Dated: December 30, 1998.

Felicia Marcus,

Regional Administrator, Region IX.

[FR Doc. 99–666 Filed 1–11–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 63 and 302

[FRL–6216–8]

RIN 2060–AI08

Redefinition of the Glycol Ethers Category Under Section 112(b)(1) of the Clean Air Act and Section 101 of the Comprehensive Environmental Response, Compensation, and Liability Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking.

SUMMARY: The proposed rule, upon promulgation, will amend the Clean Air Act (CAA) list of hazardous air pollutants (HAP) in section 112(b)(1). Under section 112(b)(3)(D), EPA may delete specific substances from listed categories. This proposed rule modifies the definition of the glycol ethers category in a manner to exclude each of the compounds known as surfactant alcohol ethoxylates and their derivatives (SAED). This delisting action is being proposed by EPA in response to an analysis of potential exposure and hazards of SAED that was prepared by the Soap and Detergent Association (SDA) and submitted to EPA. Based on this information, EPA has made an initial determination that there are adequate data on the health and environmental effects of these substances to determine that emissions, ambient concentrations, bioaccumulation, or deposition of these substances may not reasonably be anticipated to cause adverse human health or environmental effects. By today's document, EPA is also proposing to make conforming changes in the definition of glycol ethers with respect to designation of hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).

DATES: Written comments must be received by EPA on or before March 15, 1999. The EPA will hold a public hearing if EPA receives a written request for such a hearing on or before February 11, 1999. If a hearing is requested in a timely manner, EPA will publish an additional document in the **Federal Register** advising interested persons of the date, time, and location of the hearing. Moreover, if a hearing is held, EPA will keep the record open for 30 days after such hearing to receive rebuttal or supplementary information.

ADDRESSES: *Comments.* Comments on both of the proposed actions discussed in this notice should be submitted (in duplicate if possible) to the EPA's Air and Radiation and Information Docket (6101), Attention Docket Number A–98–39, Room M1500, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460. *Docket.* Docket No. A–98–39, which includes a copy of the submission by the SDA, and an EPA analysis of that submission, will be available for inspection and copying between 8 a.m. and 4 p.m., Monday through Friday, at the EPA's Air and Radiation and Information Docket, Room M1500, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Dr. Roy L. Smith, Environmental Protection Agency, Office of Air Quality Planning and Standards (MD–15), Research Triangle Park, NC 27711; (919) 541–5362.

SUPPLEMENTARY INFORMATION:

I. Listing and Delisting of HAP

Section 112 of the CAA contains a mandate for EPA to evaluate and control emissions of HAP. Section 112(b)(1) includes an initial list of HAP that is composed of specific chemical compounds and groups of compounds. This list is used to identify source categories for which the EPA will subsequently promulgate emissions standards.

Section 112(b)(2) requires EPA to conduct periodic reviews of the initial list of HAP set forth in section 112(b)(1) and outlines criteria to be applied in deciding whether to add or delete particular substances. Section 112(b)(2) identifies pollutants that should be added to the list as:

> * * * pollutants which present, or may present, through inhalation or other routes of exposure, a threat of adverse human health effects (including, but not limited to, substances which are known to be, or may reasonably be anticipated to be, carcinogenic, mutagenic, teratogenic, neurotoxic, which cause reproductive dysfunction, or which are acutely or chronically toxic) or adverse environmental effects whether through ambient concentrations, bioaccumulation, deposition, or otherwise * * *

Section 112(b)(3) establishes general requirements for petitioning EPA to modify the HAP list by adding or deleting a substance. In general, the burden is on a petitioner to include sufficient information to support the requested addition or deletion under the substantive criteria set forth in section 112(b)(3)(B) and (C). The Administrator must either grant or deny a petition within 18 months of receipt. If the Administrator decides to grant a petition, the Agency publishes a written explanation of the Administrator's decision, along with a proposed rule to add or delete the substance. If the Administrator decides to deny the petition, the Agency publishes a written explanation of the basis for denial. A decision to deny a petition is final Agency action subject to review in the D.C. Circuit Court of Appeals under section 307(b).

