. Pharmacies are the only component of Drug Stores and Proprietary Stores covered by the regulation. Accident and workers compensation insurance are not covered by the regulation.

Our calculations regarding division of costs are based on two assumptions: (1) System costs are principally fixed costs associated with the purchase of hardware and software [50]; and (2) large entities will continue to invest more heavily in hardware and software expenditures than small entities. We estimate that 80 percent of the system costs will be born by large entities. The remaining 20 percent of total systems costs will be absorbed by small entities. To calculate the effect on small businesses, we multiplied the system compliance costs cited in the RIA by the proportion of the costs we expect small entities to incur (20 percent of total). We then multiplied the total cost of system compliance for small entities by the percentage of health care revenue by industry and calculated a cost per entity.

We used HCFA's estimate of total national health expenditures to calculate the percent of total health care business that is represented by types of health care entities. We calculated the proportion of business transacted by a type of health care entity (by SIC code) and multiplied this by the total expenditures ($1.084 billion total) [51]. National expenditure data is a useful measure for allocating system compliance costs for two reasons. Even though system compliance costs are primarily fixed costs, we assume that they bear some relationship to the size and level of the activity of the entity.

[50] We are not suggesting that these investments are exclusively computer-related. They may also include costs for personnel training, reorganization, and contract negotiations with outside entities.

[51] Health Care Finance Administration, 1996 http://www.hcfa.gov/stats/nheoact/tables/t10.htm

Similarly, national expenditures vary according to both size and level of activity. Second, in contrast to the annual receipts compiled by the Business Census Survey, national expenditure information compares its data to other sources in order to validate its results. Thus, we decided that the national expenditure data are a more reliable source of overall business activity for our purposes. Based on these assumptions, we believe that the total cost of system compliance for all small health care entities will be approximately 18 million. Dividing costs by the number of small entities suggests that the average cost of system compliance is $40.13 per entity.

The cost of notice development is approximately $21 per small entity. We assume that many small providers will receive assistance developing their notice policies from professional associations. Thus, the overall cost of developing compliant notices is significant, but the cost per entity is small. The cost to small entities of developing notices is based on the proportion of expenditures generated by small entities. We recognize that this may not adequately capture the costs of developing a provider or plan's notice of their privacy policies, and invite comment on our approach.

We added the per-entity cost of privacy policy implementation to the cost of systems compliance to determine the total average cost of start-up compliance. Our figures indicate that initial compliance will cost an average of $396 per small entity. These costs vary across entity type (Table C). For example, small hospitals have a much higher cost of compliance than the average cost for all small entities, whereas dentists' offices tend to have initial compliance costs that are lower than the average for small entities. Most small practitioner offices have low costs ($320 per dentist office), whereas small hospitals ($8,942 per entity) and small insurance companies have much higher costs ($3,144 per entity) than other health care entities.

Finally, we attempted to estimate the impact of compliance costs on small entities by comparing the cost of complying with the proposed rule to an entity's annual expenditures (Table E). We computed the percent of small entity expenditures as a percent of national expenditures by calculating the proportion of small business receipts (from census data compiled for the SBA) that apply to segments of the health care market. Although we believe that the SBA data understates the amount of annual receipts, we assumed that the underestimates are consistent across all entities. Thus, although the dollar amounts reported by the SBA are incorrect, our assumption is that the proportion of small entity receipts relative to total annual receipts is correct.

Applying the percent of small entity receipts to the national expenditure data allows us to estimate the percent of national expenditures represented by small entities. We then considered the total compliance cost (initial and ongoing cost) as a percent of small business expenditures. Our estimates suggest that the cost of complying with the proposed rule represent approximately 0.12 percent of total annual expenditures for a small health care entity in the first year. The relative cost of complying with the proposed rule is substantially lower in subsequent years, representing 0.04 percent of an entity's annual expenditures. The relative cost of complying with the proposed regulation cost of complying is highest for small health insurers (1.03 percent of expenditures). These costs will be higher due to the volume and complexity of health plan billing systems; health plans are required to implement more policies and procedures to protect health information because they handle so much personally identifiable information. Because health plan costs are higher and there is a smaller number of plans than other type of entities affected by the regulation, these costs result in a higher annual cost per small health plan. Table E further illustrates the cost impact by type of entity in the first year.

TABLE E.—SMALL ENTITY BUSINESS EXPENDITURES AND PROPORTION OF ANNUAL EXPENDITURES REPRESENTED BY INITIAL AND ONGOING COMPLIANCE COSTS IN THE FIRST YEAR *

Industry	Total annual initial and ongoing costs in the first year, per small entity	Annual expenditure per small entity [1]	Compliance cost as a percentage of a small entity's annual expenditures
Drug Stores & Proprietary Stores [2]	$1,480.03	$2,046,199	0.07
Accident & Health Insurance & Medical Service Plans [2] (Accident & Health Insurance and Hospital & Medical Service Plans)	3,602.41	350,467	1.03
Offices & Clinics Of Doctors Of Medicine	680.20	695,560	0.10
Offices & Clinics Of Dentists	531.94	434,260	0.12
Offices & Clinics Of Other Health Practitioners	612.94	583,805	0.10
Nursing & Personal Care Facilities	2,457.99	1,629,755	0.15
Hospitals	10,211.62	2,660,215	0.38
Home Health Care Services	877.49	1,003,475	0.09
Other Health Care Services including Lab Services	503.55	351,146	0.14
Average Cost	732.61	625,992	0.12

* The SBA defines small health care entities as those with annual revenue under $5,000,000.
** Total Initial Compliance Cost includes policy implementation and systems compliance costs
[1] Based on the assumption that the proportion of revenue generated by small businesses approximates the proportion of expenditures faced by small businesses
[2] Includes some entities not covered by this regulation. Pharmacies are the only component of Drug Stores and Proprietary Stores covered by the regulation. Accident and workers compensation insurance are not covered by the regulation.

Ongoing Costs

In this section, we evaluate the ongoing costs of providing patient notices, the annual cost of amending and correcting medical information, the cost of providing written authorizations, and the ongoing cost of paperwork and training. We estimated the ongoing costs of compliance through calculations

similar to those used for our systems compliance estimates. Ongoing costs are most heavily influenced by the size of the business. Therefore, we assume that the number of patients an entity serves is directly proportional to its ongoing compliance costs.

We estimated market share using Small Business Administration data estimating total receipts.[52] We divided the small entity receipts by total receipts and arrived at an estimate that 22 percent of the revenue generated by the health care classifications we examined is from small businesses. Using annual receipts to estimate cost burden is more accurate than using information on the number of health care entities. The size of the small entity is more likely to be correlated with the number of patients served than the number of businesses, and therefore, the amount of business conducted by an entity. Because it is difficult to find a single good estimate of market share, we considered estimating market share over a range, using the proportion of annual receipts as a lower bound and number of entities as the higher bound. We concluded that even if the SBA data does not capture the total amount of health care receipts accurately, estimating market share by examining receipts would be much more accurate than using the number of entities.

We multiplied the percent total receipts by the total ongoing costs (by entity type) to obtain a range of ongoing costs for small entities. We were then able to divide these costs by the number of small entities by type of entity. We estimated ongoing costs in the first year that the proposed rule takes effect separately from our estimate of ongoing cost in the following years. The estimates were approximately the same; $337 and $343 respectively.

We estimate that the ongoing cost of compliance will be approximately 0.05 percent of a small entity's annual expenditures. This cost burden is fairly consistent across all types of entities.

Clearinghouses and Nonprofit Entities

We should note that the above discussion does not consider health care clearinghouses, nonprofit hospitals, home health agencies, or nursing and skilled nursing facilities. To the extent that clearinghouses and nonprofit facilities have annual receipts of less than $5 million, they were included in the preceding analysis.

Although we do not have precise information on the number of clearinghouses that qualify as small entities under the RFA, we believe that approximately half would meet the criteria. As noted in the regulatory impact analysis, as long as clearinghouses perform the function of merely reformatting information they receive and transmitting the data to other entities, the cost of complying with the proposed rule should be minimal.

A similar logic applies for nonprofit health plans and hospitals. We do know how many nonprofit organizations currently exist in the U.S., but do not have reliable revenue and expenditure data for these entities. In the absence of such data, we assume that nonprofit entities have a similar ratio of revenues to expenditures as the for-profit entities we have examined. Thus, we believe that the impact of complying with the proposed rule should be similar to that described for-profit plans and hospitals.

The preceding analysis indicates that the expected burden on small entities of implementing the proposed rule would be minimal. However, by necessity, the analysis is based on average costs, and as such, they may not reflect the actual burden on some or even a substantial number of small entities. Therefore, the Secretary does not certify that the proposed rule will not have a significant impact on a substantial number of small entities.

VI. Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires cost-benefit and other analyses for rules that would cost more than $100 million in a single year. The proposed rule qualifies as a significant rule under the statute. DHHS has carried out the cost-benefit analysis in sections D and E of this document, which includes a discussion of unfunded costs to the states resulting from this regulation.

A. Future Costs

DHHS estimates some of the future costs of the proposed rule in Section E of the Preliminary Regulatory Impact Analysis of this document. The reported costs include costs incurred during the compliance period and up to 5 years after the effective date. The same section also includes some qualitative discussion of costs that would occur beyond that time period. Most of the costs of the proposed rule, however, would occur in the years immediately after the publication of a final rule. Future costs beyond the five year period will continue but will not be as great as the initial compliance costs.

B. Particular Regions, Communities, or Industrial Sectors.

The proposed rule applies to the health care industry and would, therefore, affect that industry disproportionately. Any long-run increase in the costs of health care services would largely be passed on to the entire population of consumers.

C. National Productivity and Economic Growth

The proposed rule is not expected to substantially affect productivity or economic growth. It is possible that productivity and growth in certain sectors of the health care industry could be slightly lower than otherwise because of the need to divert research and development resources to compliance activities. The diversion of resources to compliance activities would be temporary. Moreover, DHHS anticipates that, because the benefits of privacy are large, both productivity and economic growth would be higher than in the absence of the proposed rule. In section I.A. of this document, DHHS discusses its expectation that this proposed rule would increase communication among consumers, health plans, and providers and that implementation of privacy protections will lead more people to seek health care. The increased health of the population will lead to increased productivity and economic growth.

D. Full Employment and Job Creation.

Some of the human resources devoted to delivery of health care services would be redirected by the proposed rule. The proposed rule could lead to some short-run changes in employment patterns as a result of the structural changes within the health care industry. The growth of employment (job creation) for the roles typically associated with the health care profession could also be temporarily change but be balanced by an increased need for those who can assist entities with complying with this proposed rule. Therefore, while there could be a temporary slowing of growth in traditional health care professions, that will be offset by a temporary increase in growth in fields that may assist with compliance with this proposed rule (e.g. legal professionals, and management consultants).

E. Exports

Because the proposed rule does not mandate any changes in products, current export products will not be required to change in any way.

VII. Environmental Impact

The Department has determined under 21 CFR 25.30(K) that this action

[52] Office of Advocacy, U.S. Small Business Administration, from data provided by the Bureau of the Census, Statistics of U.S. Businesses, 1996.

is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide a 60-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 OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Under the PRA, the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section are to be considered. Due to the complexity of this regulation, and to avoid redundancy of effort, we are referring readers to Section IV (Regulatory Impact Analysis) above, to review the *detailed* cost assumptions associated with these PRA requirements. We explicitly seek, and will consider public comment on our cost assumptions, as they relate to the PRA requirements summarized in this section.

SUMMARY PRA BURDEN HOURS

Provision	Burden (in hours)
§ 160.204 Process for requesting exceptions.	160
§ 164.506 General standards and implementation specifications for uses and disclosures of protected health information.	* TBD
§ 164.508 Standards and implementation specifications for uses and disclosures for which individual authorization would be required.	3,561,076
§ 164.510 Standards and implementation specifications for uses and disclosures for which individual authorization would not be required.	8,903
§ 164.512 Notice of privacy practices; rights and procedures.	7,273,952
§ 164.514 Access to protected health information; rights and procedures.	* TBD
§ 164.515 Accounting for uses and disclosures of protected health information	* TBD
§ 164.516 Amendment and correction; rights and procedures	*TBD
§ 164.520 Development and documentation of policies and procedures	2,927,000
§ 164.522 Compliance and Enforcement	2,500
Total Hours	13,773,591

* Burden to be determined based upon public comment.

Section 160.204 Process for Requesting Exceptions.

Section 160.204 would require States to: (1) Submit a written request, that meets the requirements of this section, to the Secretary to except a provision of State law from preemption under § 160.203; (2) submit a new request to the Secretary, should there be any changes to the standard, requirement, or implementation specification or provision of State law upon which an exception previously was granted, and (3) submit a written request for an extension of the exception prior to the end of the three-year approval period for a given exception. In addition, § 160.204 would require a State to submit a written request for an advisory opinion to the Secretary that meets the requirements of § 160.204.

The burden associated with these requirements is the time and effort necessary for a State to prepare and submit the written request for preemption or advisory opinion to HCFA for approval. On an annual basis it is estimated that it will take 10 States 16 hours each to prepare and submit a request. The total annual burden associated with this requirement is 160 hours.

Section 164.506 General Standards and Implementation Specifications for Uses and Disclosures of Protected Health Information

Given that the burden associated with the following information collection requirements will differ significantly, by the type and size of plan or provider, we are explicitly soliciting comment on the burden associated with the following requirements:

- Except for disclosures of protected health information by a covered entity that is a health care provider to another health care provider for treatment purposes, § 160.204(e) would require a covered entity to maintain documentation demonstrating that they have entered into a contract that meets the requirements of this part with each of their business partners;
- A covered entity would have to make all reasonable efforts not to use or disclose more than the minimum amount of protected health information necessary to accomplish the intended purpose of the use or disclosure;
- A covered entity could use protected health information to create de-identified information if the individually identifiable information has been removed, coded, encrypted, or otherwise eliminated or concealed.

Section 164.508 Standards and Implementation Specifications for Uses and Disclosures for Which Individual Authorization Would Be Required

Pursuant to the conditions set forth in this section, a covered entity would need to obtain a written request from an individual, before it uses or discloses protected health information of an individual. A copy of the model form which appears in Appendix to Subpart E of Part 164, or a form that contains the elements listed in paragraphs (c) or (d) of this section, as applicable, would need to be accepted by the covered entity.

The burden associated with these proposed requirements is the time and effort necessary for a covered entity to obtain written authorization prior to the disclosure of identifiable information. On an annual basis it is estimated that it will take 890,269 entities, a range of 0 to 80 hours per entity to obtain and

maintain authorization documentation on an annual basis. Given that we believe the majority of the covered entities will be minimally affected by this requirement, we estimate the annual average burden per entity to be 4 hours for a total annual burden of 3,561,076 hours. Collecting such authorization should have costs on the order of those associated with providing access to records (not on a per page basis). Since the proposed requirement does not apply to treatment and payment, assuming 1% of the 543 million health care encounters might be reasonable. At a cost of about $10 each, the aggregate cost would be about $54 million. Therefore, on average the cost per entity would be about $60, with many entities receiving no requests and thus having no costs.

Section 164.510 Standards and Implementation Specifications for Uses and Disclosures for Which Individual Authorization Would Not Be Required

A covered entity could disclose protected health information to a health researcher for health research purposes subject to 45 CFR part 46 and purposes other than those subject to 45 CFR part 46, provided that the covered entity has obtained written documentation demonstrating that the applicable requirements proposed in this section have been met.

The burden associated with these proposed requirements is the time and effort necessary for a covered entity to maintain documentation demonstrating that they have obtained institutional review board or privacy board approval, which meet the requirements of this section. On an annual basis it is estimated that this proposed requirement will affect 1 % or 8,903 of covered entities. We further estimate that it will take an average of 1 hour per entity to meet these proposed requirements on an annual basis. Therefore, the total estimated annual burden associated with this proposed requirement is 8,903 hours.

Section 164.512 Notice of Privacy Practices; Rights and Procedures

Section 164.512 would require covered entities to provide written notice of the entities' privacy practices, rights, and procedures that meet the requirements of this section to affected parties upon request and as summarized below.

Health plans would provide a copy of the notice to an individual covered by the plan at enrollment and whenever the content of the notice is significantly altered thereafter, but no less frequently than once every three years. Total notice counts are estimated to be about 230 million, assuming plans choose to send them out annually rather than keeping track of duration since last notice. The average number of notices per plan per year would be about 1,200. For the approximately 19,000 plans issuing notices, the number of notices can be as few as 1,000 for a small self-insured self-administered employer, or as many as a million or more for a large commercial insurer or HMO. We further estimate that it will require each plan, on average, 8 hours to disseminate the required notices. This estimate is based upon the assumption that the required notice will be incorporated and disseminated with a plan's annual policy materials. The total burden associated with this requirement is calculated to be 151,800 hours.

Health care providers would provide a copy of the notice to an individual at the time of first service delivery to the individual, provide as promptly as possible a copy of the notice to an individual served by the provider whenever the content of the notice is significantly altered, post a copy of the notice in a location where it is reasonable to expect individuals seeking services from the provider to be able to read the notice, and date each version of the notice. Total notices in the first year are estimated to be about 700 million (based on annual patient contacts with hospitals, physicians, and other providers), with subsequent year counts of 350 million. Small providers could be providing 400 or fewer notices (based on 150 million persons with ambulatory physician contacts per year and approximately 370,000 physician offices). The overall average will also be close to that amount, since the bulk of providers are small entities. Large providers could be sending out 3,000 or more notices (based on 20 million persons with hospitalizations and approximately 6600 hospitals). We further estimate that it will require each provider, on average, 8 hours to disseminate the required notices. This estimate is based upon the assumption that the required notice will be incorporated into and disseminated with other patient materials. The total burden associated with this requirement is calculated to be 7,122,152 hours.

Section 164.514 Access of Individuals to Protected Health Information

Given that the burden associated with the following information collection requirements will differ significantly, by the type and size of plan or provider, we are explicitly soliciting comment on the burden associated with the following proposed requirements:

- An individual has a right of access to, which includes a right to inspect and obtain a copy of, his or her protected health information in a designated record set of a covered entity that is a health plan or a health care provider, including such information in a business partner's designated record set that is not a duplicate of the information held by the provider or plan, for so long as the information is maintained;
- Where the request is denied in whole or in part, the health plan or a health care provider would provide the individual with a written statement of the basis for the denial and a description of how the individual may complain to the covered entity pursuant to the complaint procedures established in § 164.518 or to the Secretary pursuant to the procedures established in § 164.522 of this subpart.

Section 164.515 Accounting for Uses and Disclosures of Protected Health Information

Given that the burden associated with maintaining records to facilitate the recreation of disclosures will differ significantly, be the type and size of plan or provider, we are explicitly soliciting comment on the burden associated with the following proposed record keeping requirement:

- A covered entity that is a plan or provider would need to be able to give individuals an accurate accounting of all uses and disclosures that are for purposes other than treatment, payment, and health care operations; except that such procedures would provide for the exclusion from such accounting of protected health information which is disclosed to a health oversight or law enforcement agency, if the health oversight or law enforcement agency provides a written request stating that the exclusion is necessary because disclosure would be reasonably likely to impede the agency's activities and specifies the time for which such exclusion is required.

Section 164.516 Amendment and Correction

Given that burden will associated with the following information collection requirements will differ significantly, by the type and size of plan or provider, we are explicitly soliciting comment on the burden associated with the following proposed requirements:

- An individual would have the right to request amendment or correction of his or her protected health information in designated records created by a covered entity that is a health plan or health care provider, where the

individual asserts that the information is not accurate or complete and where the error or omission may have an adverse effect on the individual.

• Where the request is denied , provide the individual with a written statement of the basis for the denial, a description of how the individual may file a statement of disagreement with the denial, a description of how the individual may file a complaint with the covered entity, including the name and telephone number of a contact person within the covered entity who can answer questions concerning the denial and the complaint process; and a description of how the individual may file a complaint with the Secretary pursuant to § 164.522 of this subpart.

Section 164.520 Internal Privacy Practices; Standards and Procedures

A covered entity would need to ensure that all employees who have access to protected health information have received appropriate training about the entity's policies for use and disclosure of such information. Upon completion of the training and at least once every three years thereafter, covered entities would require each employee to sign a statement that he or she received the privacy training and will honor all of the entity's privacy policies and procedures.

The burden associated with these requirements is the time and effort necessary for a covered entity to obtain and maintain certification documentation demonstrating that applicable employees have received privacy training and will honor all of the entity's privacy policies and procedures. It is estimated that it will take 890,269 entities, a range of 1 hour to 40 hours per entity to obtain and maintain documentation on an annual basis. Given that we believe the majority of the covered entities will be minimally affected by this requirement, we estimate the annual average burden to be 3 hours per entity for a total annual burden of 2,700,000 hours. Using previous calculations, 900,000 (rounded) entities break down to about 95% small, 5% various types of large, and 1 burden hour for 95%, and 40 burden hours for 5%, the average burden would be 3 hours.

In addition, this section would require a covered entity that is a health plan or health care provider to develop and document its policies and procedures for implementing the requirements of this proposed rule, and amend the documentation to reflect any change to a policy or procedure.

The burden associated with these requirements is the time and effort necessary for a covered entity to maintain documentation demonstrating that they have implemented procedures that meet the requirements of this proposed rule. It is estimated that it will take 890,269 entities a range of 15 minutes to 1 hour per entity to maintain procedural documentation on an annual basis. We believe the majority (95%) of the covered entities will be minimally affected by this requirement. Using the 95% small/5% large, the average burden is 17 minutes. Multiplying by 890,269, results in a total annual burden of 256,000 hours (see discussion below).

