

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: February 15, 2011.

Carolyn M. Clancy,
Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21 to b-26, (Patient Safety Act), and its implementing regulation at 42 CFR part 3, provides for the formation of Patient Safety Organizations (PSOs), which collect, aggregate, and analyze confidential information regarding the quality and safety of healthcare delivery. On December 30, 2010, HHS issued "Guidance Regarding Patient Safety Organizations' Reporting Obligations and the Patient Safety and Quality Improvement Act of 2005" (Guidance) which can be accessed electronically at:

<http://www.PSO.AHRQ.gov/regulations/guidance.pdf>.

This notice announces the intention of AHRQ to request that the Office of Management and Budget (OMB) amend the approved clearance, OMB No. 0935-0143, that allows information collection related to implementation of the Patient Safety Act. This amendment includes a new attestation form related to the Guidance. In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ invites the public to comment on this proposed information collection. The purpose of this notice is to allow 30 days for public comment on the new attestation form related to the Guidance.

DATES: Comments on this notice must be received by March 30, 2011.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, AHRQ, Reports Clearance Officer, by fax at (301) 427-1000 (attention: AHRQ Reports Clearance Officer) or by e-mail at doris.lefkowitz@AHRQ.hhs.gov. Copies of this proposed form and specific details on the estimated burden can be obtained from AHRQ's Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ, Reports Clearance Officer, (301) 427-1477.

SUPPLEMENTARY INFORMATION:

Proposed Form

This notice proposes the addition of a new attestation form, "Supplemental Attestations Regarding FDA Reporting Obligations Of PSOs," to the existing approved clearance, "Patient Safety Organization Certification for Initial Listing and Related Forms and a Patient Safety Confidentiality Complaint Form" (OMB No. 0935-0143).

In order to implement the Patient Safety Act, HHS issued the Patient Safety and Quality Improvement Final Rule (Patient Safety Rule), published in the **Federal Register** on November 21, 2008: 73 FR 70731-70814. Pursuant to the Patient Safety Rule, entities seeking to become and remain listed by the Secretary as PSOs submit certifications to the Secretary. These entities must certify that they meet or will meet specified statutory criteria and requirements for PSOs, as further explained in the Patient Safety Rule.

On December 30, 2010, HHS issued Guidance to address questions that have arisen regarding the obligations of PSOs where they or the organization of which they are a part are legally obligated under the Federal Food, Drug, and Cosmetic Act and its implementing regulations to report certain information to the FDA and to provide FDA with

access to its records, including access during an inspection of its facilities. This proposed form will collect information from PSOs as described in the Guidance.

Methods of Collection

Existing PSOs will be required to complete this proposed form immediately; an entity seeking listing as a PSO will be required to complete this proposed form at the time it submits its certifications for initial listing. Every entity completing this proposed form will be required to attest whether it is subject to the Guidance. Entities that are subject to the Guidance will be required to make one to three additional attestations. To complete this form, a respondent will need to review each attestation, check the appropriate "yes" or "no" box that follows each applicable attestation, and complete and sign the form.

The burden estimate for completing this form is 15 minutes per respondent; fewer than 100 entities are expected to submit responses.

Estimated Annual Costs to the Federal Government

Under the Patient Safety Act and Patient Safety Rule, AHRQ collects and reviews certifications from entities that seek listing or continued listing as PSOs. Entities applying to be PSOs and existing PSOs may also be required to provide additional information to AHRQ. The cost to AHRQ of processing the information collected with the above-described form is minimal: An estimated equivalent of approximately 0.01 FTE or \$1,500 and no new overhead costs.

Request for Comments

In accordance with the Paperwork Reduction Act, comments on the above described attestation form are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research, quality improvement and information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and

included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: February 15, 2011.

Carolyn M. Clancy,

Director, AHRQ.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[ATSDR-269]

Proposed Substances To Be Evaluated for Set 25 Toxicological Profiles

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Request for comments on the proposed substances to be evaluated for Set 25 toxicological profiles.

SUMMARY: ATSDR is initiating the development of its 25th set of toxicological profiles (CERCLA Set 25). This notice announces the list of proposed substances that will be evaluated for CERCLA Set 25 toxicological profile development. ATSDR's Division of Toxicology and Environmental Medicine is soliciting public nominations from the list of proposed substances to be evaluated for toxicological profile development. ATSDR also will consider the nomination of any additional, non-CERCLA substances that may have public health implications, on the basis of ATSDR's authority to prepare toxicological profiles for substances not found at sites on the National Priorities List. The agency will do so in order to " * * * establish and maintain inventory of literature, research, and studies on the health effects of toxic substances" under CERCLA Section 104(i)(1)(B), to respond to requests for consultation under section 104(i)(4), and to support the site-specific response actions conducted by ATSDR, as otherwise necessary.

DATES: Nominations must be submitted within 30 days of the publication of this notice.

ADDRESSES: Nominations may be submitted electronically. Refer to the section *Submission of Nominations* (below) for the specific address.