To promulgate a final rule deleting a substance from the HAP list, section 112(b)(3)(C) provides that the Administrator must determine that:

> * * * there is adequate data on the health and environmental effects of the substance to determine that emissions, ambient concentrations, bioaccumulation, or deposition of the substance may not reasonably be anticipated to cause any adverse effects to the human health or adverse environmental effects.

The EPA will grant a petition to delete a substance and publish a proposed rule to delete that substance if it makes an initial determination that this criterion has been met. After affording an opportunity for comment and for a hearing, EPA will make a final determination whether the criterion has been met.

The Administrator may also act to add or delete a substance on her own initiative. In this instance, the EPA has been engaged in a substantive dialogue with the SDA, a national trade association representing manufacturers of cleaning products and ingredients, concerning the toxicity of and exposure to SAED, a group of compounds which is within the current definition of the glycol ethers category as listed in section 112(b)(1). At the request of EPA, the SDA compiled information on this class of compounds needed by EPA to apply the statutory criteria for delisting under section 112(b)(3). The SDA submitted the resulting report to EPA. Although the SDA has elected not to formally petition EPA to delete SAED compounds from the HAP list, EPA has made an initial determination based on the SDA report that the statutory criteria for delisting SAED are satisfied, and is, therefore, issuing this proposal.

EPA does not interpret section 112(b)(3)(C) to require absolute certainty that a pollutant will not cause adverse effects on human health or the environment before it may be deleted

from the list. The use of the terms ''adequate'' and ''reasonably'' indicate that the Agency must weigh the potential uncertainties and their likely significance. Uncertainties concerning the risk of adverse health or environmental effects may be mitigated if EPA can determine that projected exposures are sufficiently low to provide reasonable assurance that such adverse effects will not occur. Similarly, uncertainties concerning the magnitude of projected exposures may be mitigated if EPA can determine that the levels which might cause adverse health or environmental effects are sufficiently high to provide reasonable assurance that exposures will not reach harmful levels.

II. EPA Analysis of the SDA Submission

The SDA contended that the present definition of glycol ethers adopted by Congress in section 112(b)(1) was incorporated verbatim from the definition of glycol ethers utilized in section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA), 42 U.S.C. 11023. The SDA noted that EPA subsequently modified the definition of glycol ethers under EPCRA to exclude SAED compounds (59 FR 34386, July 5, 1994), and requested that EPA make a conforming change in the CAA list. EPA has responded that the substantive criteria for deleting chemicals under EPCRA section 313(d) are materially different than the criteria for deleting a hazardous pollutant under section 112(b)(3). It is EPA's view that, whatever the origins of the glycol ethers definition in section 112(b)(1), EPA cannot redefine the glycol ethers category to exclude particular compounds without making a substantive determination that such compounds meet the applicable criteria for HAP delisting. Under section 112(3)(D), EPA may delete specific substances included in certain listed categories without a Chemical Abstract Service number, including the glycol ethers category.

Although the SDA does not necessarily agree with EPA that deletion of individual compounds is the only manner in which EPA may adopt the requested redefinition of the glycol ethers category, the SDA agreed to assist EPA in this effort by collecting information concerning SAED compounds that would enable EPA to make a substantive assessment of potential risks under section 112(b)(3). On April 25, 1997, the SDA submitted to EPA a report entitled ''Exposure Assessment Undertaken to Support the Evaluation of the HAP Definition 'Glycol Ethers'.''