Since the requirements for developing formal processes and documentation of procedures mirror what will already have been required under the HIPAA security regulations, the burden and additional costs should be small. To the extent that national or state associations will develop guidelines or general sets of processes and procedures which will be reviewed by individual member entity, the costs would be primarily those of the individual reviewers. Assuming this process occurs, we believe that entities will review information from associations in each state and prepare a set of written policies to meet their needs. Our estimates are based on assumed costs for providers ranging from $300 to $3000, with the average being about $375. The range correlates to the size and complexity of the provider. With less than 1 million provider entities, the aggregate cost would be on the order of $300 million. For plans and clearinghouses, our estimate assumes that the legal review and development of written policies will be more costly because of the scope of their operations. They are often dealing with a large number of different providers and may be dealing with requirements from multiple states. We believe the costs for these entities will range from $300 for smaller plans to $15,000 for the largest plans. Because there are very few large plans in relation to the number of small plans, the average implementation costs will be about $3050.

Section 164.522 Compliance and Enforcement

An individual who believes that a covered entity is not complying with the requirements of this subpart may file a complaint with the Secretary within 180 days from the date of the alleged non-compliance, unless the time for filing is extended by the Secretary. The complaint would describe in detail the acts or omissions believed to be in violation of the requirements of this subpart.

The burden associated with these requirements is the time and effort necessary for an individual to prepare and submit a written complaint to the Secretary. On an annual basis it is estimated that 10,000 complaints will be filed on an annual basis. We further estimate that it will take an average of 15 minutes per individual to submit a complaint. Therefore, the total estimated annual burden associated with this requirement is 2,500 hours.

A covered entity would need to maintain documentation necessary for the Secretary to ascertain whether the covered entity has complied or is complying with the requirements of this subpart. While this section is subject to the PRA, the burden associated with this requirement is addressed under sections referenced above, which discuss specific record keeping requirements.

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements in §§ 160.204, 164.506, 164.508, 164.510, 164.512, 164.514, 164.515, 164.516, 164.520, and § 164.522. These requirements are not effective until they have been approved by OMB.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Health Care Financing Administration, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Room C2–26–17, 7500 Security Boulevard, Baltimore, MD 21244–1850. ATTN: John Burke HIPAA Privacy-P

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503. ATTN: Allison Herron Eydt, HCFA Desk Officer.

IX. Executive Order 12612: Federalism

The Department has examined the effects of provisions in the proposed privacy regulation on the relationship between the Federal government and the States, as required by Executive Order 12612 on ''Federalism.'' The agency concludes that preempting State or local proposed rules that provide less stringent privacy protection requirements than Federal law is consistent with this Executive Order. Overall, the proposed rule attempts to balance both the autonomy of the States with the necessity to create a Federal benchmark to preserve the privacy of personally identifiable health information.

It is recognized that the States generally have laws that relate to the privacy of individually identifiable health information. The HIPAA statute dictates the relationship between State law and this proposed rule. Except for laws that are specifically exempted by the HIPAA statute, State laws continue to be enforceable, unless they are contrary to Part C of Title XI of the standards, requirements, or implementation specifications adopted or pursuant to subpart x. However, under section 264(c)(2), not all contrary provisions of State privacy laws are preempted; rather, the law provides that contrary provisions that are also ''more stringent'' than the federal regulatory requirements or implementation specifications will continue to be enforceable.

Section 3(b) of Executive Order 12612 recognizes that Federal action limiting the discretion of State and local governments is appropriate ''where constitutional authority for the action is clear and certain and the national activity is necessitated by the presence of a problem of national scope.'' Personal privacy issues are widely identified as a national concern by virtue of the scope of interstate health commerce. HIPAA's provisions reflect this position. HIPAA attempts to facilitate the electronic exchange of financial and administrative health plan transactions while recognizing challenges that local, national, and international information sharing raise to confidentiality and privacy of health information.

Section 3(d)(2) of the Executive Order 12612 requires that the Federal government refrain from ''establishing uniform, national standards for programs and, when possible, defer to the States to establish standards.'' HIPAA requires HHS to establish standards, and we have done so accordingly. This approach is a key component of the proposed privacy rule, and it adheres to Section 4(a) of Executive Order 12612, which expressly contemplates preemption when there is a conflict between exercising State and Federal authority under Federal statute. Section 262 of HIPAA enacted Section 1178 of the Social Security Act, developing a ''general rule'' that State laws or provisions that are contrary to the provisions or requirements of Part C of Title XI, or the standards or implementation specifications adopted, or established thereunder are preempted. Several exceptions to this rule exist, each of which is designed to maintain a high degree of State autonomy.

Moreover, Section 4(b) of the Executive Order authorizes preemption of State law in the Federal rule making context when there is ''firm and palpable evidence compelling the conclusion that the Congress intended to delegate to the * * * agency the authority to issue regulations preempting State law.'' Section 1178 (a)(2)(B) of HIPAA specifically preempts State laws related to the privacy of individually identifiable health information unless the State law is more stringent. Thus, we have interpreted State and local laws and regulations that would impose less stringent requirements for protection of individually identifiable health information as undermining the agency's goal of ensuring that all patients who receive medical services are assured a minimum level of personal privacy. Particularly where the absence of privacy protection undermines an individual's access to health care services, both the personal and public interest is served by establishing Federal rules.

The proposed rule would establish national minimum standards with respect to the collection, maintenance, access, transfer, and disclosure of personally identifiable health information. The Federal law will preempt State law only where State and Federal laws are ''contradictory'' and the Federal regulation is judged to establish ''more stringent'' privacy protections than State laws.

As required by the Executive Order, States and local governments will be given, through this notice of proposed rule making, an opportunity to participate in the proceedings to preempt State and local laws (section 4(e) of Executive Order 12612). However, it should be noted that the preemption of state law is based on the HIPAA statute. The Secretary will also provide a review of preemption issues upon requests from States. In addition, under the Order, appropriate officials and organizations will be consulted before this proposed action is implemented (section 3(a) of Executive Order 12612).

Finally, we have considered the cost burden that this proposed rule would impose on State-operated health care entities, Medicaid, and other State health benefits programs. We do not have access to reliable information on the number of State-operated entities and programs, nor do we have access to data on the costs these entities and programs would incur in order to comply with the proposed rule. A discussion of possible compliance costs that covered entities may incur is contained in the Unfunded Mandates section above. We believe that requiring State health care entities covered by the proposed rule to comply with the proposed rule would cost less than one percent of a State's annual budget.

The agency concludes that the policy proposed in this document has been assessed in light of the principles, criteria, and requirements in Executive Order 12612; that this policy is not inconsistent with that Order; that this policy will not impose significant additional costs and burdens on the States; and that this policy will not affect the ability of the States to discharge traditional State governmental functions.

During our consultation with the States, representatives from various State agencies and offices expressed concern that the proposed regulation would pre-empt all State privacy laws. As explained in this section, the regulation would only pre-empt state laws where there is a direct conflict between state laws and the regulation, and where the regulation provides more stringent privacy protection than State law. We discussed this issue during our consultation with State representatives, who generally accepted our approach to the preemption issue. During the consultation, we requested further information from the States about whether they currently have laws requiring that providers have a ''duty to warn'' family members or third parties about a patient's condition other than in emergency circumstances. Since the consultation, we have not received additional comments or questions from the States.

X. Executive Order 13086: Consultation and Coordination with Indian Tribal Governments

In drafting the proposed rule, the Department consulted with representatives of the National Congress of American Indians and the National Indian Health Board, as well as with a representative of the self-governance Tribes. During the consultation, we discussed issues regarding the application of Title II of HIPAA to the Tribes, and potential variations based on the relationship of each Tribe with the IHS for the purpose of providing health services. Participants raised questions about the status of Tribal laws regarding the privacy of health information.

List of Subjects in 45 CFR Parts 160 and 164

Employer benefit plan, Health, Health care, Health facilities, Health insurance, Health records, Medicaid, Medical

research, Medicare, Privacy, Reporting and recordkeeping requirements, security measures.

Note to reader: This proposed rule is one of several proposed rules that are being published to implement the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996. We propose to establish a new 45 CFR subchapter C, parts 160 through 164. Part 160 will consist of general provisions, part 162 will consists of the various Administrative Simplification regulations relating to transactions and identifiers, and part 164 will consists of the regulations implementing the security and privacy requirements of the legislation. Proposed part 160, consisting of two subparts (Subpart A General Provisions, and Subpart B—Preemption of State Law) will be exactly the same in each rule, unless we add new sections or definitions to incorporate additional general information in the later rules.

Dated: October 26, 1999.

Donna Shalala,

Secretary.

Appendix to the Preamble: Sample Contact of Provider Notice

PROVIDER NOTICE OF INFORMATION PRACTICES (as of 1/1/1999)

Uses and Disclosures of Health Information

We use health information about you for treatment, to obtain payment for treatment, for administrative purposes, and to evaluate the quality of care that you receive.

We may use or disclose identifiable health information about you without your authorization for several other reasons. Subject to certain requirements, we may give out health information without your authorization for public health purposes, for auditing purposes, for research studies, and for emergencies. We provide information when otherwise required by law, such as for law enforcement in specific circumstances. In any other situation, we will ask for your written authorization before using or disclosing any identifiable health information about you. If you choose to sign an authorization to disclose information, you can later revoke that authorization to stop any future uses and disclosures.

We may change our policies at any time. Before we make a significant change in our policies, we will change our notice and post the new notice in the waiting area and in each examination room. You can also request a copy of our notice at any time. For more information about our privacy practices, contact the person listed below.

Individual Rights

In most cases, you have the right to look at or get a copy of health information about you that we use to make decisions about you. If you request copies, we will charge you $0.05 (5 cents) for each page. You also have the right to receive a list of instances where we have disclosed health information about you for reasons other than treatment, payment or related administrative purposes. If you believe that information in your record is incorrect or if important information is missing, you have the right to request that we correct the existing information or add the missing information.

You may request in writing that we not use or disclose your information for treatment, payment and administrative purposes except when specifically authorized by you, when required by law, or in emergency circumstances. We will consider your request but are not legally required to accept it.

Complaints

If you are concerned that we have violated your privacy rights, or you disagree with a decision we made about access to your records, you may contact the person listed below. You also may send a written complaint to the U.S. Department of Health and Human Services. The person listed below can provide you with the appropriate address upon request.

Our Legal Duty

We are required by law to protect the privacy of your information, provide this notice about our information practices, and follow the information practices that are described in this notice.

If you have any questions or complaints, please contact: Office Administrator, 111 Main Street, Suite 101, Anytown, OH 41111. Phone: (111) 555–6789, Email: admin@docshop.com.

For the reasons set forth in the preamble, it is proposed to amend 45 CFR subtitle A by adding a new subchapter C, consisting of parts 160 through 164, to read as follows:

SUBCHAPTER C—ADMINISTRATIVE DATA STANDARDS AND RELATED REQUIREMENTS

Part

PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS

Subpart A—General Provisions

Subpart B—Preemption of State Law

Authority: 42 U.S.C. 1320d–2 and 1320d–4.

Subpart A—General Provisions

§ 160.101 Statutory basis and purpose.

The requirements of this subchapter implement sections 1171 through 1179 of the Social Security Act, as amended, which require HHS to adopt national standards to enable the electronic exchange of health information in the health care system. The requirements of this subchapter also implement section 264 of Pub. L 104–191, which requires that HHS adopt national standards with respect to the privacy of individually identifiable health information transmitted in connection with the transactions described in section 1173(a)(1) of the Social Security Act. The purpose of these provisions is to promote administrative simplification.

§ 160.102 Applicability.

Except as otherwise provided, the standards, requirements, and implementation specifications adopted or designated under the parts of this subchapter apply to any entity that is:

(a) A health plan;

(b) A health care clearinghouse; and

(c) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

§ 160.103 Definitions.

Except as otherwise provided, the following definitions apply to this subchapter:

Act means the Social Security Act, as amended.

Covered entity means an entity described in § 160.102.

Health care means the provision of care, services, or supplies to a patient and includes any:

(1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, counseling, service, or procedure with respect to the physical or mental condition, or functional status, of a patient or affecting the structure or function of the body;

(2) Sale or dispensing of a drug, device, equipment, or other item pursuant to a prescription; or

(3) Procurement or banking of blood, sperm, organs, or any other tissue for administration to patients.

Health care clearinghouse means a public or private entity that processes or facilitates the processing of nonstandard data elements of health information into standard data elements. The entity receives health care transactions from health care providers or other entities, translates the data from a given format into one acceptable to the intended payer or payers, and forwards the processed transaction to appropriate payers and clearinghouses. Billing services, repricing companies, community health management information systems, community health information systems, and ''value-added''

networks and switches are considered to be health care clearinghouses for purposes of this part, if they perform the functions of health care clearinghouses as described in the preceding sentences.

Health care provider means a provider of services as defined in section 1861(u) of the Act, a provider of medical or health services as defined in section 1861(s) of the Act, and any other person or organization who furnishes, bills, or is paid for health care services or supplies in the normal course of business.

Health information means any information, whether oral or recorded in any form or medium, that:

(1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.

Health plan means an individual or group plan that provides, or pays the cost of, medical care. Such term includes, when applied to government funded or assisted programs, the components of the government agency administering the program. ''Health plan'' includes the following, singly or in combination:

(1) A group health plan, defined as an employee welfare benefit plan (as currently defined in section 3(1) of the Employee Retirement Income and Security Act of 1974, 29 U.S.C. 1002(1)), including insured and self-insured plans, to the extent that the plan provides medical care (as defined in section 2791(a)(2) of the Public Health Service Act, 42 U.S.C. 300gg–91(a)(2)), including items and services paid for as medical care, to employees or their dependents directly or through insurance or otherwise, that:

(i) Has 50 or more participants; or

(ii) Is administered by an entity other than the employer that established and maintains the plan.

(2) A health insurance issuer, defined as an insurance company, insurance service, or insurance organization that is licensed to engage in the business of insurance in a State and is subject to State or other law that regulates insurance.

(3) A health maintenance organization, defined as a federally qualified health maintenance organization, an organization recognized as a health maintenance organization under State law, or a similar organization regulated for solvency under State law in the same manner and to the same extent as such a health maintenance organization.

(4) Part A or Part B of the Medicare program under title XVIII of the Act.

(5) The Medicaid program under title XIX of the Act.

(6) A Medicare supplemental policy (as defined in section 1882(g)(1) of the Act, 42 U.S.C. 1395ss).

(7) A long-term care policy, including a nursing home fixed-indemnity policy.

(8) An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.

(9) The health care program for active military personnel under title 10 of the United States Code.

(10) The veterans health care program under 38 U.S.C. chapter 17.

(11) The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), as defined in 10 U.S.C. 1072(4).

(12) The Indian Health Service program under the Indian Health Care Improvement Act (25 U.S.C. 1601, *et seq.*).

(13) The Federal Employees Health Benefits Program under 5 U.S.C. chapter 89.

(14) An approved State child health plan for child health assistance that meets the requirements of section 2103 of the Act.

(15) A Medicare Plus Choice organization as defined in 42 CFR 422.2, with a contract under 42 CFR part 422, subpart K.

(16) Any other individual or group health plan, or combination thereof, that provides or pays for the cost of medical care.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

Small health plan means a health plan with annual receipts of $5 million or less.

Standard means a prescribed set of rules, conditions, or requirements concerning classification of components, specification of materials, performance or operations, or delineation of procedures, in describing products, systems, services or practices.

State includes the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, and Guam.

Transaction means the exchange of information between two parties to carry out financial or administrative activities related to health care. It includes the following:

(1) Health claims or equivalent encounter information;

(2) Health care payment and remittance advice;

(3) Coordination of benefits;

(4) Health claims status;

(5) Enrollment and disenrollment in a health plan;

(6) Eligibility for a health plan;

(7) Health plan premium payments;

(8) Referral certification and authorization;

(9) First report of injury;

(10) Health claims attachments; and

(11) Other transactions as the Secretary may prescribe by regulation.

§ 160.104 Effective dates of a modification to a standard or implementation specification.

The Secretary may modify a standard or implementation specification after the first year in which the standard or implementation specification is required to be used, but not more frequently than once every 12 months. If the Secretary adopts a modification to a standard or implementation specification, the implementation date of the modified standard or implementation specification may be no earlier than 180 days following the adoption of the modification. The Secretary will determine the actual date, taking into account the time needed to comply due to the nature and extent of the modification. The Secretary may extend the time for compliance for small health plans.

Subpart B—Preemption of State Law

§ 160.201 Applicability.

The provisions of this subpart apply to determinations and advisory opinions issued by the Secretary pursuant to 42 U.S.C. 1320d–7.

§ 160.202 Definitions.

For the purpose of this subpart, the following terms have the following meanings:

Contrary, when used to compare a provision of State law to a standard, requirement, or implementation specification adopted under this subchapter, means:

(1) A party would find it impossible to comply with both the State and federal requirements; or

(2) The provision of State law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of part C of title XI of the Act or section 264 of Pub. L. 104–191, as applicable.

More stringent means, in the context of a comparison of a provision of State

law and a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter, a law which meets one or more of the following criteria, as applicable:

(1) With respect to a use or disclosure, provides a more limited use or disclosure (in terms of the number of potential recipients of the information, the amount of information to be disclosed, or the circumstances under which information may be disclosed).

(2) With respect to the rights of individuals of access to or amendment of individually identifiable health information, permits greater rights or access or amendment, as applicable, provided, however, that nothing in this subchapter shall be construed to preempt any State law to the extent that it authorizes or prohibits disclosure of protected health information regarding a minor to a parent, guardian or person acting *in loco parentis* of such minor.

(3) With respect to penalties, provides greater penalties.

(4) With respect to information to be provided to an individual about a proposed use, disclosure, rights, remedies, and similar issues, provides the greater amount of information.

(5) With respect to form or substance of authorizations for use or disclosure of information, provides requirements that narrow the scope or duration, increase the difficulty of obtaining, or reduce the coercive effect of the circumstances surrounding the authorization.

(6) With respect to recordkeeping or accounting requirements, provides for the retention or reporting of more detailed information or for a longer duration.

(7) With respect to any other matter, provides greater privacy protection for the individual.

Relates to the privacy of individually identifiable health information means, with respect to a State law, that the State law has the specific purpose of protecting the privacy of health information or the effect of affecting the privacy of health information in a direct, clear, and substantial way.

State law means a law, decision, rule, regulation, or other State action having the effect of law.

§ 160.203 General rule and exceptions.

General rule. A standard, requirement, or implementation specification adopted under or pursuant to this subchapter that is contrary to a provision of State law preempts the provision of State law. This general rule applies, except where one or more of the following conditions is met:

(a) A determination is made by the Secretary pursuant to § 160.204(a) that the provision of State law:

(1) Is necessary:

(i) To prevent fraud and abuse;

(ii) To ensure appropriate State regulation of insurance and health plans;

(iii) For State reporting on health care delivery or costs; or

(iv) For other purposes related to improving the Medicare program, the Medicaid program, or the efficiency and effectiveness of the health care system; or

(2) Addresses controlled substances.

(b) The provision of State law relates to the privacy of health information and is more stringent than a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter.

(c) The provision of State law, or the State established procedures, are established under a State law providing for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention.

(d) The provision of State law requires a health plan to report, or to provide access to, information for the purpose of management audits, financial audits, program monitoring and evaluation, facility licensure or certification, or individual licensure or certification.

§ 160.204 Process for requesting exception determinations or advisory opinions.

(a) *Determinations.* (1) A State may submit a written request to the Secretary to except a provision of State law from preemption under § 160.203(a). The request must include the following information:

(i) The State law for which the exception is requested;

(ii) The particular standard(s), requirement(s), or implementation specification(s) for which the exception is requested;

(iii) The part of the standard or other provision that will not be implemented based on the exception or the additional data to be collected based on the exception, as appropriate;

(iv) How health care providers, health plans, and other entities would be affected by the exception;

(v) The length of time for which the exception would be in effect, if less than three years;

(vi) The reasons why the State law should not be preempted by the federal standard, requirement, or implementation specification, including how the State law meets one or more of the criteria at § 160.203(a); and

(vii) Any other information the Secretary may request in order to make the determination.

(2) Requests for exception under this section must be submitted to the Secretary at an address which will be published in the **Federal Register**. Until the Secretary's determination is made, the standard, requirement, or implementation specification under this subchapter remains in effect.

(3) The Secretary's determination under this paragraph will be made on the basis of the extent to which the information provided and other factors demonstrate that one or more of the criteria at § 160.203(a) has been met. If it is determined that the federal standard, requirement, or implementation specification accomplishes the purposes of the criterion or criteria at § 160.203(a) as well as or better than the State law for which the request is made, the request will be denied.

(4) An exception granted under this paragraph is effective for three years or for such lesser time as is specified in the determination granting the request.

(5) If an exception is granted under this paragraph, the exception has effect only with respect to transactions taking place wholly within the State for which the exception was requested.

(6) Any change to the standard, requirement, or implementation specification or provision of State law upon which an exception was granted requires a new request for an exception. Absent such a request and a favorable determination thereon, the standard, requirement, or implementation specification remains in effect. The responsibility for recognizing the need for and making the request lies with the original requestor.

(7) The Secretary may seek changes to a standard, requirement, or implementation specification based on requested exceptions or may urge the requesting State or other organizations or persons to do so.