SUPPLEMENTARY INFORMATION: The Superfund Amendments and

Reauthorization Act of 1986 (SARA) [42 U.S.C. 9601 *et seq.*] amended the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA or Superfund) [42 U.S.C. 9601 *et seq.*] by establishing certain requirements for ATSDR and the U.S. Environmental Protection Agency (EPA) with regard to hazardous substances most commonly found at facilities on the CERCLA National Priorities List (NPL). Among these statutory requirements is a mandate for the Administrator of ATSDR to prepare toxicological profiles for each substance included on the Priority List of Hazardous Substances. This list identifies 275 hazardous substances that ATSDR and EPA have determined pose the most significant current potential threat to human health. The availability of the revised list of the 275 priority substances was announced in the **Federal Register** on March 6, 2008 (73 FR 12178). For prior versions of the list of substances, see **Federal Register** notices dated April 17, 1987 (52 FR 12866); October 20, 1988 (53 FR 41280); October 26, 1989 (54 FR 43619); October 17, 1990 (55 FR 42067); October 17, 1991 (56 FR 52166); October 28, 1992 (57 FR 48801); February 28, 1994 (59 FR 9486); April 29, 1996 (61 FR 18744); November 17, 1997 (62 FR 61332); October 21, 1999 (64 FR 56792); October 25, 2001 (66 FR 54014); November 7, 2003 (68 FR 63098); and November 29, 2005 (70 FR 71506).

Proposed Substances To Be Evaluated for Set 25 Toxicological Profiles

Each year, ATSDR develops a list of substances to be considered for toxicological profile development; this list is compiled from ATSDR's Priority List of Hazardous Substances and from previously nominated substances of public health concern. The following 74 proposed substances will be considered for Set 25 Toxicological Profile development:

Candidate Substances for Profile Development

1. s,s,s-Tributyl phosphorotrithioate (CAS No. 000078-48-8).
2. 2,4-Dimethylphenol (CAS No. 000105-67-9).
3. Bromine (CAS No. 007726-95-6).
4. Bromodichloroethane (CAS No. 0000683-53-4).
5. Butyl benzyl phthalate (CAS No. 000085-68-7).
6. Dibenzofuran (CAS No. 000132-64-9).
7. Dicofol (CAS No. 000115-32-2).
8. Methane (CAS No. 74-82-8).
9. Neptunium-237 (CAS No. 013994-20-2).

10. Palladium (CAS No. 007440-05-3).
11. Parathion (CAS No. 000056-38-2).
12. Pentachlorobenzene (CAS No. 000608-93-5).
13. Polonium-210 (CAS No. 013981-52-7).
14. Treflan (Trifluralin) (CAS No. 001582-09-8).
15. Trichlorofluoroethane (CAS No. 027154-33-2).
16. Fluorides (CAS Nos. 007782-41-4, 007664-39-3, 016984-48-8).
17. Selenium (CAS No. 007782-49-2).
18. Aldrin/Dieldrin (CAS Nos. 000309-00-2, 000060-57-1).
19. Beryllium (CAS No. 007440-41-7).
20. Creosote/Coal Tar (CAS Nos. 008021-39-4, 008007-45-2, 008001-58-9, 065996-93-2).
21. DDT, DDE, DDD (CAS Nos. 000050-29-3, 000072-55-9, 000072-54-8, 000789-02-6, 000053-19, 003424-82-6).
22. Di(2-ethylhexyl)phthalate (CAS No. 000117-81-7).
23. Hexachlorobenzene (CAS No. 000118-74-1).
24. Methoxychlor (CAS No. 000072-43-5).
25. 1,2-Dichloroethane (CAS No. 000107-06-2).
26. Asbestos (CAS Nos. 001332-21-4, 012001-29-5, 012172-73-5).
27. Benzidine (CAS No. 000092-87-5).
28. Di-n-butyl phthalate (CAS No. 000084-74-2).
29. Pentachlorophenol (CAS No. 000087-86-5).
30. Endosulfan (CAS Nos. 000115-29-7, 001031-07-8, 000959-98-8, 033213-65-9).
31. Ethion (CAS No. 000563-12-2).
32. Methylene chloride (CAS No. 000075-09-2).
33. Polychlorinated biphenyls (CAS Nos. 001336-36-3, 011097-69-1, 011096-82-5, 012672-29-6, 053469-21-9, 012767-79-2, 011104-28-2, 012674-11-2, 011141-16-5, 071328-89-7, 026914-33-0).
34. Toluene (CAS No. 000108-88-3).
35. Chlorophenols (CAS Nos. 000088-06-2, 025167-83-3, 000120-83-2, 000095-95-4, 000095-57-8, 004901-51-3, 000935-95-5, 000058-90-2, 000106-48-9, 025167-80-0).
36. Hexachlorocyclopentadiene (CAS No. 000077-47-4).
37. Mercury (CAS Nos. 007439-97-6, 022967-92-6, 007487-94-7).
38. 3,3'-Dichlorobenzidine (CAS No. 000091-94-1).
39. Chlorinated Dibenzodioxin (CDDs) (CAS Nos. 001746-01-6, 034465-46-8, 037871-00-4, 041903-57-5, 036088-22-9, 035822-46-9, 003268-87-9,