Surfactant alcohol ethoxylates and their derivatives comprise a group of compounds that, individually, satisfy the following definition:

$R–(OCH_2CH_2)_n–OR'$

Where:

n = 1, 2, or 3;
R = alkyl C8 or greater
R′= any group

Rather than asking the SDA to compile an exhaustive list of each specified SAED compound, EPA requested that the SDA undertake a generic analysis of the potential toxicity of, and potential exposure to, SAED compounds as a group. EPA requested that the analysis be based to the extent possible on worst-case assumptions which could be deemed to be conservative with respect to each and every individual compound in the SAED group. Such an approach to delisting would normally be impracticable due to the likelihood that use of such extreme assumptions would greatly exaggerate the magnitude of potential risks. In this instance, such an approach was considered practical only because of assertions by the SDA that SAED compounds present both very low potential toxicity and very limited exposure potential.

The report submitted by the SDA presented estimates of both the potential exposure to, and potential toxicity of, SAED compounds. The principal emissions estimate in the report was based on a hypothetical facility using 600 million pounds per year of SAED, a figure coinciding with the total annual domestic production of Shell Chemical Company, the largest SAED manufacturer. The report then conservatively estimated emissions for this hypothetical facility associated with the storage and transmission, processing, and fugitive releases of the SAED compounds.

Emissions of SAED from raw materials during storage and handling were estimated by assuming emissions of a total volume of air, fully saturated with SAED, equal to the total volume of liquid SAED. This estimate was based, in turn, on the vapor pressure of the lowest molecular weight compound in the SAED category, although typical SAED compounds have greater molecular weight and substantially lower volatility. Additional SAED emissions from manufacture of SAED compounds and formulation of other products containing SAED were estimated by making assumptions concerning the effect on emissions of increased temperatures and ventilation rates and reduced SAED concentrations in the finished products. Finally, an estimate of fugitive emissions was calculated from the estimated point source emissions by applying a proportionality factor derived from reported emissions for all glycol ethers in the EPA Toxics Release Inventory database, although it is likely that the proportion of total emissions attributable to fugitive releases would be much less for SAED compounds than for the lower molecular weight glycol ethers. This analysis produced an aggregate emissions rate for the hypothetical facility of 105 pounds of SAED per year.

Exposures at the fence line for the hypothetical facility were then estimated using the SCREEN3 dispersion model and the calculated aggregate emissions rate, based on a variety of assumptions concerning terrain, stack height and configuration, and distance to the fence line. The predicted annual average SAED concentration associated with an emissions rate of 105 pounds/year was 0.03 micrograms of SAED per cubic meter of air for a ''representative'' facility and 97.3 micrograms per cubic meter for a ''hypothetical worst-case'' facility.

The SDA submission also summarized the available toxicity data on SAED compounds. There have been few acute and no subchronic inhalation studies utilizing SAED compounds. Available animal study data do not indicate any adverse effects at air concentrations up to those produced by full saturation with SAED vapors. Acute toxicity has been demonstrated only when animals inhaled undiluted SAED in the form of a respirable aerosol. In one 10-day repeated inhalation study, test animals exhibited local respiratory irritation. Long-term animal studies of SAED administered by the oral or dermal routes have not reported any significant effects such as skin sensitization, reproductive or developmental toxicity, genetic mutations, or cancer. Evidence on the toxic potential of glycol ethers as a group strongly suggests that toxic potency decreases as molecular weight increases. Therefore, SAED (which have high molecular weight) are likely to be substantially less toxic than lighter glycol ether compounds for which more complete toxicity data are available.

There is no verified or proposed reference concentration (RfC) for any SAED compound. The SDA developed a proposed ''key exposure index'' for chronic exposure to SAED compounds based on the subchronic RfC for 2-methoxy-1-propanol (MP), a structurally similar compound which also has no demonstrated systemic toxicity by

inhalation. Two-methoxy-1-propanol has a lower molecular weight (90 grams per mole) than the lightest SAED compound (ethylene glycol octyl ether, 174 grams per mole). Therefore, MP is expected to be more toxic than any SAED compound, and its use as a surrogate should be conservative.