(8) Determinations made by the Secretary pursuant to this paragraph will be published annually in the **Federal Register**.

(b) *Advisory opinions.*—(1) The Secretary may issue advisory opinions as to whether a provision of State law constitutes an exception under § 160.203(b) to the general rule of preemption under that section. The Secretary may issue such opinions at the request of a State or at the Secretary's own initiative.

(2) A State may submit a written request to the Secretary for an advisory opinion under this paragraph. The

request must include the following information:

(i) The State law for which the exception is requested;

(ii) The particular standard(s), requirement(s), or implementation specification(s) for which the exception is requested;

(iii) How health care providers, health plans, and other entities would be affected by the exception;

(iv) The reasons why the State law should not be preempted by the federal standard, requirement, or implementation specification, including how the State law meets the criteria at § 160.203(b); and

(v) Any other information the Secretary may request in order to issue the advisory opinion.

(3) The requirements of paragraphs (a)(2), (a)(5)–(a)(7) of this section apply to requests for advisory opinions under this paragraph.

(4) The Secretary's decision under this paragraph will be made on the basis of the extent to which the information provided and other factors demonstrate that the criteria at § 160.203(b) are met.

(5) Advisory opinions made by the Secretary pursuant to this paragraph will be published annually in the **Federal Register**.

PARTS 161–163—[RESERVED]

PART 164—SECURITY AND PRIVACY

Subpart A—General Provisions

Subparts B–D—[Reserved]

Subpart E—Privacy of Individually Identifiable Health Information

Authority: 42 U.S.C. 1320d–2 and 1320d–4.

Subpart A—General Provisions

§ 164.102 Statutory basis.

The provisions of this part are adopted pursuant to the Secretary's authority to prescribe standards, requirements, and implementation standards under part C of title XI of the Act and section 264 of Public Law 104–191.

§ 164.104 Applicability.

Except as otherwise provided, the provisions of this part apply to covered entities: health plans, health care clearinghouses, and health care providers who transmit health information in electronic form in connection with any transaction referred to in section 1173(a)(1) of the Act.

Subpart B–D—[Reserved]

Subpart E—Privacy of Individually Identifiable Health Information

§ 164.502 Applicability.

In addition to the applicable provisions of part 160 of this subchapter and except as otherwise herein provided, the requirements, standards, and implementation specifications of this subpart apply to covered entities with respect to protected health information.

§ 164.504 Definitions.

As used in this subpart, the following terms have the following meanings:

Business partner means, with respect to a covered entity, a person to whom the covered entity discloses protected health information so that the person can carry out, assist with the performance of, or perform on behalf of, a function or activity for the covered entity. ''Business partner'' includes contractors or other persons who receive protected health information from the covered entity (or from another business partner of the covered entity) for the purposes described in the previous sentence, including lawyers, auditors, consultants, third-party administrators, health care clearinghouses, data processing firms, billing firms, and other covered entities. ''Business partner'' excludes persons who are within the covered entity's workforce, as defined in this section.

Designated record set means a group of records under the control of a covered entity from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual and which is used by the covered entity to make decisions about the individual. For purposes of this paragraph, the term *record* means any item, collection, or grouping of protected health information maintained, collected, used, or disseminated by a covered entity.

Disclosure means the release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information.

Health care operations means the following activities undertaken by or on behalf of a covered entity that is a health plan or health care provider for the purpose of carrying out the management functions of such entity necessary for the support of treatment or payment:

(1) Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines;

(2) Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which undergraduate and graduate students and trainees in areas of health care learn under supervision to practice as health care providers, accreditation, certification, licensing or credentialing activities;

(3) Insurance rating and other insurance activities relating to the renewal of a contract for insurance, including underwriting, experience rating, and reinsurance, but only when the individuals are already enrolled in the health plan conducting such activities and the use or disclosure of protected health information relates to an existing contract of insurance (including the renewal of such a contract);

(4) Conducting or arranging for medical review and auditing services, including fraud and abuse detection and compliance programs; and

(5) Compiling and analyzing information in anticipation of or for use in a civil or criminal legal proceeding.

Health oversight agency means an agency, person or entity, including the employees or agents thereof,

(1) That is:

(i) A public agency; or

(ii) A person or entity acting under grant of authority from or contract with a public agency; and

(2) Which performs or oversees the performance of any audit; investigation; inspection; licensure or discipline; civil, criminal, or administrative proceeding or action; or other activity necessary for appropriate oversight of the health care system, of government benefit programs for which health information is relevant to beneficiary eligibility, or of government regulatory programs for which health information is necessary

for determining compliance with program standards.

Individual means the person who is the subject of protected health information, except that:

(1) ''Individual'' includes:

(i) With respect to adults and emancipated minors, legal representatives (such as court-appointed guardians or persons with a power of attorney), to the extent to which applicable law permits such legal representatives to exercise the person's rights in such contexts.

(ii) With respect to unemancipated minors, a parent, guardian, or person acting *in loco parentis*, provided that when a minor lawfully obtains a health care service without the consent of or notification to a parent, guardian, or other person acting *in loco parentis*, the minor shall have the exclusive right to exercise the rights of an individual under this subpart with respect to the protected health information relating to such care.

(iii) With respect to deceased persons, an executor, administrator, or other person authorized under applicable law to act on behalf of the decedent's estate.

(2) ''Individual'' excludes:

(i) Foreign military and diplomatic personnel and their dependents who receive health care provided by or paid for by the Department of Defense or other federal agency, or by an entity acting on its behalf, pursuant to a country-to-country agreement or federal statute; and

(ii) Overseas foreign national beneficiaries of health care provided by the Department of Defense or other federal agency, or by a non-governmental organization acting on its behalf.

Individually identifiable health information is information that is a subset of health information, including demographic information collected from an individual, and that:

(1) Is created by or received from a health care provider, health plan, employer, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual, and

(i) Which identifies the individual, or

(ii) With respect to which there is a reasonable basis to believe that the information can be used to identify the individual.

Law enforcement official means an officer of an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, who is empowered by law to conduct:

(1) An investigation or official proceeding inquiring into a violation of, or failure to comply with, any law; or

(2) A criminal, civil, or administrative proceeding arising from a violation of, or failure to comply with, any law.

Payment means:

(1) The activities undertaken by or on behalf of a covered entity that is:

(i) A health plan, or by a business partner on behalf of a health plan, to obtain premiums or to determine or fulfill its responsibility for coverage under the health plan and for provision of benefits under the health plan; or

(ii) A health care provider or health plan, or a business partner on behalf of such provider or plan, to obtain reimbursement for the provision of health care.

(2) Activities that constitute payment include:

(i) Determinations of coverage, improving methods of paying or coverage policies, adjudication or subrogation of health benefit claims;

(ii) Risk adjusting amounts due based on enrollee health status and demographic characteristics;

(iii) Billing, claims management, and medical data processing;

(iv) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges; and

(v) Utilization review activities, including precertification and preauthorization of services.

Protected health information means individually identifiable health information that is or has been electronically transmitted or electronically maintained by a covered entity and includes such information in any other form.

(1) For purposes of this definition,

(i) ''Electronically transmitted'' includes information exchanged with a computer using electronic media, such as the movement of information from one location to another by magnetic or optical media, transmissions over the Internet, Extranet, leased lines, dial-up lines, private networks, telephone voice response, and ''faxback'' systems.

(ii) ''Electronically maintained'' means information stored by a computer or on any electronic medium from which information may be retrieved by a computer, such as electronic memory chips, magnetic tape, magnetic disk, or compact disc optical media.

(2) ''Protected health information'' excludes:

(i) Individually identifiable health information in education records covered by the Family Educational Right and Privacy Act, as amended, 20 U.S.C. 1232g; and

(ii) Individually identifiable health information of inmates of correctional facilities and detainees in detention facilities.

Public health authority means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe that is responsible for public health matters as part of its official mandate.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. ''Generalizable knowledge'' is knowledge related to health that can be applied to populations outside of the population served by the covered entity.

Treatment means the provision of health care by, or the coordination of health care (including health care management of the individual through risk assessment, case management, and disease management) among, health care providers; the referral of a patient from one provider to another; or the coordination of health care or other services among health care providers and third parties authorized by the health plan or the individual.

Use means the employment, application, utilization, examination, or analysis of information within an entity that holds the information.

Workforce means employees, volunteers, trainees, and other persons under the direct control of a covered entity, including persons providing labor on an unpaid basis.

§ 164.506 Uses and disclosures of protected health information: general rules.

(a) *Standard.* A covered entity may not use or disclose an individual's protected health information, except as otherwise permitted or required by this part or as required to comply with applicable requirements of this subchapter.

(1) *Permitted uses and disclosures.* A covered entity is permitted to use or disclose protected health information as follows:

(i) Except for research information unrelated to treatment, to carry out treatment, payment, or health care operations;

(ii) Pursuant to an authorization by the individual that complies with § 164.508; or

(iii) As permitted by and in compliance with this section or § 164.510.

(2) *Required disclosures.* A covered entity is required to disclose protected health information:

(i) To an individual, when a request is made under § 164.514; or

(ii) When required by the Secretary under § 164.522 to investigate or determine the entity's compliance with this part.

(b)(1) *Standard: Minimum necessary.* A covered entity must make all reasonable efforts not to use or disclose more than the minimum amount of protected health information necessary to accomplish the intended purpose of the use or disclosure. This requirement does not apply to uses or disclosures that are:

(i) Made in accordance with §§ 164.508(a)(1), 164.514, or § 164.522;

(ii) Required by law and permitted under § 164.510;

(iii) Required for compliance with applicable requirements of this subchapter; or

(iv) Made by a covered health care provider to a covered health plan, when the information is requested for audit and related purposes.

(2) *Implementation specification: Procedures.* To comply with the standard in this paragraph, a covered entity must have procedures to:

(i) Identify appropriate persons within the entity to determine what information should be used or disclosed consistent with the minimum necessary standard;

(ii) Ensure that the persons identified under paragraph (b)(2)(i) of this section make the minimum necessary determinations, when required;

(iii) Within the limits of the entity's technological capabilities, provide for the making of such determinations individually.

(3) *Implementation specification: Reliance.* When making disclosures to public officials that are permitted under § 164.510 but not required by other law, a covered entity may reasonably rely on the representations of such officials that the information requested is the minimum necessary for the stated purpose(s).

(c)(1) *Standard: Right of an individual to restrict uses and disclosures.* (i) A covered entity that is a health care provider must permit individuals to request that uses or disclosures of protected health information for treatment, payment, or health care operations be restricted, and, if the requested restrictions are agreed to by the provider, not make uses or disclosures inconsistent with such restrictions.

(ii) This requirement does not apply:

(A) To uses or disclosures permitted under § 164.510;

(B) When the health care services provided are emergency services or the information is requested pursuant to § 164.510(k) and

(C) To disclosures to the Secretary pursuant to § 164.522.

(iii) A provider is not required to agree to a requested restriction.

(2) *Implementation specifications.* A covered entity must have procedures that:

(i) Provide individuals an opportunity to request a restriction on the uses and disclosures of their protected health information;

(ii) Provide that restrictions that are agreed to by the entity are reduced to writing or otherwise documented;

(iii) Enable the entity to honor such restrictions; and

(iv) Provide for the notification of others to whom such information is disclosed of such restriction.

(d)(1) *Standard: use or disclosure of de-identified protected health information.* The requirements of this subpart do not apply to protected health information that a covered entity has de-identified, provided, however, that:

(i) Disclosure of a key or other device designed to enable coded or otherwise de-identified information to be re-identified constitutes disclosure of protected health information; and

(ii) If a covered entity re-identifies de-identified information, it may use or disclose such re-identified information only in accordance with this subpart.

(2) *Implementation specifications.* (i) A covered entity may use protected health information to create de-identified information by removing, coding, encrypting, or otherwise eliminating or concealing the information that makes such information individually identifiable.

(ii) Information is presumed not to be individually identifiable (de-identified), if:

(A) The following identifiers have been removed or otherwise concealed:

(*1*) Name;

(*2*) Address, including street address, city, county, zip code, and equivalent geocodes;

(*3*) Names of relatives;

(*4*) Name of employers;

(*5*) Birth date;

(*6*) Telephone numbers;

(*7*) Fax numbers;

(*8*) Electronic mail addresses;

(*9*) Social security number;

(*10*) Medical record number;

(*11*) Health plan beneficiary number;

(*12*) Account number;

(*13*) Certificate/license number;

(*14*) Any vehicle or other device serial number;

(*15*) Web Universal Resource Locator (URL);

(*16*) Internet Protocol (IP) address number;

(*17*) Finger or voice prints;

(*18*) Photographic images; and

(*19*) Any other unique identifying number, characteristic, or code that the covered entity has reason to believe may be available to an anticipated recipient of the information; and

(B) The covered entity has no reason to believe that any anticipated recipient of such information could use the information, alone or in combination with other information, to identify an individual.

(iii) Notwithstanding paragraph (d)(2)(ii) of this section, entities with appropriate statistical experience and expertise may treat information as de-identified, if they include information listed in paragraph (d)(2)(ii) of this section and they determine that the probability of identifying individuals with such identifying information retained is very low, or may remove additional information, if they have a reasonable basis to believe such additional information could be used to identify an individual.

(e)(1) *Standards: Business partners.* (i) Except for disclosures of protected health information by a covered entity that is a health care provider to another health care provider for consultation or referral purposes, a covered entity may not disclose protected health information to a business partner without satisfactory assurance from the business partner that it will appropriately safeguard the information.

(ii) A covered entity must take reasonable steps to ensure that each business partner complies with the requirements of this subpart with respect to any task or other activity it performs on behalf of the entity, to the extent the covered entity would be required to comply with such requirements.

(2) *Implementation specifications.* (i) For the purposes of this section, *satisfactory assurance* means a contract between the covered entity and the business partner to which such information is to be disclosed that establishes the permitted and required uses and disclosures of such information by the partner. The contract must provide that the business partner will:

(A) Not use or further disclose the information other than as permitted or required by the contract;

(B) Not use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity;

(C) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by its contract;

(D) Report to the covered entity any use or disclosure of the information not provided for by its contract of which it becomes aware;

(E) Ensure that any subcontractors or agents to whom it provides protected health information received from the covered entity agree to the same restrictions and conditions that apply to the business partner with respect to such information;

(F) Make available protected health information in accordance with § 164.514(a);

(G) Make its internal practices, books, and records relating to the use and disclosure of protected health information received from the covered entity available to the Secretary for purposes of determining the covered entity's compliance with this subpart;

(H) At termination of the contract, return or destroy all protected health information received from the covered entity that the business partner still maintains in any form and retain no copies of such information; and

(I) Incorporate any amendments or corrections to protected health information when notified pursuant to § 164.516(c)(3).

(ii) The contract required by paragraph (e)(2)(i) of this section must:

(A) State that the individuals whose protected health information is disclosed under the contract are intended third party beneficiaries of the contract; and

(B) Authorize the covered entity to terminate the contract, if the covered entity determines that the business partner has violated a material term of the contract required by this paragraph.

(iii) A material breach by a business partner of its obligations under the contract required by paragraph (e)(2)(i) of this section will be considered to be noncompliance of the covered entity with the applicable requirements of this subpart, if the covered entity knew or reasonably should have known of such breach and failed to take reasonable steps to cure the breach or terminate the contract.

(f) *Standard: Deceased individuals.* A covered entity must comply with the requirements of this subpart with respect to the protected health information of a deceased individual for two years following the death of such individual. This requirement does not apply to uses or disclosures for research purposes.

(g) *Standard: uses and disclosures consistent with notice.* Except as provided by § 164.520(g)(2), a covered entity that is required by § 164.512 to have a notice may not use or disclose protected health information in a manner inconsistent with such notice.

§ 164.508 Uses and disclosures for which individual authorization is required.

(a) *Standard.* An authorization executed in accordance with this section is required in order for the covered entity to use or disclose protected health information in the following situations:

(1) *Request by individual.* Where the individual requests the covered entity to use or disclose the information.

(2) *Request by covered entity.* (i) Where the covered entity requests the individual to authorize the use or disclosure of the information. The covered entity must request and obtain an authorization from the individual for all uses and disclosures that are not:

(A) Except as provided in paragraph (a)(3) of this section, compatible with or directly related to treatment, payment, or health care operations;

(B) Covered by § 164.510;

(C) Covered by paragraph (a)(1) of this section; or

(D) Required by this subpart.

(ii) Uses and disclosures of protected health information for which individual authorization is required include, but are not limited to, the following:

(A) Use for marketing of health and non-health items and services by the covered entity;

(B) Disclosure by sale, rental, or barter;

(C) Use and disclosure to non-health related divisions of the covered entity, e.g., for use in marketing life or casualty insurance or banking services;

(D) Disclosure, prior to an individual's enrollment in a health plan, to the health plan or health care provider for making eligibility or enrollment determinations relating to the individual or for underwriting or risk rating determinations;

(E) Disclosure to an employer for use in employment determinations; and

(F) Use or disclosure for fundraising purposes.

(iii) A covered entity may not condition the provision to an individual of treatment or payment on the provision by the individual of a requested authorization for use or disclosure, except where the authorization is requested in connection with a clinical trial.

(iv) Except where required by law, a covered entity may not require an individual to sign an authorization for use or disclosure of protected health information for treatment, payment, or health care operations purposes.

(3) *Authorization required: Special cases.* (i) Except as otherwise required by this subpart or permitted under § 164.510, a covered entity must obtain the authorization of the individual for the following uses and disclosures of protected health information about the individual:

(A) Use by a person other than the creator, or disclosure, of psychotherapy notes; and

(B) Use or disclosure of research information unrelated to treatment.

(ii) The requirements of paragraphs (b) through (e) of this section apply to such authorizations, as appropriate.

(iii) A covered entity may not condition treatment, enrollment in a health plan, or payment on a requirement that the individual authorize use or disclosure of psychotherapy notes relating to the individual.

(iv) For purposes of this section:

(A) *Psychotherapy notes* means notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session. For purposes of this definition, ''psychotherapy notes'' excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis and progress to date.

(B) *Research information unrelated to treatment* means health information that is received or created by a covered entity in the course of conducting research, for which there is insufficient scientific and medical evidence regarding the validity or utility of the information such that it should not be used for the purpose of providing health care, and with respect to which the covered entity has not requested payment from a third party payor.

(b) *General implementation specifications for authorizations.*—(1) *General requirements.* A copy of the model form which appears in Appendix A hereto, or a document that contains the elements listed in paragraphs (c) or (d) of this section, as applicable, must be accepted by the covered entity.

(2) *Defective authorizations.* There is no ''authorization'' within the meaning of this section, if the submitted form has any of the following defects:

(i) The expiration date has passed;

(ii) The form has not been filled out completely;

(iii) The authorization is known by the covered entity to have been revoked;

(iv) The form lacks an element required by paragraph (c) or (d) of this section, as applicable;

(v) The information on the form is known by the covered entity to be false.

(3) *Compound authorizations.* Except where authorization is requested in connection with a clinical trial, an authorization for use or disclosure of protected health information for purposes other than treatment or payment may not be in the same document as an authorization for or consent to treatment or payment.

(c) *Implementation specifications for authorizations requested by an individual.*—(1) *Required elements.* Before a covered entity may use or disclose protected health information of an individual pursuant to a request from the individual, it must obtain a completed authorization for use or disclosure executed by the individual that contains at least the following elements:

(i) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion;

(ii) The name of the covered entity, or class of entities or persons, authorized to make the requested use or disclosure;

(iii) The name or other specific identification of the person(s) or entity(ies), which may include the covered entity itself, to whom the covered entity may make the requested use or disclosure;

(iv) An expiration date;

(v) Signature and date;

(vi) If the authorization is executed by a legal representative or other person authorized to act for the individual, a description of his or her authority to act or relationship to the individual;

(vii) A statement in which the individual acknowledges that he or she has the right to revoke the authorization, except to the extent that information has already been released under the authorization; and

(viii) A statement in which the individual acknowledges that information used or disclosed to any entity other than a health plan or health care provider may no longer be protected by the federal privacy law.

(2) *Plain language requirement.* The model form at appendix A to this subpart may be used. If the model form at appendix A to this subpart is not used, the authorization form must be written in plain language.

(d) *Implementation specifications for authorizations for uses and disclosures requested by covered entities.*—(1) *Required elements.* Before a covered entity may use or disclose protected health information of an individual pursuant to a request that it has made, it must obtain a completed authorization for use or disclosure executed by the individual that meets the requirements of paragraph (c) of this section and contains the following additional elements:

(i) Except where the authorization is requested for a clinical trial, a statement that it will not condition treatment or payment on the individual's providing authorization for the requested use or disclosure;

(ii) A description of the purpose(s) of the requested use or disclosure;

(iii) A statement that the individual may:

(A) Inspect or copy the protected health information to be used or disclosed as provided in § 164.514; and

(B) Refuse to sign the authorization; and

(iv) Where use or disclosure of the requested information will result in financial gain to the entity, a statement that such gain will result.

(2) *Required procedures.* In requesting authorization from an individual under this paragraph, a covered entity must:

(i) Have procedures designed to enable it to request only the minimum amount of protected health information necessary to accomplish the purpose for which the request is made; and

(ii) Provide the individual with a copy of the executed authorization.

(e) *Revocation of authorizations.* An individual may revoke an authorization to use or disclose his or her protected health information at any time, except to the extent that the covered entity has taken action in reliance thereon.

§ 164.510 Uses and disclosures for which individual authorization is not required.

A covered entity may use or disclose protected health information, for purposes other than treatment, payment, or health care operations, without the authorization of the individual, in the situations covered by this section and subject to the applicable requirements provided for by this section.

(a) *General requirements.* In using or disclosing protected health information under this section:

(1) *Verification.* A covered entity must comply with any applicable verification requirements under § 164.518(c).

(2) *Health care clearinghouses.* A health care clearinghouse that uses or discloses protected health information it maintains as a business partner of a covered entity may not make uses or disclosures otherwise permitted under this section that are not permitted by the terms of its contract with the covered entity under § 164.506(e).

(b) *Disclosures and uses for public health activities.*—(1) *Permitted disclosures.* A covered entity may disclose protected health information for the public health activities and purposes described in this paragraph to:

(i) A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions;

(ii) A public health authority or other appropriate authority authorized by law to receive reports of child abuse or neglect;

(iii) A person or entity other than a governmental authority that can demonstrate or demonstrates that it is acting to comply with requirements or direction of a public health authority; or

(iv) A person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition and is authorized by law to be notified as necessary in the conduct of a public health intervention or investigation.

(2) *Permitted use.* Where the covered entity also is a public health authority, the covered entity is permitted to use protected health information in all cases in which it is permitted to disclose such information for public health activities under paragraph (b)(1) of this section.

(c) *Disclosures and uses for health oversight activities.*—(1) *Permitted disclosures.* A covered entity may disclose protected health information to a health oversight agency for oversight activities authorized by law, including audit, investigation, inspection, civil, criminal, or administrative proceeding or action, or other activity necessary for appropriate oversight of:

(i) The health care system;

(ii) Government benefit programs for which health information is relevant to beneficiary eligibility; or

(iii) Government regulatory programs for which health information is necessary for determining compliance with program standards.

(2) *Permitted use.* Where a covered entity is itself a health oversight agency, the covered entity may use protected health information for health oversight activities described by paragraph (c)(1) of this section.

(d) *Disclosures and uses for judicial and administrative proceedings.*—(1) *Permitted disclosures.* A covered entity may disclose protected health

information in the course of any judicial or administrative proceeding:

(i) In response to an order of a court or administrative tribunal; or

(ii) Where the individual is a party to the proceeding and his or her medical condition or history is at issue and the disclosure is pursuant to lawful process or otherwise authorized by law.

(2) *Permitted use.* Where the covered entity is itself a government agency, the covered entity may use protected health information in all cases in which it is permitted to disclose such information in the course of any judicial or administrative proceeding under paragraph (d)(1) of this section.

(3) *Additional restriction.* (i) Where the request for disclosure of protected health information is accompanied by a court order, the covered entity may disclose only that protected health information which the court order authorizes to be disclosed.

(ii) Where the request for disclosure of protected health information is not accompanied by a court order, the covered entity may not disclose the information requested unless a request authorized by law has been made by the agency requesting the information or by legal counsel representing a party to litigation, with a written statement certifying that the protected health information requested concerns a litigant to the proceeding and that the health condition of such litigant is at issue at such proceeding.

(e) *Disclosures to coroners and medical examiners.* A covered entity may disclose protected health information to a coroner or medical examiner, consistent with applicable law, for the purposes of identifying a deceased person or determining a cause of death.

(f) *Disclosures for law enforcement purposes.* A covered entity may disclose protected health information to a law enforcement official if:

(1) *Pursuant to process.* (i) The law enforcement official is conducting or supervising a law enforcement inquiry or proceeding authorized by law and the disclosure is:

(A) Pursuant to a warrant, subpoena, or order issued by a judicial officer that documents a finding by the judicial officer;

(B) Pursuant to a grand jury subpoena; or

(C) Pursuant to an administrative request, including an administrative subpoena or summons, a civil investigative demand, or similar process authorized under law, provided that:

(*1*) The information sought is relevant and material to a legitimate law enforcement inquiry;

(*2*) The request is as specific and narrowly drawn as is reasonably practicable; and

(*3*) De-identified information could not reasonably be used.

(ii) For the purposes of this paragraph, ''law enforcement inquiry or proceeding'' means:

(A) An investigation or official proceeding inquiring into a violation of, or failure to comply with, law; or

(B) A criminal, civil, or administrative proceeding arising from a violation of, or failure to comply with, law.

(2) *Limited information for identifying purposes.* The disclosure is for the purpose of identifying a suspect, fugitive, material witness, or missing person, *provided* that, the covered entity may disclose only the following information:

(i) Name;

(ii) Address;

(iii) Social security number;

(iv) Date of birth;

(v) Place of birth;

(vi) Type of injury or other distinguishing characteristic; and

(vii) Date and time of treatment.

(3) *Information about a victim of crime or abuse.* The disclosure is of the protected health information of an individual who is or is suspected to be a victim of a crime, abuse, or other harm, if the law enforcement official represents that:

(i) Such information is needed to determine whether a violation of law by a person other than the victim has occurred; and

(ii) Immediate law enforcement activity that depends upon obtaining such information may be necessary.

(4) *Intelligence and national security activities.* The disclosure is:

(i) For the conduct of lawful intelligence activities conducted pursuant to the National Security Act (50 U.S.C. 401, *et seq.*);

(ii) Made in connection with providing protective services to the President or other persons pursuant to 18 U.S.C. 3056; or

(iii) Made pursuant to 22 U.S.C. 2709(a)(3).

(5) *Health care fraud.* The covered entity believes in good faith that the information disclosed constitutes evidence of criminal conduct:

(i) That arises out of and is directly related to:

(A) The receipt of health care or payment for health care, including a fraudulent claim for health care;

(B) Qualification for or receipt of benefits, payments, or services based on a fraudulent statement or material misrepresentation of the health of the individual;

(ii) That occurred on the premises of the covered entity; or

(iii) Was witnessed by a member of the covered entity's workforce.

(5) *Urgent circumstances.* The disclosure is of the protected health information of an individual who is or is suspected to be a victim of a crime, abuse, or other harm, if the law enforcement official represents that:

(i) Such information is needed to determine whether a violation of law by a person other than the victim has occurred; and

(ii) Immediate law enforcement activity that depends upon obtaining such information may be necessary.

(g) *Disclosures and uses for governmental health data systems.*—(1) *Permitted disclosures.* A covered entity may disclose protected health information to a government agency, or private entity acting on behalf of a government agency, for inclusion in a governmental health data system that collects health data for analysis in support of policy, planning, regulatory, or management functions authorized by law.

(2) *Permitted uses.* Where a covered entity is itself a government agency that collects health data for analysis in support of policy, planning, regulatory, or management functions, the covered entity may use protected health information in all cases in which it is permitted to disclose such information for government health data systems under paragraph (g)(1) of this section.

(h) *Disclosures of directory information.* (1) *Individuals with capacity.* For individuals with the capacity to make their own health care decisions, a covered entity that is a health care provider may disclose protected health information for directory purposes, provided that, the individual has agreed to such disclosure.

(2) *Incapacitated individuals.* For individuals who are incapacitated, a covered entity that is a health care provider may, at its discretion and consistent with good medical practice and any prior expressions of preference of which the covered entity is aware, disclose protected health information for directory purposes.

(3) *Information to be disclosed.* The information that may be disclosed for directory purposes pursuant to paragraphs (h)(1) and (2) of this section, is limited to:

(i) Name of the individual;

(ii) Location of the individual in the health care provider's facility; and

(iii) Description of the individual's condition in general terms that do not

communicate specific medical information about the individual.

(i) *Disclosures for banking and payment processes.* A covered entity may disclose, in connection with routine banking activities or payment by debit, credit, or other payment card, or other payment means, the minimum amount of protected health information necessary to complete a banking or payment activity to:

(1) *Financial institutions.* An entity engaged in the activities of a financial institution (as defined in section 1101 of the Right to Financial Privacy Act of 1978); or

(2) *Entities acting on behalf of financial institutions.* An entity engaged in authorizing, processing, clearing, settling, billing, transferring, reconciling, or collecting payments, for an entity described in paragraph (i)(1) of this section.

(j) *Uses and disclosures for research purposes.* A covered entity may use or disclose protected health information for research, regardless of the source of funding of the research, provided that, the covered entity has obtained written documentation of the following:

(1) *Waiver of authorization.* A waiver, in whole or in part, of authorization for use or disclosure of protected health information that has been approved by either:

(i) An Institutional Review Board, established in accordance with 7 CFR 1c.107, 10 CFR 745.107, 14 CFR 1230.107, 15 CFR 27.107, 16 CFR 1028.107, 21 CFR 56.107, 22 CFR 225.107, 28 CFR 46.107.32 CFR 219.107, 34 CFR 97.107, 38 CFR 16.107, 40 CFR 26.107.45 CFR 46.107, 45 CFR 690.107, or 49 CFR 11.107; or

(ii) A privacy board that:

(A) Has members with varying backgrounds and appropriate professional competency as necessary to review the research protocol;

(B) Includes at least one member who is not affiliated with the entity conducting the research or related to a person who is affiliated with such entity; and

(C) Does not have any member participating in a review of any project in which the member has a conflict of interest.

(2) *Date of approval.* The date of approval of the waiver, in whole or in part, of authorization by an Institutional Review Board or privacy board.

(3) *Criteria.* The Institutional Review Board or privacy board has determined that the waiver, in whole or in part, of authorization satisfies the following criteria:

(i) The use or disclosure of protected health information involves no more than minimal risk to the subjects;

(ii) The waiver will not adversely affect the rights and welfare of the subjects;

(iii) The research could not practicably be conducted without the waiver;

(iv) Whenever appropriate, the subjects will be provided with additional pertinent information after participation;

(v) The research could not practicably be conducted without access to and use of the protected health information;

(vi) The research is of sufficient importance so as to outweigh the intrusion of the privacy of the individual whose information is subject to the disclosure;

(vii) There is an adequate plan to protect the identifiers from improper use and disclosure; and

(viii) There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers.

(4) *Required signature.* The written documentation must be signed by the chair of, as applicable, the Institutional Review Board or the privacy board.

(k) *Uses and disclosures in emergency circumstances.*—(1) *Permitted disclosures.* A covered entity may, consistent with applicable law and standards of ethical conduct and based on a reasonable belief that the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of an individual or the public, use or disclose protected health information to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat.

(2) *Presumption of reasonable belief.* A covered entity that makes a disclosure pursuant to paragraph (k)(1) of this section is presumed to have acted under a reasonable belief, if the disclosure is made in good faith based upon a credible representation by a person with apparent knowledge or authority (such as a doctor or law enforcement or other government official).

(l) *Disclosures to next-of-kin.*—(1) *Permitted disclosures.* A covered entity may disclose protected health information to a person who is a next-of-kin, other family member, or close personal friend of an individual who possesses the capacity to make his or her own health care decisions, if:

(i) The individual has verbally agreed to the disclosure; or

(ii) In circumstances where such agreement cannot practicably or reasonably be obtained, only the protected health information that is directly relevant to the person's involvement in the individual's health care is disclosed, consistent with good health professional practices and ethics.

(2) *Next-of-kin defined.* For purposes of this paragraph, ''next-of-kin'' is defined as defined under applicable law.

(m) *Uses and disclosures for specialized classes.*—(1) *Military purposes.* A covered entity that is a health care provider or health plan providing health care to individuals who are Armed Forces personnel may use and disclose protected health information for activities deemed necessary by appropriate military command authorities to assure the proper execution of the military mission, where the appropriate military authority has published by notice in the **Federal Register** the following information:

(i) Appropriate military command authorities;

(ii) The circumstances for which use or disclosure without individual authorization would be required; and

(iii) Activities for which such use or disclosure would occur in order to assure proper execution of the military mission.

(2) *Department of Veterans Affairs.* The Department of Veterans Affairs may use and disclose protected health information among components of the Department that determine eligibility for or entitlement to, or that provide, benefits under laws administered by the Secretary of Veterans Affairs.

(3) *Intelligence community.* A covered entity may disclose protected health information of an individual who is an employee of the intelligence community, as defined in section 4 of the National Security Act, 50 U.S.C. 401a, and his or her dependents, if such dependents are being considered for posting abroad, to intelligence community agencies, where authorized by law.

(4) *Department of State.* The Department of State may use protected health information about the following individuals for the following purposes:

(i) As to applicants to the Foreign Service, for medical clearance determinations about physical fitness to serve in the Foreign Service on a worldwide basis, including about medical and mental conditions limiting assignability abroad; determinations of conformance to occupational physical standards, where applicable; and determinations of suitability.

(ii) As to members of the Foreign Service and other United States Government employees assigned to serve abroad under Chief of Mission authority, for medical clearance determinations for assignment to posts abroad, including medical and mental conditions limiting such assignment; determinations of conformance to occupational physical standards, where applicable; determinations about continued fitness for duty, suitability, and continuation of service at post (including decisions on curtailment); separation medical examinations; and determinations of eligibility of members of the Foreign Service for disability retirement (whether on application of the employee or the Secretary of State).

(iii) As to eligible family members of Foreign Service or other United States Government employees, for medical clearance determinations as described in paragraph (m)(4)(ii) of this section to permit eligible family members to accompany employees to posts abroad on Government orders; determinations regarding family members remaining at post; and separation medical examinations.

(n) *Uses and disclosures otherwise required by law.* A covered entity may use or disclose protected health information where such use or disclosure is required by law and the use or disclosure meets all relevant requirements of such law. This paragraph does not apply to uses or disclosures that are covered by paragraphs (b) through (m) of this section.

§ 164.512 Notice to individuals of information practices.

(a) *Standard.* An individual has a right to adequate notice of the policies and procedures of a covered entity that is a health plan or a health care provider with respect to protected health information.

(b) *Standard for notice procedures.* A covered entity that is a health plan or health care provider must have procedures that provide adequate notice to individuals of their rights and the procedures for exercising their rights under this subpart with respect to protected health information about them.

(c) *General implementation specification.* A covered entity that has and follows procedures that meet the requirements of this section will be presumed to have provided adequate notice under this section.

(d) *Implementation specifications: content of notice.*—(1) *Required elements.* Notices required to be provided under this section must include in plain language a statement of each of the following elements:

(i) *Uses and disclosures.* The uses and disclosures, and the entity's policies and procedures with respect to such uses and disclosures, must be described in sufficient detail to put the individual on notice of the uses and disclosures expected to be made of his or her protected health information. Such statement must:

(A) Describe the uses and disclosures that will be made without individual authorization; and

(B) Distinguish between those uses and disclosures the entity makes that are required by law and those that are permitted but not required by law.

(ii) *Required statements.* State that:

(A) Other uses and disclosures will be made only with the individual's authorization and that such authorization may be revoked;

(B) An individual may request that certain uses and disclosures of his or her protected health information be restricted, and the covered entity is not required to agree to such a request;

(C) An individual has the right to request, and a description of the procedures for exercising, the following with respect to his or her protected health information:

(*1*) Inspection and copying;

(*2*) Amendment or correction; and

(*3*) An accounting of the disclosures of such information by the covered entity;

(D) The covered entity is required by law to protect the privacy of its individually identifiable health information, provide a notice of its policies and procedures with respect to such information, and abide by the terms of the notice currently in effect;

(E) The entity may change its policies and procedures relating to protected health information at any time, with a description of how individuals will be informed of material changes; and

(F) Individuals may complain to the covered entity and to the Secretary if they believe that their privacy rights have been violated.

(iii) *Contact.* The name and telephone number of a contact person or office required by § 164.518(a)(2).

(iv) *Date.* The date the version of the notice was produced.

(2) *Revisions.* A covered health plan or health care provider may change its policies or procedures required by this subpart at any time. When a covered health plan or health care provider materially revises its policies and procedures, it must update its notice as provided for by § 164.520(g).

(e) *Implementation specifications: Provision of notice.* A covered entity must make the notice required by this section available:

(1) *General requirement.* On request; and

(2) *Specific requirements.* As follows:

(i) *Health plans.* Health plans must provide a copy of the notice to an individual covered by the plan:

(A) As of the date on which the health plan is required to be in compliance with this subpart;

(B) After the date described in paragraph (e)(2)(i)(A) of this section, at enrollment;

(C) After enrollment, within 60 days of a material revision to the content of the notice; and

(D) No less frequently than once every three years.

(ii) *Health care providers.* A health care provider must:

(A) During the one year period following the date by which the provider is required to come into compliance with this subpart, provide a copy to individuals currently served by the provider at the first service delivery to such individuals during such period, provided that, where service is not provided through a face-to-face contact, the provider must provide the notice in an appropriate manner within a reasonable period of time following first service delivery;

(B) After the one year period provided for by paragraph (e)(2)(ii)(A) of this section, provide a copy to individuals served by the provider at the first service delivery to such individuals, provided that, where service is not provided through a face-to-face contact, the provider must provide the notice in an appropriate manner within a reasonable period of time following first service delivery; and

(C) Post a copy of the notice in a clear and prominent location where it is reasonable to expect individuals seeking service from the provider to be able to read the notice. Any revision to the notice must be posted promptly.

§ 164.514 Access of individuals to protected health information

(a) *Standard: Right of access.* An individual has a right of access to, which includes a right to inspect and obtain a copy of, his or her protected health information in designated record sets of a covered entity that is a health plan or a health care provider, including such information in a business partner's designated record set that is not a duplicate of the information held by the provider or plan, for so long as the information is maintained.

(b) *Standard: denial of access to protected health information.*—(1) *Grounds.* Except where the protected

health information to which access is requested is subject to 5 U.S.C. 552a, a covered entity may deny a request for access under paragraph (a) of this section where:

(i) A licensed health care professional has determined that, in the exercise of reasonable professional judgment, the inspection and copying requested is reasonably likely to endanger the life or physical safety of the individual or another person;

(ii) The information is about another person (other than a health care provider) and a licensed health care professional has determined that the inspection and copying requested is reasonably likely to cause substantial harm to such other person;

(iii) The information was obtained under a promise of confidentiality from someone other than a health care provider and such access would be likely to reveal the source of the information;

(iv) The information was obtained by a covered entity that is a health care provider in the course of a clinical trial, the individual has agreed to the denial of access when consenting to participate in the trial (if the individual's consent to participate was obtained), and the clinical trial is in progress; or

(v) The information was compiled in reasonable anticipation of, or for use in, a legal proceeding.

(2) *Other information available.* Where a denial of protected health information is made pursuant to paragraph (b)(1) of this section, the covered entity must make any other protected health information requested available to the individual to the extent possible consistent with the denial.

(c) *Standard: procedures to protect rights of access.* A covered entity that is a health plan or a health care provider must have procedures that enable individuals to exercise their rights under paragraph (a) of this section.

(d) *Implementation specifications: Access to protected health information.* The procedures required by paragraph (c) of this section must:

(1) *Means of request.* Provide a means by which an individual can request inspection or a copy of protected health information about him or her.

(2) *Time limit.* Provide for taking action on such requests as soon as possible but not later than 30 days following receipt of the request.

(3) *Request accepted.* Where the request is accepted, provide:

(i) For notification of the individual of the decision and of any steps necessary to fulfill the request;

(ii) The information requested in the form or format requested, if it is readily producible in such form or format;

(iii) For facilitating the process of inspection and copying; and

(iv) For a reasonable, cost-based fee for copying health information provided pursuant to this paragraph, if deemed desirable by the entity.

(4) *Request denied.* Where the request is denied in whole or in part, provide the individual with a written statement in plain language of:

(i) The basis for the denial; and

(ii) A description of how the individual may complain to the covered entity pursuant to the complaint procedures established in § 164.518(d)(2) or to the Secretary pursuant to the procedures established in § 164.522(b). The description must include:

(A) The name and telephone number of the contact person or office required by § 164.518(a)(2) of this subpart; and

(B) Information relevant to filing a complaint with the Secretary under § 164.522(b).

§ 164.515 Accounting for disclosures of protected health information.

(a) *Standard: Right to an accounting of disclosures of protected health information.* An individual has a right to receive an accounting of all disclosures of protected health information made by a covered entity as long as such information is maintained by the entity, except for disclosures:

(1) For treatment, payment and health care operations; and

(2) To health oversight or law enforcement agencies, if the health oversight or law enforcement agency has provided a written request stating that the exclusion is necessary because disclosure would be reasonably likely to impede the agency's activities and specifying the time for which such exclusion is required.

(b) *Standard: Procedures for accounting.* A covered entity must have procedures to give individuals an accurate accounting of disclosures for which an accounting is required by paragraph (a) of this section.

(c) *Implementation specifications: Accounting procedures.* The procedures required by paragraph (b) of this section must:

(1) Provide for an accounting of the following:

(i) The date of each disclosure;

(ii) The name and address of the organization or person who received the protected health information;

(iii) A brief description of the information disclosed;

(iv) For disclosures other than those made at the request of the individual, the purpose for which the information was disclosed; and (v) Provision of copies of all requests for disclosure.

(2) Provide the accounting to the individual as soon as possible, but no later than 30 days of receipt of the request therefor.

(3) Provide for a means of accounting for as long as the entity maintains the protected health information.

(4) Provide for a means of requiring business partners to provide such an accounting upon request of the covered entity.

§ 164.516 Amendment and correction.

(a) *Standard: right to request amendment or correction.*—(1) *Right to request.* An individual has the right to request a covered entity that is a health plan or health care provider to amend or correct protected health information about him or her in designated record sets of the covered entity for as long as the covered entity maintains the information.

(2) *Grounds for denial of request.* A covered entity may deny a request for amendment or correction of the individual's protected health information, if it determines that the information that is the subject of the request:

(i) Was not created by the covered entity;

(ii) Would not be available for inspection and copying under § 164.514 or

(iii) Is accurate and complete.