The SDA's analysis began with the subchronic RfC for MP, then reduced it by a factor of 10 to account for the differences between subchronic effects and chronic effects, and by an additional factor of between 1 and 10 to account for the use of data for a structurally related compound. This resulted in a proposed concentration range of 0.2 to 2.0 milligrams per cubic meter (mg/m^3) at which no adverse effects would be expected in human populations, including sensitive individuals. The SDA's proposed concentration range is approximately 1,000 to 10,000 times lower than the acutely toxic level for inhalation in rats. It is also approximately 1,000 to 10,000 times greater than the exposure estimated by the SDA for a ''representative'' facility and 2 to 20 times greater than the estimated exposure for a ''hypothetical worst-case'' facility.

The proposed chronic no-effect concentration range for SAED of 0.2 to 2.0 mg/m^3 is also consistent with chronic RfCs available from EPA's Integrated Risk Information System (IRIS) for lower-molecular weight, non-SAED glycol ethers (i.e., 0.2 mg/m^3 for 2-ethoxyethanol and 0.09 mg/m^3 for 2-methoxyethanol acetate). A third IRIS assessment will shortly be proposed for 2-butoxyethanol, in which EPA expects to include an RfC in the range of 10 to 70 mg/m^3. The SDA's analysis has, therefore, treated SAED as if they were as toxic as much lighter glycol ether compounds, which EPA considers to be unlikely.

Although the SDA document does not include a discussion of levels of SAED that would be protective of non-human species, the toxicity data used to support the health impact assessment were obtained from animal studies. The derivation of human no-effect levels from these animal data, appropriately adjusted for uncertainty, should be protective of non-human animal species as well. Overall, there is no evidence to suggest that any species or any ecosystem would be harmed by any exposure below the SAED no-effect level proposed for humans.

Based on the SDA submission as a whole, EPA believes that the available data on potential exposure to, and toxicity of, SAED compounds are considerably more limited than would normally be necessary to support the findings required by section 112(b)(3) before EPA may delete a substance from the HAP list. However, there is a sufficiently large discrepancy between the maximum predicted exposure level for these compounds based on plausible worst-case assumptions and the lowest concentration likely to present any potential risk of adverse effects to compensate for the paucity of the data. The conservative techniques used by the SDA in its submission, which tend to overestimate both exposure to and toxicity of SAED, are appropriate in the context of the limited data which are available on SAED compounds.

Unlike the SDA, EPA does not believe that the process by which Congress adopted the current definition of glycol ethers in section 112(b)(1) can be construed as relieving EPA of the obligation to apply the statutory criteria before deleting any substance included in the present definition. Nevertheless, it is important to observe that there is no evidence suggesting that the current broader definition of glycol ethers was adopted because of any actual concerns regarding the potential hazards of SAED compounds. EPA believes that the absence of any discernable affirmative rationale for the initial inclusion of SAED compounds in the statutory HAP list, while not dispositive in itself, lends additional support to the Agency's conclusion that the available evidence supports deletion of these compounds.

Based on the available information, EPA has made an initial determination, with respect to each and every individual substance which satisfies the definition of SAED compounds set forth above, that there is adequate data on the health and environmental effects of those substances to determine that emissions, ambient concentrations, bioaccumulation or deposition of the substances may not reasonably be anticipated to cause adverse human health or environmental effects. As such, EPA is proposing to effectuate this determination by redefining the entire glycol ethers category in a manner which excludes each of the deleted substances.

III. Proposed Revision of CERCLA Designation

When a HAP is listed under section 112 of the CAA, it is also defined as a hazardous substance under section 101(14) of CERCLA, 42 U.S.C. 9601(14). In an April 4, 1985 final rule, under its authority in section 102(a) of CERCLA, EPA designated and listed, in the table at 40 CFR 302.4, all the elements and compounds and hazardous wastes incorporated as hazardous substances by reference to other environmental statutes under section 101(14)(see 50 FR 13456). In a June 12, 1995 final rule, EPA revised Table 302.4 to add, among other HAP newly listed by the 1990 CAA Amendments, the broad generic category of glycol ethers (see 60 FR 30926). The EPA designated the broad generic category of glycol ethers as hazardous under CERCLA based solely on its inclusion in the CAA HAP list. The Agency has no independent basis upon which to retain the current definition of the glycol ethers category in order to include the SAED compounds as CERCLA hazardous substances. Therefore, should the definition of glycol ethers in the HAP list in the CAA be amended as proposed in today's rulemaking, the Agency is also proposing to make a corresponding change to the list of CERCLA hazardous substances at 40 CFR Part 302, Table 302.4.