(b) *Standard: Amendment and correction procedures.* A covered entity that is a health plan or health care provider must have procedures to enable individuals to request amendment or correction, to determine whether the requests should be granted or denied, and to disseminate amendments or corrections to its business partners and others to whom erroneous information has been disclosed.

(c) *Implementation specifications: Procedures.* The procedures required by paragraph (b) of this section must provide that the covered entity will:

(1) *Means of request.* Provide a means by which an individual can request amendment or correction of his or her protected health information.

(2) *Time limit.* Take action on such request within 60 days of receipt of the request;

(3) *Request accepted.* Where the request is accepted in whole or in part:

(i) As otherwise required by this part, make the appropriate amendments or corrections;

(ii) As otherwise required by this part, identify the challenged entries as

amended or corrected and indicate their location;

(iii) Make reasonable efforts to notify:

(A) Persons, organizations, or other entities the individual identifies as needing to be notified; and (B) Persons, organizations, or other entities, including business partners, who the covered entity knows have received the erroneous or incomplete information and who may have relied, or could foreseeably rely, on such information to the detriment of the individual; and (iv) Notify the individual of the decision to correct or amend the information.

(4) *Request denied.* Where the request is denied in whole or in part:

(i) Provide the individual with a written statement in plain language of:

(A) The basis for the denial;

(B) A description of how the individual may file a written statement of disagreement with the denial; and

(C) A description of how the individual may complain to the covered entity pursuant to the complaint procedures established in § 164.518(d) or to the Secretary pursuant to the procedures established in § 164.522(b). The description must include:

(*1*) The name and telephone number of the contact person or office required by § 164.518(a)(2); and

(*2*) Information relevant to filing a complaint with the Secretary under § 164.522(b).

(ii) The procedures of the covered entity must:

(A) Permit the individual to file a statement of the individual's disagreement with the denial and the basis of such disagreement.

(B) Provide for inclusion of the covered entity's statement of denial and the individual's statement of disagreement with any subsequent disclosure of the information to which the disagreement relates, provided, however, that the covered entity may establish a limit to the length of the statement of disagreement, and may summarize the statement of disagreement if necessary.

(C) Permit the covered entity to provide a rebuttal to the statement of disagreement in subsequent disclosures under paragraph (c)(4)(ii)(B) of this section.

(d) *Standard: Effectuating a notice of amendment or correction.* Any covered entity that receives a notice of amendment or correction must have procedures in place to make the amendment or correction in any of its designated record sets and to notify its business partners, as appropriate, of necessary amendments or corrections of protected health information.

(e) *Implementation specification: effectuating a notice of amendment or correction.* The procedures required by paragraph (d) of this section must specify the process for correction or amendment of information in all appropriate designated record sets maintained by the covered entity and its business partners.

§ 164.518 Administrative requirements.

Except as otherwise provided, a covered entity must meet the requirements of this section.

(a) *Designated privacy official: standard.*—(1) *Responsibilities of designated privacy official.* A covered entity must designate a privacy official who is responsible for the development and implementation of the privacy policies and procedures of the entity.

(2) *Contact person or office.* A covered entity must designate a contact person or office who is responsible for receiving complaints under this section and who is able to provide further information about matters covered by the notice required by § 164.512. If a covered entity designates a contact person, it may designate the privacy official as the contact person.

(b) *Training.*—(1) *Standard.* All members of the covered entity's workforce who, by virtue of their positions, are likely to obtain access to protected health information must receive training on the entity's policies and procedures required by this subpart that are relevant to carrying out their function within the entity.

(2) *Implementation specification.* A covered entity must train all members of its workforce who, by virtue of their positions, are likely to obtain access to protected health information. Such training must meet the following requirements:

(i) The training must occur:

(A) For members of the covered entity's workforce as of the date on which this subpart becomes applicable to such entity, by such date; and

(B) For persons joining the covered entity's workforce after the date in paragraph (b)(2)(i)(A) of this section, within a reasonable period after the person joins the workforce.

(ii) The covered entity must require members of its workforce trained as required by this section to sign, upon completing training, a certification. The certification must state:

(A) The date of training; and

(B) That the person completing the training will honor all of the entity's policies and procedures required by this subpart.

(iii) The covered entity must require members of its workforce trained as required by this section to sign, at least once every three years, a statement certifying that the person will honor all of the entity's policies and procedures required by this subpart.

(iv) The covered entity must provide all members of its workforce with access to protected health information within the entity with further training, as relevant to their function within the entity, whenever the entity materially changes its privacy policies or procedures.

(c) *Safeguards.*—(1) *Standard.* A covered entity must have in place appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information.

(2) *Implementation specification: Verification procedures.* A covered entity must have administrative, technical, and physical procedures in place to protect the privacy of protected health information. Such procedures must include adequate procedures for verification of the identity and/or authority, as required by this subpart, of persons requesting such information, where such identity or authority is not known to the entity, as follows:

(i) The covered entity must use procedures that are reasonably likely to establish that the individual or person making the request has the appropriate identity for the use or disclosure requested, except for uses and disclosures that are:

(A) Permitted by this subpart and made on a routine basis to persons or other entities with which the covered entity interacts in the normal course of business or otherwise known to the covered entity; or

(B) Covered by paragraphs (c)(2)(ii), (iii), or (iv) of this section.

(ii) When the request for information is made by a government agency under § 164.510(b), § 164.510(c), § 164.510(e), § 164.510(f), § 164.510(g), § 164.510(m), § 164.510(n), or § 164.522, and the identity and/or authority are not known to the covered entity, the covered entity may not disclose such information without reasonable evidence of identity and/or authority to obtain the information.

(A) For purposes of this paragraph, ''reasonable evidence of identity'' means:

(*1*) A written request on the agency's letterhead;

(*2*) Presentation of an agency identification badge or official credentials; or

(*3*) Similar proof of government status.

(B) For purposes of this paragraph, *reasonable evidence of authority* means:

(*1*) A written statement of the legal authority under which the information is requested; a request for disclosure made by official legal process issued by a grand jury or a judicial or administrative body is presumed to constitute reasonable legal authority; or

(*2*) Where the request is made orally, an oral statement of such authority.

(iii) When the request for information is made by a person or entity acting on behalf of a government agency under § 164.510(b), § 164.510(c), § 164.510(g), or § 164.510(n), and the identity and/or authority are not known to the covered entity, the covered entity may not disclose such information without reasonable evidence of identity and/or authority to obtain the information.

(A) For the purposes of this paragraph, *reasonable evidence of identity* means:

(*1*) A written statement from the government agency, on the agency's letterhead, that the person or entity is acting under the agency's authority; or

(*2*) Other evidence or documentation, such as a contract for services, memorandum of understanding, or purchase order, that establishes that the person or entity is acting on behalf of or under the agency's authority.

(B) For the purposes of this paragraph, ''reasonable evidence of authority'' means a statement that complies with paragraph (c)(ii)(B) of this section.

(iv) For uses and disclosures under § 164.510(d), § 164.510(h), or § 164.510(j), compliance with the applicable requirements of those sections constitutes adequate verification under this section.

(v)(A) A covered entity may reasonably rely on evidence of identity and legal authority that meets the requirements of this paragraph.

(B) Where presentation of particular documentation or statements are required by this subpart as a condition of disclosure, a covered entity may reasonably rely on documentation or statements that on their face meet the applicable requirements.

(3) *Implementation specification: Other safeguards.* A covered entity must have safeguards to ensure that information is not used in violation of the requirements of this subpart or by members of its workforce or components of the entity or employees and other persons associated with, or components of, its business partners who are not authorized to access the information.

(4) *Implementation specification: Disclosures by whistleblowers.* A covered entity is not considered to have violated the requirements of this subpart where a member of its workforce or an employee or other person associated with a business partner discloses protected health information that such member or other person believes is evidence of a violation of law to:

(i) The law enforcement official or oversight agency authorized to enforce such law; or

(ii) An attorney, for the purpose of determining whether a violation of law has occurred or assessing what remedies or actions at law may be available to the employee.

(d) *Complaints to the covered entity*—(1) *Standard.* A covered entity that is a health plan or health care provider must provide a process whereby individuals may make complaints concerning the entity's compliance with the requirements established by this subpart.

(2) *Implementation specifications.* A covered entity that is a health plan or health care provider must develop and implement procedures under which an individual may file a complaint alleging that the covered entity failed to comply with one or more requirements of this subpart. Such procedures must provide for:

(i) The identification of the contact person or office required by paragraph (a)(2) of this section; and

(ii) Maintenance by the covered entity of a record of all complaints and their disposition, if any.

(e) *Sanctions: Standard.* A covered entity must develop and apply when appropriate sanctions against members of its workforce who fail to comply with the policies and procedures of the covered entity or the requirements of this subpart in connection with protected health information held by the covered entity or its business partners.

(f) *Duty to mitigate: standard.* A covered entity must have procedures for mitigating, to the extent practicable, any deleterious effect of a use or disclosure of protected health information in violation of this subpart.

§ 164.520 Documentation of policies and procedures.

(a) *Standard.* A covered entity must adequately document its compliance with the applicable requirements of this subpart.

(b) *Implementation specification: General.* A covered entity must document its policies and procedures for complying with the applicable requirements of this subpart. Such documentation must include, but is not limited to, documentation that meets the requirements of paragraphs (c) through (g) of this section.

(c) *Implementation specification: Uses and disclosures.* With respect to uses by the covered entity or its business partners of protected health information, a covered entity must document its policies and procedures regarding:

(1) Uses and disclosures of such information, including:

(i) Uses and disclosures with authorization, including for revocation of authorizations; and

(ii) Uses and disclosures without authorization, including:

(A) For treatment, payment, and health care operations;

(B) For disclosures to business partners, including monitoring and mitigation; and

(C) For uses and disclosures pursuant to § 164.510.

(2) For implementation of the minimum necessary requirement of § 164.506(b).

(3) For implementation of the right to request a restriction under § 164.506(c), including:

(A) Who, if anyone, in the covered entity is authorized to agree to such a request; and

(B) How restrictions agreed to are implemented.

(4) For creation of de-identified information in accordance with § 164.506(d).

(d) *Implementation specification: Individual rights.* A covered entity must document its policies and procedures under §§ 164.512, 164.514, 164.515, and 164.516, as applicable, including:

(1) How notices will be disseminated in accordance with § 164.512;

(2) Designated record sets to which access will be granted under § 164.514;

(3) Grounds for denying requests for access under § 164.514;

(4) Copying fees, if any;

(5) Procedures for providing accounting pursuant to § 164.515;

(6) Procedures for accepting or denying requests for amendment or correction under § 164.516;

(7) How other entities will be notified of amendments or corrections accepted under § 164.516; and

(8) Identification of persons responsible for making decisions or otherwise taking action, including serving as a contact person, under §§ 164.512, 164.514, 164.515, and 164.516.

(e) *Implementation specification: Administrative requirements.* A covered entity must provide documentation of its procedures for complying with § 164.518, including:

(1) Identification of the persons or offices required by § 164.518(a) and their duties;

(2) Training provided as required by § 164.518(b);

(3) How access to protected health information is regulated by the covered entity and its business partners, including safeguards required by § 164.518(c);

(4) For a covered entity that is a health plan or health care provider, for receiving complaints under § 164.518(d);

(5) Sanctions, and the application thereof, required by § 164.518(e); and

(6) Procedures for mitigation under § 164.518(f).

(f) *Implementation specification: Specific documentation required.* A covered entity must retain documentation of the following for six years from when the documentation is created, unless a longer period applies under this subpart:

(1) Restrictions agreed to pursuant to § 164.506(c);

(2) Contracts pursuant to § 164.506(e);

(3) Authorization forms used pursuant to § 164.508;

(4) Samples of all notices issued pursuant to § 164.512;

(5) Written statements required by § 164.514;

(6) The accounting required by § 164.515;

(7) Documents relating to denials of requests for amendment and correction pursuant to § 164.516;

(8) Certifications under § 164.518(b); and

(9) Complaints received and any responses thereto pursuant to § 164.518(d).

(g) *Implementation specification: Change in policy or procedure.* (1) Except as provided in paragraph (g)(2) of this section, a covered entity may not implement a change to a policy or procedure required or permitted under this subpart until it has made the appropriate changes to the documentation required by this section and the notice required by § 164.512.

(2) Where the covered entity determines that a compelling reason exists to make a use or disclosure or take another action permitted under this subpart that its notice and policies and procedures do not permit, it may make the use or disclosure or take the other action if:

(1) It documents the reasons supporting the use, disclosure, or other action; and

(2) Within 30 days of the use, disclosure, or other action, changes its notice, policies and procedures to permit such use, disclosure, or other action.

§ 164.522 Compliance and enforcement.

(a) *Principles for achieving compliance.*—(1) *Cooperation.* The Secretary will, to the extent practicable, seek the cooperation of covered entities in obtaining compliance with the requirements established under this subpart.

(2) *Assistance.* The Secretary may provide technical assistance to covered entities to help them comply voluntarily with this subpart.

(b) *Individual complaints to the Secretary.* An individual who believes that a covered entity is not complying with the requirements of this subpart may file a complaint with the Secretary, provided that, where the complaint relates to the alleged failure of a covered entity to amend or correct protected health information pursuant to § 164.516, the Secretary may determine whether the covered entity has followed procedures that comply with § 164.516, but will not determine whether the information involved is accurate, complete, or whether errors or omissions might have an adverse effect on the individual.

(1) *Requirements for filing complaints.* Complaints under this section must meet the following requirements:

(i) A complaint must be filed in writing, either on paper or electronically.

(ii) A complaint should name the entity that is the subject of the complaint and describe in detail the acts or omissions believed to be in violation of the requirements of this subpart.

(iii) The Secretary may prescribe additional requirements for the filing of complaints, as well as the place and manner of filing, by notice in the **Federal Register**.

(2) *Investigation.* The Secretary may investigate complaints filed under this section. Such investigation may include a review of the pertinent policies, practices, and procedures of the covered entity and of the circumstances regarding any alleged acts or omissions concerning compliance.

(c) *Compliance reviews.* The Secretary may conduct compliance reviews to determine whether covered entities are complying with this subpart.

(d) *Responsibilities of covered entities.*—(1) *Provide records and compliance reports.* A covered entity must keep such records and submit such compliance reports, in such time and manner and containing such information, as the Secretary may determine to be necessary to enable the Secretary to ascertain whether the covered entity has complied or is complying with the requirements of this subpart.

(2) *Cooperate with periodic compliance reviews.* The covered entity shall cooperate with the Secretary if the Secretary undertakes a review of the policies, procedures, and practices of a covered entity to determine whether it is complying with this subpart.

(3) *Permit access to information.* A covered entity must permit access by the Secretary during normal business hours to its books, records, accounts, and other sources of information, including protected health information, and its facilities, that are pertinent to ascertaining compliance with this subpart. Where any information required of a covered entity under this section is in the exclusive possession of any other agency, institution, or person and the other agency, institution, or person fails or refuses to furnish the information, the covered entity must so certify and set forth what efforts it has made to obtain the information. Protected health information obtained in connection with a compliance review or investigation under this subpart will not be disclosed by the Secretary, except where necessary to enable the Secretary to ascertain compliance with this subpart, in formal enforcement proceedings, or where otherwise required by law.

(4) *Refrain from intimidating or retaliatory acts.* A covered entity may not intimidate, threaten, coerce, discriminate against, or take other retaliatory action against any individual for the filing of a complaint under this section, for testifying, assisting, participating in any manner in an investigation, compliance review, proceeding or hearing under this Act, or opposing any act or practice made unlawful by this subpart.

(e) *Secretarial action regarding complaints and compliance reviews.*—(1) *Resolution where noncompliance is indicated.* (i) If an investigation pursuant to paragraph (b)(2) of this section or a compliance review pursuant to paragraph (c) of this section indicates a failure to comply, the Secretary will so inform the covered entity and, where the matter arose from a complaint, the individual, and resolve the matter by informal means whenever possible.

(ii) If the Secretary determines that the matter cannot be resolved by informal means, the Secretary may issue written findings documenting the non-compliance to the covered entity and, where the matter arose from a complaint, to the complainant. The Secretary may use such findings as a basis for initiating action under section 1176 of the Act or initiating a criminal referral under section 1177.

(2) *Resolution where no violation is found.* If an investigation or compliance review does not warrant action pursuant

to paragraph (e)(1) of this section, the Secretary will so inform the covered entity and, where the matter arose from a complaint, the individual in writing.

§ 164.524 Effective date.

A covered entity must be in compliance with this subpart not later than 24 months following the effective date of this rule, except that a covered entity that is a small health plan must be in compliance with this subpart not later than 36 months following the effective date of the rule.

Appendix to Subpart E of Part 164—Model Authorization Form

AUTHORIZATION FOR RELEASE OF INFORMATION

Section A: Must be completed for all authorizations

I hereby authorize the use or disclosure of my individually identifiable health information as described below. I understand that this authorization is voluntary. I understand that if the organization authorized to receive the informatior is not a health plan or health care provider, the released information may no longer be protected by federal privacy regulations.

Patient name: _____ **ID Number**: _____

Persons/organizations providing the information:

_____
_____
_____
_____

Persons/organizations receiving the information:

_____
_____
_____
_____

Specific description of information (including date(s)): _____
_____
_____
_____
_____

Section B: Must be completed only if a health plan or a health care provider has requested the authorization

1. The health plan or health care provider must complete the following:
   a. What is the purpose of the use or disclosure?:_____
   _____
   b. Will the health plan or health care provider requesting the authorization receive financial or in-kind compensation in exchange for using or disclosing the health information described above? Yes_____ No_____

2. The patient or the patient's representative must read and initial the following statements:
   a. I understand that my health care and the payment for my health care will not be affected if I do not sign this form. Initials: _____
   b. I understand that I may see and copy the information described on this form if I ask for it, and that I get a copy of this form after I sign it. Initials: _____

Section C: Must be completed for all authorizations

The patient or the patient's representative must read and initial the following statements:

1. I understand that this authorization will expire on __ __/__ __/__ __ __ __ (DD/MM/YR) Initials: _____
2. I understand that I may revoke this authorization at any time by notifying the providing organization in writing, but if I do it won't have any affect on any actions they took before they received the revocation. Initials: _____

_____ _____

Signature of patient or patient's representative **Date**

(Form MUST be completed before signing.)

Printed name of patient's representative: _____

Relationship to the patient: _____

**** YOU MAY REFUSE TO SIGN THIS AUTHORIZATION ****

You may not use this form to release information for treatment or payment except when the information to be released is psychotherapy notes or certain research information.

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Wednesday
November 3, 1999

Part V

Department of Transportation

Federal Aviation Administration

14 CFR Part 139

Year 2000 Airport Safety Inspections; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 139

[Docket No. FAA–1999–5924; SFAR No. 85]

RIN 2120–AG83

Year 2000 Airport Safety Inspections

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule requires operators of certificated airports to conduct one-time operational readiness checks of certain airfield equipment and systems on, or shortly after, January 1, 2000, and report the results of these checks to the FAA. In addition, this rule temporarily revises the time period these airport operators have to repair or replace certain emergency equipment. These temporary requirements are needed to ensure that operators of certificated airports maintain safety by identifying and addressing any unforeseen problems with date-sensitive equipment and systems at the earliest practical time after January 1, 2000.

EFFECTIVE DATES: January 1, 2000 to January 5, 2000.

FOR FURTHER INFORMATION CONTACT: Robert E. David, Airport Safety and Operations Division (AAS–300), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–8721.

SUPPLEMENTARY INFORMATION:

Availability of Final Rules

An electronic copy of this document may be downloaded using a modem and suitable communications software from the FAA regulations section of the FedWorld electronic bulletin board service (telephone: (703) 321–3339) or the Government Printing Office's (GPO) electronic bulletin board service (telephone: (202) 512–1661).

Internet users may reach the FAA's web page at http://www.faa.gov/avr/arm/nprm/nprm.htm or the GPO's web page at http://www.access.gpo.gov/nara for access to recently published rulemaking documents.

Any person may obtain a copy of this document by submitting a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267–9680. Communications must identify the amendment number or docket number of this final rule.

Persons interested in being placed on the mailing list for future rulemaking documents should request from the above office a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996, requires the FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. Therefore, any small entity that has a question regarding this document may contact their local FAA official. Internet users can find additional information on SBREFA in the ''Quick Jump'' section of the FAA's web page at *http://www.faa.gov* and may send electronic inquiries to the following Internet address: *9–AWA-SBREFA@faa.gov*.

Background

On January 1, 2000, many computer systems worldwide could malfunction or shut down because of the year change from 1999 to 2000. The problem, often referred to as the Year 2000 (Y2K) problem, is the result of how computers and other microprocessors have traditionally recorded and computed dates. Typically, these machines have used two digits to represent the year, *e.g.*, ''98'' for 1998, to save electronic storage space and reduce operating costs. However, this format fails to distinguish the year 2000 (represented as ''00'') from the year 1900. Software and computer experts are concerned that this could cause computers and equipment with internal microprocessors to malfunction in unforeseen ways or to fail completely.

Many airport operators use computers or equipment with embedded microprocessors to meet certain requirements of Title 14, Code of Federal Regulations (14 CFR) part 139, Certification and Operations: Land Airports Serving Certain Air Carriers. For example, an operator of a certificated airport may have computer systems that control when airfield lighting is turned on, or that control access to the airfield through vehicle and passenger gates. Safety and maintenance vehicles, such firefighting trucks, and emergency communications systems may likewise have computerized systems.