IV. Administrative Requirements

A. Executive Order 12866

Today's proposed actions do not meet the definition of ''significant regulatory action'' as set forth in Executive Order (E.O.) 12866 and are, therefore, not subject to review by the Office of Management and Budget (OMB). The E.O. 12886 defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O.

Although EPA is not aware of any adverse effects associated with the present inclusion of SAED compounds on the CAA HAP and the CERCLA hazardous substance lists, the effect of the proposed rules will be to reduce potential regulatory obligations. There are no identifiable adverse effects associated with either of the proposed rules. Neither of the proposed rules meets any of the criteria enumerated above, and EPA, therefore, has determined that neither of these actions

constitutes a ''significant regulatory action'' under the terms of E.O. 12866.

B. Paperwork Reduction Act

As required by the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, OMB must clear any reporting and recordkeeping requirements that qualify as an ''information collection request'' under PRA. Neither of the proposed rules in this notice contain any new information collection requirements.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 requires that a Regulatory Flexibility Analysis be performed for proposed rules that potentially have ''significant impact on a substantial number of small entities.'' Small entities are small businesses, organizations, and governmental jurisdictions.

Present Regulatory Flexibility Act guidelines indicate that an economic impact should be considered significant if it meets one of the following criteria: (1) Compliance increases annual production costs by more than 5 percent, assuming costs are passed on to consumers; (2) compliance costs as a percentage of sales for small entities are at least 10 percent more than compliance costs as a percentage of sales for large entities; (3) capital costs of compliance represent a ''significant'' portion of capital available to small entities, considering internal cash flow plus external financial capabilities; or (4) regulatory requirements are likely to result in closure of small entities.

Pursuant to the provisions of 5 U.S.C. 605(b), I hereby certify that neither of the proposed rules, if promulgated, will have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local and tribal governments and the private sector. Neither of the proposed rules in this document contain any Federal mandate (under the regulatory provisions of title II of UMRA) for State, local or tribal governments or the private sector.

E. Executive Order 13045

The E.O. 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks,'' (62 FR 19885, April 23, 1997) requires EPA rulemaking that involves decisions on environmental health risks or safety risks to consider whether such risks may disproportionately affect children. Toxicological data used to support this proposed rule were obtained from animal studies. Estimated human no-effect levels were derived by applying an intraspecies uncertainty factor designed to protect children and other sensitive members of human populations. EPA anticipates that, in the absence of studies of exposed children, that this uncertainty factor will adequately protect the entire human population, including children.

F. Executive Order 12875

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.

G. 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, or EPA consults with those 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 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 because it will result in no increase either in air pollution or reporting requirements. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

H. National Technology Transfer and Advancement Act of 1995

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Pub. L. 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 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.

This proposed rulemaking does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

List of Subjects

40 CFR Part 63

Air pollution control, Chemicals, Glycol ethers.

40 CFR Part 302

Hazardous substances, Chemicals, Glycol ethers.

Dated: December 30, 1998.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble, it is proposed that title 40, chapter I, parts 63 and 302 of the Code of Federal Regulations be amended as follows:

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

1. The authority citation for part 63 continues to read as follows:

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

2. Part 63, subpart C is amended by adding § 63.61 to read as follows:

§ 63.61 Redefinition of glycol ethers listed as hazardous air pollutants.