Since October 1998, the FAA has worked with operators of airports certificated under part 139 to ensure that all airfield equipment and systems used to comply with part 139 requirements are Y2K compliant, or that the airport operator has developed an alternative means of complying with the part 139 requirements. The FAA also formed an internal Y2K airport team to contact operators of certificated airports to monitor the Y2K status of each of these operator's systems that are used to comply with part 139 requirements. This team will continue to work with the operators of certificated airports throughout the remainder of 1999 to ensure that the agency is kept informed of the Y2K status at each part 139 airport.

Despite these efforts, the FAA is concerned that part 139 inspection and reporting requirements will not be adequate to address the unique circumstances associated with the date rollover to January 1, 2000. Part 139 requires operators of certificated airports to conduct daily inspections of their facilities to ensure compliance with the regulation. Such inspections include a visual check of movement areas (areas used by air carriers to land, takeoff, and taxi) and operational tests of equipment and systems used to comply with part 139 requirements. As a matter of practicality, various elements of the self-inspection are conducted throughout the day. As such, the existing inspection requirements do not require inspections early on January 1, 2000, before most operations begin, and do not necessarily require the kind of tests that would determine if there is a Y2K-related problem that was not detected by pre-January Y2K validation testing.

In addition, part 139 provisions regarding the repair or replacement of inoperative aircraft rescue and firefighting (ARFF) vehicles, and associated reporting requirements, are not well adapted to the unique circumstances of the possible Y2K disruption on equipment. Emergency equipment required by part 139, unlike other aviation systems, is intended for use only in an emergency, and under the current requirement may not be tested and reported to the FAA until an actual emergency or scheduled maintenance require it, both of which may occur well after operations begin on January 1, 2000.

Part 139 also allows certain airport operators a 48-hour grace period to repair or replace inoperative ARFF vehicles, with no effect on the number and type of ARFF equipment an airport must provide, commonly known as the ARFF index. The ARFF index for an airport is determined by the size of the aircraft using the airport and the number of daily departures. The index establishes the number and size of ARFF trucks needed. Conversely, the ARFF equipment available determines

the index and, thereby, limits the size of the aircraft that the airport may serve. The 48-hour provision is intended to allow airport operators sufficient time to acquire parts to repair a required ARFF vehicle, or to arrange for a replacement vehicle, without impacting air carrier operations.

Under normal operations, this is an acceptable procedure as an inoperative ARFF vehicle is a rare occurrence, and parts can be obtained quickly. However, since some ARFF vehicles may have embedded computer chips, a Y2K-related problem, while highly unlikely, is possible. Since similar models of ARFF vehicles are widely used, a failure of even one model of ARFF equipment could affect many airports. As such, a delay in repairing a Y2K problem at a number of airports could have a system-wide impact.

Alternatives

The FAA evaluated four alternatives to address Y2K issues. The FAA first considered not making changes to part 139 for the January 1, 2000, date rollover. Under this alternative, operators of certificated airports would continue to comply with current part 139 requirements. Alternatively, the FAA then contemplated making the determination that Y2K compliance is an ''unusual condition'' under § 139.327(a)(2), thus requiring all certificate holders to conduct an inspection within a specified time period to identify and correct any deficiencies. Further, the FAA considered requiring these inspections only at airports holding an airport operating certificate (those certificate holders serving scheduled operations of air carrier aircraft with more than 30 passenger seats). In this alternative, operational readiness checks would not have been required at airports holding a limited airport operating certificate (those certificate holders serving unscheduled air carrier operations).

Finally, the FAA considered, and ultimately pursued, mandating both the self-inspections and reporting requirements, as well as the suspension of the 48-hour grace period for repair of ARFF vehicles. While this alternative is the most comprehensive and costly of the four alternatives considered, the FAA has determined that associated costs would be minimal and only marginally greater than the other alternatives considered, and that the benefits of mandatory safety inspections fully justify this approach.

The Notice of Proposed Rulemaking (NPRM)

On July 8, 1999, the FAA published in the **Federal Register** a notice of proposed rulemaking (64 FR 37026) that proposed to require operators of airports certificated under part 139 to conduct one-time operational readiness checks of certain airfield equipment and systems starting January 1, 2000. In addition, this notice proposed to temporarily revise the time period these airport operators have to repair or replace certain emergency equipment.

In response to this proposal, the FAA received 14 comments from industry associations, airport operators and owners, and one individual.

Commenters were generally in favor of the SFAR but recommended several modifications to and clarifications of certain testing and reporting requirements. Two commenters (Airports Council International and American Association of Airport Executives) recommended the FAA rescind the proposal, claiming that existing part 139 requirements are more than adequate to address any Y2K issues. In particular, both associations strongly opposed the temporary revocation of the 48-hour grace period for repair and replacement of inoperative ARFF vehicles. Neither association provided operational and cost data to substantiate their positions. All of these comments are discussed in detail in the Section-by-Section analysis below.

Section-by-Section Discussion of Comments

General

After consideration of the comments received, the FAA has modified the proposed SFAR and this final rule reflects those changes.

As noted above, comments received were generally supportive of the proposal. Several airport operators noted that they already plan to conduct readiness tests very similar to those proposed. Air carrier and pilot organizations offered their support of system-wide testing to ensure the safety and integrity of airports certificated under part 139.

While most commenters agreed with the FAA's conclusion that the possibility of a systemic failure due to the date rollover to January 1, 2000, is small, a few commenters challenged the FAA's conclusion that the date rollover is a significant event that warrants special attention. The FAA disagrees with such comments and believes Y2K issues present unique problems for part 139 airports.

One commenter stated that the SFAR is unnecessary since the International Civil Aviation Organization (ICAO) or Transport Canada are not requiring similar Y2K tests. The FAA disagrees. ICAO does not impose requirements, and in any event, the U.S. system of airports is far larger and more complex than Canada's or most member countries of ICAO. If by chance there is a system-wide problem resulting from the date rollover, it will have a far greater impact on the U.S. aviation system.

A majority of commenters further expressed the concern that the testing required by the SFAR would be redundant to those tests airport operators are currently conducting to ensure Y2K compliance. Many airport operators noted that they have spent considerable time and money testing part 139 systems and equipment, and obtaining certification from vendors. As such, they would not support protracting such tests. The FAA concurs and did not intend for this SFAR to require a repeat of the extensive Y2K testing that certificated holders have already completed.

Instead, the FAA intends that this SFAR merely require certificate holders to conduct operational readiness checks to verify that certain part 139 systems and equipment are functioning normally after the Y2K date rollover. For the most part, this will require airport operators to ensure a system, such as runway lighting, has turned on properly, and that equipment is functioning adequately, e.g., vehicle radios turn on and allow for communication between users.

The FAA believes that concerns about the burden of this SFAR are due to the use of the term ''test'' throughout the SFAR. For clarity, the term ''test'' has been replaced throughout the SFAR with the term ''operational readiness check.'' To further clarify this rule, the systems and equipment that must be checked, and suggested methods for completing such checks, are discussed in the Operational Readiness Check Requirements section.

Also, many commenters expressed general confusion over the relation of this SFAR to part 139. Unless otherwise noted, the requirements of part 139 are still applicable during the duration of this SFAR. For example, the notification requirements of § 139.339 (Airport condition reporting) will still be applicable from January 1 to January 5, 2000, even though airport operators will have additional reporting requirements under the SFAR.

Finally, another commenter recommended that the FAA prohibit

airport operators from closing their facilities to conduct required operational readiness checks. The FAA disagrees with this recommendation. Even though an airport operator has the authority to close its facility, or portions thereof, for safety reasons, the FAA believes that closing an airport to conduct required operational readiness checks will not be an issue. Typically, operators of these airports are able to conduct part 139 self-inspections and accommodate air carrier schedules without interruption of those schedules. However, if an air carrier still is concerned that required Y2K operational readiness checks will affect its operations, the FAA encourages the air carrier to contact the airport operator as soon as possible.

Section 1: Operational Readiness Check Requirements

Paragraph 1(a)

As proposed, this paragraph defines the applicability of this SFAR. Other than clarifying changes, this paragraph remains the same. Several commenters recommended that the FAA revise this section to extend this SFAR to operators of those airports that air carriers use as alternate airports. The FAA disagrees with this recommendation. Under part 121 (Operating Requirements: Domestic, Flag, and Supplemental Operations) air carriers are required to operate at airports that are certificated under part 139. Part 121 also requires that under certain conditions air carriers designate an alternate airport as part of their required flight planning. However, § 121.590 permits an air carrier to designate a required alternate airport that is not certificated under part 139.

Since an air carrier could designate any airport as an alternate, extending this SFAR to operators of alternate airports would effectively extend its requirements to all airport operators. Yet, the requirements of this SFAR are intended to check systems and equipment specially required at airports certificated under part 139 (approximately 568 civilian airports). The FAA does not require compliance with these safety standards at any other U.S. airport. Therefore, it would be inappropriate for the FAA to require airport operators to check systems and equipment that they are not required to have, and in many instances, do not own or maintain.

In addition, the term ''unless otherwise authorized by the Administrator'' has been added to this paragraph. Since the rule language cannot be specific enough to address every unique circumstance at all certificated airports, the FAA has determined that this change will allow for alternative means of compliance. For example, some airport operators will not be able to conduct the required operational readiness checks of emergency communications with the air traffic control tower prior to the first air carrier operation. Not all air traffic control towers are in operation 24 hours a day and air carrier operations may normally occur when the tower is closed. On a case-by-case basis, the FAA will determine the appropriate compliance methods to address such local issues.

Paragraph 1(b)

As proposed, this paragraph sets forth general descriptions of those systems and equipment that needed to be checked for Y2K compliance. A majority of commenters recommended that this paragraph be expanded to identify all airport systems and equipment that the FAA would require to be checked. The overall concern was that airport operators needed more information to determine whether or not required operational readiness checks could be accomplished within the specified time frame and make adequate preparations. The FAA concurs that this section needs clarification, and has expanded the section to specify each part 139 system and piece of equipment that must undergo an operational readiness check.

In addition, several commenters expressed concern over a reference in the NPRM preamble regarding systems that control access by vehicles and pedestrians to the airfield. This reference was interpreted to mean that required operational readiness checks would include a functionality test of access control systems required under 14 CFR part 107 (Airport security). This is not the case. Operational readiness checks are only required of part 139 systems and equipment. The reference to access control was intended to only illustrate possible part 139 systems and equipment that may contain computers or microprocessors that could be affected by the date rollover, including those automated systems that control inadvertent entry to the movement area by unauthorized personnel, as required under § 139.335, Public protection.

One commenter recommended that airport operators be required to consult with their tenant air carriers when determining which part 139 systems and equipment will be checked. The FAA does not concur with this recommendation. The certificate holder should already know what systems and equipment to check since required operational readiness checks cover the same systems and equipment as the daily checks conducted by airport operators to comply with part 139 self-inspection requirements. These checks should not affect air carrier operations any differently than a daily airfield self-inspection. Further, if problems arise as the result of operational readiness checks, the same procedures airport operators use to notify their tenant air carriers of airfield conditions under § 139.339 still are applicable. Systemic problems will be reported to air carriers on a national basis (see discussion under Reporting Requirements). The FAA encourages any air carrier that is uncertain as to an individual airport's notification procedures to contact the airport operator as soon as possible for clarification.

Based on comments received, the FAA also has modified proposed paragraph 1(b)(5). Several commenters felt that this paragraph is so broad that it would essentially allow the FAA to indiscriminately require any type of system or equipment check. This was not the FAA's intent. Instead, this paragraph of section 1 was included to ensure the flexibility to accommodate local circumstances or address problems with systems and equipment not discovered until after the publication of this SFAR.

In the final rule, this proposed paragraph is renumbered as paragraph 1(b)(9) and has been combined with proposed paragraph 1(d) (notification information). This modification is intended to clarify that the FAA will consult with an airport operator if additional operational checks of part 139 systems or equipment are needed. However, the final determination of any additional operational readiness checks needed to ensure safety of air carrier operations will remain with the FAA.

The FAA still will notify individual certificate holders to confirm systems and equipment that will be checked, address any local or unique issues, and provide specific details on reporting procedures, including regional contact names and telephone numbers. In addition, this notification will provide guidance on methods to conduct operational checks to minimize the impact on operations. For example, certificate holders will be advised that operational readiness checks of snow and ice removal equipment need only involve the starting and operating of each make and model of motorized equipment and corresponding attachments, such as blades, blowers, and brooms.

One commenter suggested that the FAA complete this notification no later than October 15, 1999. While the FAA

hopes to complete all such notifications as soon as possible after the publication of the final rule, the FAA believes further time may be needed to address any unforeseen delays and to finalize internal reporting procedures.

Finally, commenters recommended that the FAA conduct operational readiness checks of its own equipment located at part 139 airports, such as navigation aides, and report the results of these checks to the local airport operator. While the FAA concurs with this recommendation, it is beyond the scope of this SFAR. However, to ensure such notification occurs during the effective date of this SFAR, the FAA will instruct managers of its air traffic control towers to meet with airport operators prior to the date rollover and develop a mutually acceptable notification procedure. This type of coordination already exists at many airports certificated under part 139, but this additional effort will help ensure there are no gaps in the information flow. At airports where there are no air traffic control towers, the FAA will use existing notification procedures to alert airport and aircraft operators of equipment problems.

Paragraph 1(c)

As proposed, paragraph 1(c) would require that all ARFF vehicles discharge fire extinguishing agents, regardless of the type of agent. ARFF vehicles typically carry two types of fire extinguishing agents, aqueous film forming foam (AFFF) that is dispensed with water and dry chemical that is dispensed by pressured gas. Several airport operators raised concerns regarding the operational readiness checks of ARFF vehicles that carry dry chemical extinguishing agents. These commenters pointed out that most dry chemical extinguishing agents are harmful to the environment and special care must be taken to dispose of it once discharged from an ARFF vehicle. They stated this would be difficult, and possibly unsafe, to do during hours of darkness. Also, these commenters noted that once a truck that carries dry chemical discharges its agent, it takes more time to recharge pressurized gas tanks and restore the truck to service than a truck that carries AFFF.

The FAA agrees that dispensing dry chemical agent is more problematic than dispensing AFFF. Further, systems used to discharge dry chemicals are mechanical and do not contain microprocessors. As such, the FAA has determined that it is not necessary for certificate holders to conduct an operational readiness check of systems that dispense dry chemical or other similar secondary agents. Subsequently, paragraph 1(c) has been modified to require certificate holders to dispense only AFFF extinguishing agents. Regardless of the type of fire extinguishing agent that these vehicles carry, the certificate holder is still required to check the operation of all ARFF vehicles, i.e., starting the vehicle and driving it at speeds typically used to respond to an emergency and verifying that radios and emergency communications are operational.

Finally, this paragraph has been modified to clarify the extent of operational readiness checks of ARFF vehicles. This change requires that the certificate holder start vehicles and drive them at speeds normally driven in an emergency, in addition to dispensing fire-extinguishing agents. The FAA believes this change will eliminate any confusion as to the extent of the operational readiness check required for each ARFF vehicle.

Section 2: Schedule

Prior to the discussion of scheduling requirements, it should be noted that the order of proposed section 2 (Reporting Requirements) and section 3 (Test Schedule) have been reversed and renumbered. Section 2 is now titled Schedule, and section 3 is now titled Reporting Requirements. This change is intended to present the requirements of this SFAR in a more logical sequence.

Paragraph 2(a)(1)

This paragraph (proposed paragraph 3(a)) establishes schedules for conducting operational readiness checks. This paragraph has been modified based on comments received.

Some airport operators recommended that the certificate holders be given additional time to complete required operational readiness checks, particularly at those airports where air carrier operations are scheduled before 1:00 a.m. on January 1, 2000. Suggestions ranged from one to six additional hours to complete operational readiness checks.

The FAA believes these commenters based their concerns on the assumption that operational readiness checks proposed in section 1 were more extensive than the FAA intended (see above discussion under Operational readiness checks). As such, it was difficult for these commenters to determine whether or not required operational readiness checks could be accomplished within the specified time frame. Even so, the FAA has reevaluated time estimates for airport operators to complete required operational readiness checks and concurs that an additional hour is warranted, especially for those operators with early morning operations on January 1, 2000.

Conversely, another commenter recommended that the FAA require certificate holders to conduct all operational readiness checks within two hours after midnight on January 1, 2000, regardless of when the first flight is scheduled to occur. This commenter also suggested that the FAA allow a certificate holder that can document no air carrier operations within the first 48 hours of the date rollover additional time to complete operational readiness checks so long as required checks are completed 24 hours before the first scheduled operations. While this approach would simplify the schedule for required checks by requiring certificated holders with air carrier operations on the first two days of the new year to complete operational readiness checks at the same time, the FAA believes it would be unduly burdensome for most certificate holders. In particular, for those certificate holders that do not have scheduled air carrier operations until later in the day on January 1, 2000, and would be required to make arrangements for staff to be available at times other than their normal duty hours.

Many certificate holders have indicated to the FAA that, regardless of the time of the first scheduled air carrier operation, they plan to have operational and maintenance personnel on duty during the date rollover, and will begin operational readiness checks immediately after midnight on January 1, 2000. Not all certificate holders have such staffing levels and the FAA believes that it is a more reasonable approach to allow operational readiness checks to be conducted closer to the time of the first scheduled operation when airport personnel are routinely on duty.

Paragraph 2(b)

Proposed paragraph 3(b) that would require all operational readiness checks to be completed by January 5, 2000, has been renumbered 2(c). A new paragraph 2(b) has been added to allow those certificate holders at airports that have scheduled air carrier operations on January 1, 2000, some flexibility in completing operational readiness checks of systems and equipment that are operating and remain operational during the date rollover, but that may pose a safety hazard if they are turned off and could not be returned to operation.

A majority of commenters expressed concern that certain operational readiness checks of systems that are operational at the time of the date

rollover may inadvertently initiate a failure of these systems or pieces of equipment. On the other hand, if these systems or pieces of equipment were left alone, they would continue to work on January 1, 2000, until their normal shut down time. At that point, commenters suggested they could be checked without adversely affecting air carrier operations scheduled to occur in the early morning. The FAA concurs with this recommendation.

A good example of such systems and equipment is runway and taxiway lighting systems that automatically turn on at dusk and remain lit until sunrise the following day. On the evening of December 31, 1999, such a lighting system would automatically turn on, and if there is no interruption in its power source, should remain lit until daybreak the following morning. While unlikely, if such a system has a date sensitive micro-processor it is most likely used to turn the system on or off, and if it were to fail, this would probably occur when the system switches on the evening of January 1, 2000.

A new paragraph 2(b) has been added to address systems and equipment that are operational at the time of the date rollover to January 1, 2000. Specifically, certificate holders that have scheduled air carrier operations on January 1 will have until 1 p.m. that day to check runway/taxiway lighting and lighted sign systems, and motorized snow and ice removal equipment if such systems and equipment are operational as of midnight on January 2000. In some instances, this means a certificate holder whose first scheduled operation will occur in the afternoon or evening of January 1 will be required to complete operational readiness checks on these systems or pieces of equipment earlier than other checks required by this SFAR.

Another commenter requested that the final rule clarify that times required for conducting operational readiness checks be based on published or scheduled times, not actual arrival or departure time of the first air carrier operation. Without clarification, the commenter worried that if a flight scheduled for departure on the evening of December 31 is delayed until early the next morning, this flight could be interpreted as the first air carrier operation scheduled for January 1, 2000, rather than a flight scheduled to depart later in the day.

The FAA agrees. Since it is difficult to plan for unforeseen delays and other schedule problems, certificate holders should interpret the phase ''first air carrier operation is scheduled to occur'' as meaning required operational readiness checks shall be planned around the departure or arrival time that is published or scheduled for first air carrier operation after midnight on January 1, 2000, not actual arrival or departure times.

In addition, comments were received suggesting that the schedule for completing operational readiness checks be expanded to include other possible problematic dates, such as February 29, 2000. The FAA disagrees with this recommendation. During the duration of this SFAR, the FAA believes problematic systems or equipment will be identified during both operational readiness checks and routine operations. Based on this experience, certificate holders can repair or replace such systems and equipment in order to remain in compliance with part 139 safety standards during other similar date rollovers.

Section 3: Reporting Requirements

As noted above, the order of proposed section 2 (Reporting Requirements) and section 3 (Test Schedule) has been reversed and those sections have been renumbered. New section 3 is now titled, Reporting Requirements. As proposed, this section establishes a deadline for reporting the results of operational readiness checks. The FAA has modified and reorganized the reporting requirements under new section 3 pursuant to comments received.

Several commenters requested clarification on the type of information certificate holders are required to report and how this information should be reported. Other commenters recommended that the expansion of reporting requirements include any contingency measures that are implemented, and additional reports once the airport has returned to normal operations.

New paragraph (a) of this section requires all certificate holders to report the results of required operational readiness checks, plus report contingency measures implemented, and any changes that may affect ARFF Index levels or air carrier operations. New paragraph (b) of this section specifies when a certificate holder is required to report. Finally, new paragraph (c) reminds certificate holders of their obligations under part 139 to collect and disseminate airport condition information to air carriers, including use of the Notice to Airmen (NOTAM) system.

The FAA believes these modifications will clarify the certificate holder's reporting responsibilities under this SFAR. In addition, the FAA will include reporting guidance that is specific to each airport in the confirmation notice to be sent to each certificate holder (see discussion of paragraph 1(b)). This guidance will include a reporting form, airport-specific information on how and when to report, and alternative means to contact the FAA in the event of a telephone system failure.

Two commenters also recommended that the FAA amend the SFAR to require certificate holders that experience no Y2K problems, and do not implement any contingency measures, to report an ''all clear.'' These commenters felt that this would eliminate any ambiguity regarding the status of part 139 airports, and allow pilots and dispatchers as much time as possible to take appropriate action. The FAA agrees, and has modified proposed section 2 (new paragraph 3(a)) to clarify that all certificate holders must report the results of required operational readiness checks, even if these checks reveal no problems. Information that an airport has experienced no Y2K problems with airfield safety systems will be useful to the FAA, air carriers, other airport operators, and the traveling public.

In addition, several commenters expressed concern about the FAA's ability to gather and disseminate information reported by certificate holders. One commenter went so far to remind the FAA of how many airports it certificates and questioned the agency's ability to field telephone calls from all of these airports.

The FAA does not agree with these comments. The FAA is satisfied that the existing communication system established through the FAA's Regional Airports Division Managers is adequate for reporting the results of required operational readiness checks. Certificate holders routinely report information regarding part 139 compliance to the Regional Airports Division Manager using these established procedures.

These established communication procedures will be utilized to report the results of operational readiness checks to the FAA. FAA regional offices will then communicate these results to FAA Headquarters for further dissemination. In addition, air carrier operations occur at different times at each part 139 airport so certificate holders will be contacting the FAA at various times between January 1 and January 5, 2000, so the FAA does not anticipate a flood of telephone calls at the same time.

As noted above, each certificate holder will be notified of reporting procedures specific to its locality. This will include procedures to notify the

FAA in the event of a failure of telephone systems. Working with its telephone service providers, and air traffic control and flight service systems, the FAA has developed several alternative communication systems for both local and systemic telephone failures.

Finally, a commenter suggested that the results of operational readiness checks be disseminated to airlines, airports, and other users through FAA's Air Traffic Control System Command Center. The commenter felt this would greatly assist all parties involved in taking timely and adequate actions should problems arise.

The FAA concurs. As the FAA receives reports from airport operators, those reports will be disseminated through the FAA's air traffic control system and regional airports division offices. The status report for each part 139 airport will either contain an ''all clear;'' or include a brief description of changes to ARFF Index level, failure of any part 139 systems and equipment, and a description of any limitation or reduction in airport services, up to a notice of closure. Again, such status reports required by this SFAR would be in addition to local airport condition reporting, required under § 139.339.

Section 4: Contingency Measures (New)

Comments were received from several airport operators that the proposed SFAR was unclear as to what action a certificate holder would be required to take if a system or equipment required to be checked failed due to the date rollover to January 1, 2000. The FAA agrees and has added this section to clarify certificate holders' obligations to implement contingency measures.

The FAA assumed that certificate holders would revert to existing contingency measures contained in the Airport Certification Manual (Specifications) in the event of equipment or system failure. As noted above, the requirements of part 139 are still applicable during the duration of this SFAR (with the exception of certain ARFF vehicle readiness requirements—see discussion under section 5, Vehicle Readiness). Operators of part 139 certificated airports already have developed and specified such contingency measures in their Airport Certification Manual (Specifications) to address failure of part 139 systems and equipment.

However, to eliminate any possible confusion, the final SFAR contains a new section 4, Contingency Measures. This section specifies that a certificate holder will implement contingency measures to remain compliant with part 139 in the event that a system or equipment required to be checked fails to operate, or functions improperly due to the date change to January 1, 2000.

This new section is not intended to allow part 139 certificate holders to use their discretion in implementing contingency measures if they believe that a system or equipment failure is not due to the date rollover. If a required system or piece of equipment fails to operate, or performs improperly after a required operational readiness check is performed, the certificate holder must implement contingency measures and sort out the cause of the problem later.

Section 5: Vehicle Readiness

This section (proposed section 4) temporarily rescinded the requirements of § 139.319(h)(3) pertaining to inoperative ARFF vehicles. This section has been renumbered as section 5 and modified based on comments received.

Most comments received concerned the proposed changes to the ARFF vehicle readiness provisions of § 139.319(h)(3). These comments varied widely, ranging from suggestions to expand the proposal to recommendations that it be rescinded.

Commenters that requested the FAA to reinstate the 48-hour grace period to replace or repair ARFF vehicles felt the temporary elimination of this provision of part 139 would increase the likelihood of disruptions and do nothing to accelerate repair of ARFF equipment. Instead, they suggested the FAA contact the manufacturers of ARFF vehicle about the possibility of systemic failures, and then simply require airport operators to arrange for adequate back up prior to the date rollover.

The FAA disagrees. The FAA has contacted the manufactures of ARFF vehicles and they have not provided adequate certification that all components of their vehicles are Y2K compliant, particularly those components that they did not manufacture. Without such assurances, the FAA believes additional efforts must be made to address the possibility, however small, of a system-wide failure of similar models of ARFF vehicles. Part 139 provisions regarding the repair or replacement of inoperative ARFF vehicles do not adequately address this possibility.

Further, these same commenters seemed unclear as to the applicability of part 139 during the effective dates of the SFAR or do not have a clear understanding of the regulation. In particular, these commenters questioned how many backup ARFF vehicles would be needed in the event primary equipment become inoperable and were alarmed by the language of this section that would require any inoperative equipment to be replaced ''immediately with equipment having at least equal capabilities.''

The only part 139 ARFF requirement that changes while the SFAR is in effect is the time period for replacing or repairing inoperable ARFF vehicles. Instead of 48 hours, the time period temporarily has been reduced. Otherwise, certificate holders would comply with part 139 as they do under normal conditions, including implementing contingency measures in the event required ARFF equipment cannot be repaired or replaced in the time specified. Such contingency measures may include lowering the ARFF index (some airport operators maintain a higher Index level than required), implementing mutual aid agreements with the local community, bringing into service older vehicles that are no longer used to meet the required ARFF Index, or closing the airport to certain air carrier operations. Further, the requirement to replace inoperative equipment immediately with the equivalent equipment is currently a requirement of part 139 and would not change under this SFAR.

In addition, part 139 allows for some flexibility in the event the certificate holder cannot maintain its ARFF index level, and this SFAR will not change this. Specifically, part 139.315(c) allows the certificate holder to serve up to four daily operations of an air carrier aircraft requiring the next higher ARFF index level before the operator is required to have more equipment or limit the operations of these larger aircraft. Also, a certificate holder may temporarily deviate from part 139 requirements in the event of an extreme emergency situation, as described under § 139.113.

Due to this confusion, a commenter interpreted the proposal to mean that a certificate holder was required to provide duplicate ARFF vehicles if a primary vehicle failed its operational readiness checks. This commenter noted that it is unlikely that sufficient redundant vehicles could be procured or leased at any price, and such new vehicles would be more likely to contain hidden computer chips and be more susceptible to Y2K problems. As such, the commenter disagreed with the FAA's conclusion that because the probability of an ARFF vehicle failing its operational readiness check is low, the expense of ARFF backup is minimal. In actuality, this commenter felt, this section would be more expensive than calculated because certificate holders would be required to purchase backup

ARFF vehicles at an average cost of $200,000 each.

The FAA disagrees and believes these concerns are the result of the commenter making an assumption that certificate holders must have ARFF vehicle backup available the instant that an ARFF vehicle fails its operational readiness check, and that an identical replacement to the vehicle is required. As explained above, the FAA did not intend that duplicate vehicles be idling next to the ARFF station during operational readiness checks, rather that the certificate holder must initiate contingency measures immediately. Several options are available for contingency measures and are currently used by certificate holders if a required ARFF vehicle becomes inoperative and cannot be repaired or replaced within 48 hours.

These contingency measures would be used until the inoperative vehicle is fixed or, in an extreme case, replaced. So the cost to repair or replace an ARFF vehicle would eventually be incurred even if the FAA did not implement this SFAR. However, if an ARFF vehicle were to fail its operational readiness check, the certificate holder will incur costs for implementing contingency measures that it would not normally incur during the 48-hour grace period. Thus an assessment of the expected cost that may be incurred should include the probability of a Y2K failure even if this probability is small.

Two commenters supported the temporary suspension of the 48-hour grace period but recommended that airport operators be required to make arrangements with local governments to ensure that backup equipment also remains operational. The FAA does not concur with this recommendation. It would be unreasonable to require certificate holders to conduct operational readiness checks on equipment that they do not own. Such backup equipment is the property of local governments, national guard units or the Department of Defense, all of which have their own efforts underway to ensure such equipment is Y2K compliant and remains operational after the date rollover to January 1, 2000.

Also, comments were received from individual operators of part 139 airports. These were very helpful in refining this section, and the FAA has adopted a modified approach to vehicle readiness as a result of their input. Primarily, these commenters were concerned that if no grace period was allowed, then certificate holders could not comply with the SFAR, as backup measures cannot be implemented immediately. For example, certificate holders relying on assistance through a mutual aid agreement need time to initiate this assistance, and emergency personnel responding need time to assemble and reposition equipment to the airport. Recommendations were made to allow certificate holders a minimum of six to eight hours to implement their ARFF contingency measures.

The FAA agrees with these concerns, and did not intend when it proposed to eliminate the grace period to mean that backup personnel and equipment must be on ready status as the certificate holder conducts required operational readiness checks of primary equipment. Instead, the FAA intended for certificate holders to implement contingency measures immediately to ensure compliance with part 139 requirements. To remedy this, the final SFAR allows certificate holders to repair or replace inoperative vehicles as soon as possible, but within four hours of completion of operational readiness checks with equipment having at least equal capabilities of inoperative equipment. If the vehicle cannot be replaced within four hours (and is needed to maintain the index for aircraft currently serving the airport), the revised section requires the certificate holder to either implement contingency measures required under new section 4 or lower the ARFF index to that corresponding to the remaining operative equipment.

Another airport operator noted that the SFAR lacks a provision that would allow certificate holders, during the effective period of the SFAR, to revert to the 48-hour grace period for repairing or replacing vehicles once these vehicles successfully pass their operational readiness checks. For example, if a certificate holder successfully conducts a operational readiness check of an ARFF vehicle on January 2 and reports this to the FAA but two days later the same vehicle breaks down due to a mechanical problem. Under the proposal, this commenter worried that such a mechanical problem would require immediate repair or replacement even though the breakdown was not Y2K related. The FAA agrees, and has added a new paragraph to this section (paragraph 5(b)) that allows the certificate holder, after complying with the section 3 reporting requirements, 48 hours to repair or replace aircraft rescue and firefighting vehicles that subsequently become inoperative.

Finally, several airport operators also raised concerns regarding the operational readiness checks of ARFF vehicles that carry dry chemical extinguishing agents. These comments are addressed under paragraph 1(c).

Section 6: Self-Inspection Requirements

Proposed section 5 (new section 6) has been shortened for clarity. The requirements of the section did not change.

Section 7: Effective Times

Proposed section 6 (new section 7) specifies all times in the SFAR are in local time at the airport.

Several comments were received regarding the requirements of this section. Some commenters agreed with the use of local time, while others recommended using Universal Time Coordinate (UTC). One commenter even suggested that required checks should commence at 1:00 a.m. local time at the International Dateline.

All these recommendations are valid. There are several different times that time-sensitive equipment could be using. For example, a date-sensitive micro-processor manufactured in California for worldwide distribution may be set to the local, Pacific time zone. Conversely, such a part manufactured for a specific airport may be set to the local time of the airport. So the uncertainty of the functionality of unknown date-sensitive systems and equipment is further complicated by the uncertainty of which time such systems and equipment are set to.

To simplify matters, the FAA has determined the final rule will continue to reference local time. At some airports, this may result in certain time-sensitive systems or equipment making the date change to January 1, 2000, prior to midnight local time, while at other airports this event may take place well after midnight local time. Nevertheless, the FAA believes using local time is the most reasonable approach for certificate holders to comply with the requirements of this SFAR.

To lessen the potential impact of varying times, the FAA is exploring the possibility of operators of certificated airports located in the South Pacific voluntarily conducting additional operational readiness checks to obtain information on the reliability of commonly used systems and equipment as soon as possible after midnight at the International Dateline. These airports will be the first part 139 certificated airports to experience the date rollover to January 1, 2000.

Such operational readiness checks will help alert the FAA, and subsequently certificate holders, of equipment and systems that are experiencing problems. Further, as the FAA receives reports from other airport

operators, both domestic airports and international airports, this information will be disseminated to those certificate holders still waiting the date rollover (see discussion under Reporting Section).

Section 8: Expiration.

Proposed section 7 (new section 8) has been shortened for clarity. The requirements of the section did not change.

Paperwork Reduction Act

Information collection requirements in the amendment to part 139 previously have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), and have been assigned OMB Control Number 2120–0063.

International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to comply with International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA determined that there are no ICAO Standards and Recommended Practices that correspond to these proposed regulations.

Regulatory Evaluation Summary

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 directs that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 requires agencies to analyze the economic effect of regulatory changes on small entities. Third, the Office of Management and Budget directs agencies to assess the effect of regulatory changes on international trade. And fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by private sector, or $100 million or more annually (adjusted for inflation).

In conducting these analyses, the FAA has determined that this rulemaking does not meet the standards for a ''significant regulatory action'' under section 3(f) of Executive Order 12866 and under the Department of Transportation's Regulatory Policies and Procedures for Simplification, Analysis, and Review of Regulations (44 FR 11034, February 26, 1979) and, therefore, is not subject to review by the Office of Management and Budget. Additionally, this rule would not have a significant impact on a substantial number of small entities, would not constitute a barrier to international trade, and does not contain a significant intergovernmental or private sector mandate.

If an agency determines that the expected impact is so minimal that the rule does not warrant a full evaluation, a statement to that effect, and the basis for it, is included in the preamble to the final rule. The FAA has determined that the expected impact of this rule will be so minimal as to not warrant a full regulatory evaluation.

In summary, this SFAR establishes a one-time operational readiness check and reporting requirement that is essentially identical to the existing self-inspection requirements. The SFAR requires that certain airport operators arrange for backup ARFF services or implement contingency measures, as currently required, but in a more timely manner, if an ARFF vehicle fails its operational readiness check. Since self-inspections and reporting are already required under § 139.327(a), this regulation imposes little additional costs on airport operators. The FAA estimates that the operational readiness checks required by this rule may be completed in less than two hours, including reporting results to the FAA. In addition, the expense of complying with the ARFF backup requirement in a more timely manner is small and considered a low-probability event.

This SFAR requires airports certificated under part 139 to maintain the current ARFF Index level, reduce their ARFF Index level, or implement contingency measures, as currently required. Operators of most certificated airports are required to maintain the required ARFF Index to serve current scheduled air carrier operations. Many of these operators already have in place an ARFF backup plan. Those that do not have a backup plan can, on short notice, make such arrangements, at a nominal cost. Such contingency measures may include lowering the ARFF Index (some airport operators maintain a higher ARFF Index level than required), implementing mutual aid agreements with the local community, bringing into service older vehicles that are no longer used to meet the required ARFF Index, or closing the airport to certain air carrier operations. Further, the requirement to replace inoperative equipment immediately with equivalent equipment is currently a requirement of part 139 and would not change under this SFAR.

An economic impact could occur in the following scenario. For those operators of certificated airports that are required to meet a specified ARFF Index, this rule does not allow the currently permitted 48-hour grace period to repair or replace inoperative ARFF equipment. Rather, this time period has been temporarily reduced to 4 hours in which the certificate holders must implement ARFF backup measures, as described above. Using this scenario, the rule could result in ARFF costs equal to the 44-hour expense of providing these backup ARFF measures.

In such an event, the cost of maintaining an airport's current ARFF Index for 44 hours is very low in terms of overall airport expenses. For such an expense to occur, all of the following conditions must be met:

1. A vehicle necessary to maintain the ARFF Index does not pass the Y2K operational readiness check.
2. No other ARFF equipment is readily available to maintain the ARFF Index.
3. Air carrier aircraft serving the airport on that day do not allow the airport operator to temporarily step down to a lower ARFF Index.

The probability of a series of connected events in which each event must occur is calculated by multiplying across all events the probability assigned to each event. In this case, the probability of the first event (a required ARFF vehicle does not pass the Y2K operational readiness check) is multiplied by the probability assigned to the second, and then multiplied by the probability of the third event. If the probability of just two events each equal 10 percent, the probability assigned to an airport incurring an ARFF expense resulting from this rule cannot be higher than one percent. Thus, while an ARFF expense can occur, the expected likelihood is thought to be very low.

The FAA has determined that it is unlikely that all three events will occur. However, in the event an airport does incur the cost of having backup ARFF vehicles available, only 44 hours of that cost is attributable to this rule because the current rule imposes the same requirement after a 48-hour grace period. The cost for an airport that might need to provide a backup vehicle could be zero, if the vehicle is obtained from other fire units of the airport owner, or from other local governments through a mutual aid agreement. Accordingly, the costs that an airport operator may incur to obtain the services of one or more backup ARFF

vehicles is expected to be very small. Finally, if the ARFF Index level is affected, an airport operator may choose to accept a lower ARFF Index level temporarily, with no effect on scheduled service, if aircraft currently used for scheduled service at the airport do not require the higher index. Thus the FAA expects this element of the rule to be minimal.

The benefit of the rule is that it provides assurances that airport operator's preparations for the date rollover have been effective and that compliance with part 139 requirements is not compromised due to the January 1, 2000 date rollover. In the unlikely event that this date rollover will interrupt systems that are used to comply with part 139, the rule will ensure an early knowledge of such interruption and facilitate immediate action to maintain safety.

Final Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (the Act), as amended, establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objective of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the business, organizations, and governmental jurisdictions subject to regulation.'' To achieve that principle, the Act requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their actions. The Act covers a wide-range of small entities, including small businesses, not-for-profit organizations and small governmental jurisdictions.

Agencies must perform a review to determine whether a proposed or final rule would have a significant economic impact on a substantial number of small entities. If the determination is that it would, the agency must prepare a Regulatory Flexibility Analysis (RFA) as described in the Act. However, if an agency determines that a proposed or final rule is not expected to have a significant economic impact on a substantial number of small entities, § 605(b) of the Act provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

As detailed above in the regulatory evaluation summary there are two costs that may be incurred. First, the inspection costs are expected to be minimal as the expected inspection time is thought to be two hours or less. Second, the probability that the requirement may impose an ARFF cost is expected to be very low.

Of the 568 civilian certificated airports, 177 meet the criteria for small entities. At least 135 of those 177 airports are approved for air carrier operations using mutual aid, or have other arrangements that do not require the airport operator to have ARFF equipment on the airport to meet a particular index requirement. These airports will not be financially affected by the reduction of the 48-hour ARFF grace period. The remaining 42 airports that are considered small entities must comply with ARFF Index requirements of part 139 and potentially could be affected by the SFAR. The expected ARFF cost that this rule could impose on these 42 airports is expected to be minimal.

The rule will allow airport operators only 4 hours, versus the currently permitted 48-hour grace period, to repair or replace inoperative ARFF equipment or implement contingency measures. Thus, using this scenario, the rule could impose an ARFF cost equal to a 44-hour expense to implement ARFF backup measures, as described above in the Regulatory Evaluation Summary.

Accordingly, pursuant to the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Federal Aviation Administration certifies that this rule will not have a significant economic impact on a substantial number of small entities.

International Trade Impact Statement

The rule will not constitute a barrier to international trade, including the export of U.S. goods and services to foreign countries, or the import of foreign goods and services into the United States.

Federalism Implications

The regulations herein will 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. Therefore, in accordance with Executive Order 12612, it is determined that this rule will not have sufficient federalism implications to warrant the preparation of a federalism assessment.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (the Act), codified as 2 U.S.C. 1501–1571, requires each Federal agency, to the extent permitted by law, to prepare a written assessment of the effects of any Federal mandate in a proposed or final agency rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year.

Section 204(a) of the Act, 2 U.S.C. 1534(a), requires the Federal agency to develop an effective process to permit timely input by elected officers (or their designees) of State, local, and tribal governments on a proposed ''significant intergovernmental mandate.'' A ''significant intergovernmental mandate'' under the Act is any provision in a Federal agency regulation that would impose an enforceable duty upon State, local, and tribal governments, in the aggregate, of $100 million (adjusted annually for inflation) in any one year.

Section 203 of the Act, 2 U.S.C. 1533, which supplements section 204(a), provides that before establishing any regulatory requirements that might significantly or uniquely affect small governments, the agency shall have developed a plan that, among other things, provides for notice to potentially affected small governments, if any, and for a meaningful and timely opportunity to provide input in the development of regulatory proposals.

This rule does not contain a Federal intergovernmental or private sector mandate that exceeds $100 million in any one year. Therefore, the requirements of Title II of the Unfunded Mandates Reform Act of 1995 do not apply.

Environmental Analysis

FAA Order 1050.1D defines FAA actions that may be categorically excluded from preparation of a National Environmental Policy Act (NEPA) environmental assessment or environmental impact statement. In accordance with FAA Order 1050.1D, appendix 4, paragraph 4(j), this rulemaking action qualifies for a categorical exclusion.

Energy Impact

The energy impact of the notice has been assessed in accordance with the Energy Policy and Conservation Act (EPCA) P.L. 94–163, as amended (43 U.S.C. 6362) and FAA Order 1053.1. It has been determined that the final rule is not a major regulatory action under the provisions of the EPCA.