The definition of the glycol ethers category of hazardous air pollutants, as established by 42 U.S.C. 7412(b)(1) includes mono- and di-ethers of ethylene glycol, diethylene glycol, and triethylene glycol R-$(OCH_2CH_2)_n$-OR′

Where:

n= 1, 2, or 3

R= alkyl C_7 or less, or phenyl or alkyl substituted phenyl

R′= H, or alkyl C_7 or less, or carboxylic acid ester, sulfate, phosphate, nitrate, or sulfonate.

PART 302—DESIGNATION, REPORTABLE QUANTITIES, AND NOTIFICATION

1. The authority citation for part 302 continues to read as follows:

Authority: 42 U.S.C. 9602, 9603, and 9604; 33 U.S.C. 1321 and 1361.

§ 302.4 [Amended]

2. In § 302.4, footnote d to Table 302.4 is revised to read as follows:

* * * * *

[d] Includes mono- and di-ethers of ethylene glycol, diethylene glycol, and triethylene glycol R-$(OCH_2CH_2)_n$-OR′

where:

n= 1, 2, or 3

R= alkyl C_7 or less, or phenyl or alkyl substituted phenyl

R′= H, or alkyl C_7 or less, or carboxylic acid ester, sulfate, phosphate, nitrate, or sulfonate.

[FR Doc. 99–323 Filed 1–11–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Office of the Inspector General

42 CFR Parts 409, 410, 411, 412, 413, 419, 489, 498, and 1003

[HCFA–1005–2N]

RIN 0938–AI56

Medicare Program; Prospective Payment System for Hospital Outpatient Services; Extension of Comment Period

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

ACTION: Notice of extension of comment period for proposed rule.

SUMMARY: This document extends the comment period for the second time on a proposed rule published in the **Federal Register** on September 8, 1998, (63 FR 47552). In that rule, as required by sections 4521, 4522, and 4523 of the Balanced Budget Act of 1997, we proposed to eliminate the formula-driven overpayment for certain outpatient hospital services, extend reductions in payment for costs of hospital outpatient services, and establish in regulations a prospective payment system for hospital outpatient services (and for Medicare Part B services furnished to inpatients who have no Part A coverage.) The comment period is extended for 60 days.

DATES: The comment period is extended to 5 p.m. on March 9, 1999.

ADDRESSES: Mail written comments (one original and three copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–1005–P, P.O. Box 26688, Baltimore, MD 21207–0488.

If you prefer, you may deliver your written comments (one original and three copies) to one of the following addresses: Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–09–26, Central Building, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–1005–P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443–G of the Department's offices at 200 Independence Avenue, SW, Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

For comments that relate to information collection requirements, mail a copy of comments to: 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.

FOR FURTHER INFORMATION CONTACT: Janet Wellham, (410) 786–4510.

SUPPLEMENTARY INFORMATION: On September 8, 1998, we issued a proposed rule in the **Federal Register** (63 FR 47552) that would do the following:

- Eliminate the formula-driven overpayment for certain outpatient hospital services;
- Extend reductions in payment for costs of hospital outpatient services;
- Establish in regulations a prospective payment system for hospital outpatient services, for partial hospitalization services furnished by community mental health centers, and for certain Medicare Part B services furnished to inpatients who have no Part A coverage;
- Propose new requirements for provider departments and provider-based entities;
- Implement section 9343(c) of the Omnibus Budget Reconciliation Act of 1986, which prohibits Medicare payment for nonphysician services furnished to a hospital outpatient by a provider or supplier other than a hospital unless the services are furnished under an arrangement with the hospital;
- Authorize the Department of Health and Human Services' Office of Inspector General to impose a civil money penalty against any individual or entity who knowingly presents a bill for non-physician or other bundled services not provided directly or under such an arrangement.

The comment period for the proposed rule closed on November 9, 1998. Because of the scope of the proposed rule, hospitals and numerous professional associations requested more time to analyze the potential consequences of the rule. Therefore, we published a notice on November 13, 1998 (63 FR 63429), which extended the comment period until January 8, 1999. Because of further requests from hospitals and professional associations, we are again extending the public comment period for an additional 60 days, until March 9, 1999.