List of Subjects in 14 CFR Part 139

Air carriers, Airports, Aviation safety, Reporting and recordkeeping requirements.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends part 139 of Title 14, Code of Federal Regulations as follows:

PART 139—CERTIFICATION AND OPERATIONS: LAND AIRPORTS SERVING CERTAIN AIR CARRIERS

1. The authority citation for part 139 continues to read as follows:

Authority: 49 U.S.C 106(g), 40113, 44701–44706, 44709, and 44719.

2. Part 139 is amended by adding Special Federal Aviation Regulation No. 85 to read as follows:

SFAR 85—YEAR 2000 AIRPORT SAFETY INSPECTIONS

1. *Operational readiness check requirements.* (a) Unless otherwise authorized by the Administrator, each certificate holder shall conduct an operational readiness check of each piece of equipment and system described in paragraph (b) of this section to verify that compliance with part 139 requirements has not been affected by the date change to January 1, 2000. The operational readiness checks shall demonstrate that the equipment and system is sufficiently operational to continue to support the certificate holder's compliance with the requirements of part 139.

(b) The operational readiness checks required by paragraph (a) of this section shall include a check of—

(1) Each lighting system and lighted sign system;

(2) Each system used to notify aircraft rescue and firefighting units during an emergency;

(3) Each aircraft rescue and firefighting vehicle identified in the Airport Certification Manual or Airport Certification Specifications;

(4) Each radio used to communicate with Air Traffic Control and aircraft;

(5) Each radio used for communication between aircraft rescue and firefighting vehicles and fire dispatch or command;

(6) Each system used by airport operations and maintenance personnel for internal airport communications;

(7) Each piece of motorized equipment used to remove snow and ice from movement areas;

(8) Each system used to transmit airfield condition information to air carriers, including the system used to issue a NOTAM; and

(9) Any other system or piece of equipment that the Administrator determines, after consultation with the certificate holder, is used to support the holder's compliance with part 139 requirements, and is critical to the safety and efficiency of aircraft operations.

(c) The operational readiness check of each aircraft rescue and firefighting vehicle shall include starting the vehicle and driving the vehicle at speeds typically used to respond to an emergency. In addition, the operational readiness check of each vehicle that carries AFFF and water fire extinguishing agent shall include dispensing of this agent.

2. *Schedule.* (a) Except as provided in paragraph (b) of this section, after midnight December 31, 1999, each certificate holder shall complete the operational readiness checks required by section 1 of this SFAR, as follows:

(1) By 2:00 a.m. on January 1, 2000, if the first air carrier operation is scheduled to occur at or before 3:00 a.m. on this date.

(2) At least one hour before the first air carrier operation is scheduled to occur, if the operation is scheduled to occur after 3:00 a.m. on January 1, 2000.

(b) For an airport where air carrier operations are scheduled to occur on January 1, 2000, each certificate holder shall have until 1:00 p.m. on January 1, 2000, to complete the required operational readiness checks of lighting and lighted sign systems, and motorized snow and ice removal equipment that are in use on 12:00 a.m. on January 1, 2000.

(c) All required operational readiness checks shall be completed before January 5, 2000, whether or not the airport has served air carrier operations from January 1 through January 4, 1999.

3. *Reporting Requirements.* (a) Each certificate holder shall report the results of its operational readiness checks to the Regional Airports Division Manager. This report shall include—

(1) A confirmation that the systems and equipment specified under section 1(b) are functioning as required under part 139;

(2) A description of any changes to ARFF Index level required under § 139.315;

(3) Any failure of part 139 systems and equipment specified under section 1(b) and the subsequent contingency measure implemented; and

(4) Any limitations or reductions in part 139 measures that would place a restriction on air carrier operations, including a notice of closure.

(b) The report required by paragraph (a) of this section shall be submitted no later than one hour following the completion of operational readiness checks required by section 1 of this SFAR. For systems and equipment described in section 2(b), a report on the required operational readiness checks shall be submitted no later than one hour following the completion of those checks.

(c) This reporting requirement is in addition to the notification requirements of part 139.

4. *Contingency measures.* Except as provided in section 5, the certificate holder shall implement contingency measures, if necessary, to remain compliant with part 139 in the event that a system or piece of equipment required to be checked under this SFAR becomes inoperative due to the date change to January 1, 2000.

5. *Vehicle readiness.* (a) Except as provided in paragraph (b) of this section, until January 5, 2000, each vehicle required under § 139.317 that becomes inoperative shall be replaced as soon as possible with equipment having at least equal capabilities, notwithstanding § 139.319(h)(3). A vehicle is considered inoperative if it cannot perform as required by § 139.319(h)(1). In any event, the vehicle must be replaced with four hours of failure to pass its operational readiness check. If the vehicle cannot be replaced within four hours, the certificate holder shall—

(1) Implement contingency measures required under section (4); or

(2) Limit air carrier operations on the airport to those compatible with the ARFF Index corresponding to the remaining operative rescue and firefighting equipment.

(b) Any ARFF vehicle that subsequently becomes inoperative after the certificate holder complies with the reporting requirements of section 3(a), may be replaced, as provided in § 139.319(h)(3), if the vehicle:

(1) Passed the operational readiness check required by section 1, or

(2) Is a replacement vehicle provided in accordance with paragraph (a) of this section.

6. *Self-inspection requirements.* Operational readiness checks conducted in compliance with this SFAR may be used to fulfill applicable part 139 self-inspection requirements.

7. *Effective times.* All of the times described in this SFAR are in the local time of the airport.

8. *Expiration.* This SFAR expires on January 5, 2000.

Issued in Washington, DC, on October 28, 1999.

Jane F. Garvey,

Administrator.

[FR Doc. 99–28616 Filed 11–2–99; 8:45 am]

BILLING CODE 4910–13–P

federal register

Wednesday
November 3, 1999

Part VI

Department of Housing and Urban Development

Funding Availability; Public Housing Drug Elimination Program; Gun Buyback Violence Reduction Initiative; Notice

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4451–N–05]

Notice of Funding Availability; Public Housing Drug Elimination Program; Gun Buyback Violence Reduction Initiative

AGENCY: Office of Public and Indian Housing, HUD.

ACTION: Notice of Funding Availability (NOFA) for Public Housing Drug Elimination Program Gun Buyback Violence Reduction Initiative.

SUMMARY: The purpose of this notice is to affirm that gun buyback initiatives are an eligible activity under the public housing drug elimination program and to provide funding information and program guidelines for gun buyback programs. PHAs may reprogram a portion of their FY 1999 PHDEP grant dollars in order to devote such resources to gun buyback violence reduction initiatives. To encourage PHAs to devote a nationwide total of up to $10.5 million of their FY99 PHDEP grant funds to gun buyback violence reduction initiatives in cooperation with local law enforcement agencies, HUD through this notice is making an additional $4.5 million available for gun buyback violence reduction initiatives. This $4.5 million will be awarded on a first-come, first-served basis to PHAs that submit their reprogramming requests in accordance with this notice to provide approximately an additional $43 dollars for every $100 of FY 1999 PHDEP funds reprogrammed for gun buyback violence reduction initiatives.

This notice also provides guidance to PHAs on the use of the additional $4.5 million of Drug Elimination grant funds that the Department is making available to PHAs to increase the amount available for buybacks and for the development, outreach, technical assistance, training, assessment and execution activities related to the gun buyback violence reduction initiatives. HUD estimates that this initiative has the potential to remove more than 300,000 guns from circulation.

Contained in the body of this document is further information concerning the purpose of the NOFA, applicant eligibility, available amounts, submission requirements, and application processing, including how to apply, and how selections will be made.

DATES: Applications may be submitted at any time after publication of this notice. The application due date is December 3, 1999, or until all available funds have been awarded. Eligible applications that comply with the requirements of this notice will be funded on a first-come, first-served basis to the extent funding remains available.

ADDRESSES: To participate in this initiative and apply for funding under this Notice, a housing agency must submit an application to the U.S. Department of Housing and Urban Development, Grants Management Center, 501 School Street, SW, Suite 800, Washington, DC 20024, Attention: Gun Buyback Initiative. Applications may simply consist of a letter of request as long as it contains the information required by this Notice.

FOR FURTHER INFORMATION CONTACT: Cedric Brown, Program Analyst, Community Safety and Conservation Division, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh Street, SW, Room 4206, Washington, DC 20410, telephone (202) 708–1197 x.4057. Hearing or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Information Relay Service at 1–800–877–8339. Also, please see HUD's website at http://www.hud.gov/pih/legis/titlev.html for additional PHDEP information.

SUPPLEMENTARY INFORMATION:

I. Authority

The Public Housing Drug Elimination Program is authorized under the Public and Assisted Housing Drug Elimination Act (42 U.S.C. 11901 *et. seq*).

II. Amount Allocated

Public Law 105–276 (the FY 1999 HUD Appropriations Act) appropriated $310,000,000 for the Public and Assisted Housing Drug Elimination Program. Of that amount, approximately $230,750,000 is being made available for PHDEP grants in FY99. Of the total $310,000,000 appropriated for the Public and Assisted Housing Drug Elimination Program, the FY 1999 HUD Appropriations Act also set aside $10,000,000 for ''grants, technical assistance, contracts and other assistance, training, and program assessment and execution''. Approximately $4,500,000 of this $10,000,000 set aside amount is being made available under this notice for the development, outreach, technical assistance, training, assessment and execution activities related to gun buyback violence reduction initiatives.

As discussed in this notice, HUD is encouraging PHAs to reprogram a portion of their FY 1999 PHDEP grant funds to implement and operate gun buyback violence reduction initiatives in cooperation with local law enforcement agencies. Under this notice, HUD will use the $4.5 million set aside amount described in the paragraph above to match up to $10.5 million of the $230,750,000 of PHDEP grant funds that are reprogrammed to implement and operate gun buyback violence reduction initiatives. PHAs may request to use PHDEP funds for gun buyback violence reduction efforts until the established due date, December 3, 1999, or until available funds are exhausted. The Department will no longer approve PHA applications for further gun buyback violence reduction initiatives under this notice after the established due date, December 3, 1999, or after available funds have been awarded.

III. Background

With almost one gun for every man, woman and child, America is drowning today in a flood of guns and we're paying a heavy price for this proliferation, particularly in urban areas where much of public housing is located. In 1996, we lost more Americans to gunfire than we lost in the entire Korean War. Currently, over 600 people die in gun-related incidents in the U.S. each week. That's over 30,000 every year. This includes over 1,000 accidental deaths and over 18,000 suicides. Another 100,000 are injured annually in non-fatal shootings.

Our children pay the highest price. The rate of accidental shooting deaths for children under fifteen in the United States is nine times higher than the other 25 industrialized countries combined. And the great increase in suicides among teenagers and young adults in the past four decades has been mostly due to an increase in gun related suicides. Easy access to weapons is the single most overwhelming factor contributing to the high rate of gun deaths and injuries in this country.

In an effort to curtail the hazards of accidental shootings, suicides, the tragedies of domestic violence, the dangers of gun violence, and the devastating effects that often accompany such acts, police agencies and local community organizations around the country have created various types of gun buyback initiatives. Gun reduction efforts operate on the premise that accidental shootings, unintentional injuries, suicides and violent crimes can be reduced in communities if there are fewer weapons available with which to commit such acts. PHAs have an important role to play in the reduction of the number of guns and incidents of gun-related violence in our communities.

HUD is sponsoring the initiative announced in this notice through its Public Housing Drug Elimination Program to promote the cooperation of PHAs and local law enforcement agencies in conducting gun buyback initiatives aimed at reducing accidental or unintentional shootings, suicides, domestic violence and other forms of gun violence. HUD is inviting PHAs who are recipients of FY 1999 PHDEP funding to reprogram a portion of their PHDEP funding to implement gun reduction initiatives in their localities. To encourage the participation of PHAs in this initiative, HUD will provide a participating PHA with additional funding to increase the amounts available for gun buybacks and maximize the number of guns taken out of circulation, and for the development, outreach, technical assistance, training, assessment and execution activities related to gun buyback violence reduction initiatives. Funding being made available for this purpose will be equal to approximately 43 percent of the amount of PHDEP funding the PHA devotes to the gun buyback violence reduction initiative.

In addition to reducing the number of accidental shootings, suicides, domestic and gun violence, gun reductions efforts have other positive aspects for housing and community residents such as:

- Raising public consciousness about community safety and soliciting neighborhood participation in crime control efforts.
- Acting as a visible deterrent to criminal activity.
- Increasing police presence in communities.
- Establishing stronger bonds between the community and the police, which might aid in more cooperative crime prevention and crime resolutions.
- Increasing trust in the police on the part of the community.
- Affording the community an active role in the fight against accidental shootings, suicides, domestic violence, violent crimes and firearm related criminal activity.
- Involving community businesses as cosponsors of these programs, which could bring about more resources and publicity in support of the gun reduction efforts.

While these factors and reports of the success of gun buyback initiatives have been sufficiently favorable to encourage HUD to undertake this effort, the total amount of HUD assistance being devoted to this effort under this notice is capped at a total of $10.5 million in Fiscal Year 1999 (FY99) PHDEP program funding, plus the additional $4.5 million. HUD will sponsor an independent assessment of this initial effort to more accurately and objectively determine the effectiveness of such initiatives before expanding this effort further. PHAs and local law enforcement agencies participating in the initiative under this notice may be contacted to participate in this assessment.

IV. Application Procedures and Requirements

A. General Overview

PHDEP funds are made available to a PHA to be used in a manner consistent with the PHA's PHDEP plan to address drug-related, violent and criminal activity in and around public housing. Therefore, to participate in this initiative, a PHA must reprogram a portion of the funds in its PHDEP plan for gun buyback violence reduction activities. Before funds are awarded under this notice, a PHA will have to submit a reprogramming request for HUD approval. HUD will review each reprogramming request as it is received and upon approval of the request will authorize additional funding at a rate of approximately $43 for every $100 dollars of FY 1999 PHDEP funding reprogrammed. This represents an additional 43 percent of funding for the PHA's gun buyback violence reduction. HUD approval will consist of HUD signing off on the reprogramming request and MOU (an executed agreement to carry out the gun buyback initiative) between the PHA and the local police, and having HUD amend the PHDEP grant award to the PHA to support the gun reduction effort.

Because of the security issues involved, the gun buyback activities must be conducted by the local law enforcement agency. The FY 1999 PHDEP funds for this gun reduction initiative fall under the categories of eligible PHDEP activities of ''programs designed to reduce use of drugs in and around public or federally assisted low-income housing projects, including drug-abuse prevention, intervention, referral, and treatment programs'', as provided in 42 U.S.C. 11903(a)(6) and, under appropriate circumstances, reimbursement of local law enforcement agencies for additional security and protective services, as provided in 42 U.S.C. 11903(a)(2). Funds for buyback activities may not be drawn until the grantee has executed an agreement or Memorandum of Understanding for the additional law enforcement services. The full amount of PHDEP funds that are reprogrammed should be used for the actual buyback costs. HUD also strongly recommends that the additional 43 percent of funding made available be used for gun buyback costs to maximize the number of guns taken out of circulation.

In addition to the use of reprogrammed FY 1999 PHDEP funds and the additional funding made available under this NOFA, PHAs may and are encouraged to use funding from other sources, such as contributions from local government or the private sector, for their gun buyback/violence reduction initiatives. PHAs may, for example, negotiate with businesses in the community that vouchers exchanged for guns under the initiative provide an additional discount or value increase when redeemed at that business. PHAs and local law enforcement agencies are also strongly encouraged to seek out and obtain community cooperation and resources to leverage the costs of the development, outreach, technical assistance, training, assessment and execution activities related to the initiative, because a community-wide effort is likely to have the greatest positive impact.

B. Eligible Applicants

PHAs that are (1) recipients of FY 1999 PHDEP funding, (2) devoting a portion of that funding to gun buyback violence reduction initiatives, and (3) implementing their gun buyback initiatives in cooperation with local law enforcement agencies, as evidenced by letters of intent and executed agreement, may apply for a portion of the additional $4,500,000 TA funding under this notice.

C. Amount of Funding Per Applicant

Consistent with this notice, HUD will permit a PHA to reprogram up to $500,000 of its FY 1999 PHDEP funding to gun buyback violence reduction initiatives. In addition to the amount reprogrammed, PHAs will receive an additional amount of funding equal to approximately 43 percent of the FY99 PHDEP dollars devoted to the gun buyback initiative.

D. Eligible Activities.

Police conducting the buyback activity should accept for buyback firearms as defined under Federal, State or local law. The Federal law definition of a firearm is found at 18 U.S.C. 921(a)(3). In deference to local conditions and judgments, HUD will consider a wide range of gun buyback violence reduction activities, in accordance with the following:

1. *Form of buyback exchange.* HUD encourages these initiatives to offer gift certificates, food vouchers, certificates for merchandise such as toys, or other

incentives of value to those who turn in guns, in addition to or in place of cash payments.

2. *Amount of value per exchange.* HUD suggests value equivalent to $50 of the HUD assistance provided to be offered for each gun exchanged. Additional value in the form of discounts or extra merchandise made available by businesses participating in the initiative may also be offered.

3. *Site of gun buyback activities.* While PHDEP activities must be planned to reduce drug-related, violent and criminal activity in or around the premises of public housing, perpetrators of gun violence are frequently non-resident predators of public housing. Gun buyback activities, therefore, do not need to be conducted on the PHA premises in order to be effective. However, it is anticipated that the gun reduction effort will have a noticeable impact on reducing the number of guns and the risk of unintentional shootings in the homes and communities of public housing residents.

4. *Disposal of guns.* Once the police collect the weapons from the buyback initiatives, the guns must be destroyed so as not to be put back into use or circulation, unless law enforcement needs call for another action, such as preservation of a gun as evidence or a determination of whether a gun was stolen or used in the commission of a crime. If a gun is determined to be stolen, it must be returned to its lawful owner. Guns may not be resold or exchanged for value, except in connection with their destruction and conversion to scrap; however, a gun determined to be a curio or relic under 27 CFR 178.11 may be donated to a State or Federal museum. Local law enforcement agencies will be required to include the following recovery, tracing and destruction procedures in their disposal of firearms obtained under this initiative:

(a) Certain firearms defined under the National Firearms Act (NFA), 26 U.S.C. 5845(a), e.g., short-barreled shotguns, generally must be registered with the Bureau of Alcohol, Tobacco, and Firearms (ATF). Local police will consult with the ATF where NFA firearms are surrendered in a buyback program;

(b) Local police will conduct a search of each surrendered firearm in the National Crime Information Center (NCIC).

(c) Where available, local police will test each surrendered firearm using an automated ballistics information system such as IBIS or DRUGFIRE.

(d) Where appropriate, certain surrendered firearms should be traced. For example, firearms possessed in violation of local law or ordinance, NFA firearms, firearms with an obliterated serial number, or firearms that are determined by local law enforcement to be associated with crime must be traced where possible.

E. Application Submission Requirements

Each application for funding under this notice must include the following:

1. A written statement briefly describing which activities in the PHA's PHDEP plan would be reprogrammed, and the resulting reprogrammed amount of FY 1999 PHDEP funding to be used for the gun buyback reduction activities;

2. A brief description of the proposed gun buyback initiative, including the gun recovery, tracing, and destruction procedures that will be followed, in accordance with the requirements and guidelines of this notice;

3. *Letters of intent.* A letter of intent signed by the chief of the local law enforcement agency to conduct the gun buyback initiative in accordance with the description submitted, and a letter of intent from the chief executive officer (generally the mayor or county executive) of the unit of local government for the jurisdiction indicating the cooperation and support of the local jurisdiction.

F. Award Process

As HUD receives applications, it will log them in by date and time. HUD will notify each PHA applicant that it is eligible to reprogram its PHDEP funds in the amount indicated in the application until a total of $10.5 million of FY 1999 PHDEP funding has been designated eligible for reprogramming. Before additional funds are awarded, the PHA will be required to submit its formal programming request describing which activities in the PHA's PHDEP plan are being reprogrammed, and the reprogrammed amount of FY 1999 PHDEP funding to be used for the gun buyback reduction activities. The PHA must also submit an executed agreement with the local law enforcement agency to conduct the gun buyback initiative in accordance with the description in the reprogramming request. Upon approval of the PHA's reprogramming request and executed agreement, HUD will award the additional 43 percent of funding through an amendment to the PHDEP grant agreement. All grants to PHAs and their sub-grants to local law enforcement agencies are subject to the applicable administrative requirements for grants of 24 CFR part 85, including the monitoring and reporting program performance requirements of § 85.40 and the financial reporting requirements of § 85.41.

V. Certifications and Findings

Environmental Impact

This notice 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 notice is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Paperwork Reduction Act Statement

The information collection requirements for the Public Housing Drug Elimination Program were submitted to the Office of Management and Budget for review under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and have been assigned OMB control number 2577–0124. 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 valid control number.

Federalism, Executive Order 12612

The General Counsel, as the Designated Official under section 6(a) of Executive Order 12612, Federalism, has determined that the policies contained in this notice will not have substantial direct effects on States or their political subdivisions, or on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Specifically, the notice seeks to encourage the undertaking of a specific eligible activity under the Public Housing Drug Elimination Program, and does not impinge upon the relationships between the Federal government and State and local governments. As a result, the notice is not subject to review under the Order.

Catalog of Domestic Assistance Number

The Catalog of Domestic Assistance number for the Public Housing Drug Elimination Program is 14.854.

Dated: October 28, 1999.

Harold Lucas,

Assistant Secretary for Public and Indian Housing.

[FR Doc. 99–28856 Filed 11–2–99; 8:45 am]

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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.

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