

finding and its reasons in the notice issued.

We find it unnecessary to undertake notice and comment rulemaking because the statute and regulation specify the methods of computation of annual updates, and we have no discretion in this matter. Further, this notice does not change substantive policy, but merely applies the update methods specified in statute and regulation. Therefore, for good cause, we waive notice and comment procedures.

Under the Congressional Review Act, major rules generally cannot take effect until 60 days after the rule is published in the **Federal Register**. However, section 808(2) of the Congressional Review Act states that agencies may waive this 60-day requirement for "good cause" and establish an earlier effective date. As explained above, we believe that there is "good cause" for waiver of the APA requirement for notice and comment rulemaking because it would be unnecessary for us to fulfill that requirement. For the same reason, we believe that the "good cause" exception applies to the 60-day effective date requirement for major rules in the Congressional Review Act.

#### V. Regulatory Impact Statement

We have examined the impacts of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). As stated above, the AIF (equal to the percentage increase in the CPI-U of June 30, 2005 as compared to June 30, 2004) for 2006 is 2.5 percent. We estimate that the application of the AIF will result in this notice being considered a major rule because it will result in an additional total program expenditure of approximately \$112 million in CY 2006.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses,

nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million to \$29 million in any 1 year. For purposes of the RFA, all ambulance providers or suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity.

The Department of Health and Human Services (HHS) considers that a substantial number of entities are affected if the rule impacts more than 5 percent of the total number of small entities as it does in this notice. This notice will impact every ambulance provider and supplier in the same way because all ambulance payment rates for all ambulance services furnished by all types of ambulance providers and suppliers are increased by the same ambulance inflation factor. While all ambulance payment rates are increased by the 2.5 percent AIF, the impact of this increase does not meet the threshold established by HHS to be considered a significant impact.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We have no data to indicate that a substantial number of small rural hospitals will be impacted by this notice.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This notice does not result in expenditures in any 1 year by State, local, or tribal governments of \$110 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a notice that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This notice will not have a substantial effect on State or local governments.

We estimate that the total program expenditure for CY 2006 for ambulance services covered by the Medicare program is approximately \$4.5 billion. Application of an AIF of 2.5 percent will result in an additional total

program expenditure of approximately \$112 million over CY 2005.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

**Authority:** Section 1834(l) of the Social Security Act (42 U.S.C. 1395m(l)).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 9, 2005.

**Mark B. McClellan,**

*Administrator, Centers for Medicare & Medicaid Services.*

Approved: October 7, 2005.

**Michael O. Leavitt,**

*Secretary.*

[FR Doc. 05-23163 Filed 11-23-05; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005N-0443]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Focus Groups as Used by the Food and Drug Administration

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on focus groups as used by FDA to gauge public opinion. Policymakers can use focus group results to test and refine their ideas so they can conduct further research, as well as, adopt new policies and to allocate or redirect significant resources to support these policies.

**DATES:** Submit written or electronic comments on the collection of information by January 24, 2006.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets

Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

JonnaLynn P. Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an

existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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.

**Focus Groups as Used by the Food and Drug Administration—(OMB Control Number 0910-0497)**

FDA will collect and use information gathered through the focus group vehicle. This information will be used to develop programmatic proposals, and as such, compliments other important research findings to develop these proposals. Focus groups do provide an important role in gathering information because they allow for a more in-depth understanding of consumers' attitudes, beliefs, motivations, and feelings than do quantitative studies.

Also, information from these focus groups will be used to develop policy and redirect resources, when necessary, to our constituents. If this information is not collected, a vital link in information gathering by FDA to develop policy and programmatic proposals will be missed causing further delays in policy and program development.

FDA estimates the burden for completing the forms for this collection of information as follows:

The total annual estimated burden imposed by this collection of information is 4,252 hours annually.

TABLE 1.<sup>1</sup>

Center	Subject	No. of Focus Groups per Study	No. of Focus Groups Sessions Conducted Annually	No. of Participants per Group	Hours of Duration for Each Group (Includes Screening)	Total Hours
Center for Biologics Evaluation and Research	May Use Focus Groups When Appropriate	1	5	9	1.58	71
Center for Drug Evaluation and Research	Varies (e.g., Direct-to-Consumer Rx Drug Promotion, Physician Labeling of Rx Drugs, Medication Guides, Over-the-Counter Drug Labeling, Risk Communication)	10	200	9	1.58	2,844
Center for Devices and Radiological Health	Varies (e.g., FDA Seal of Approval, Patient Labeling, Tampons, On-line Sales of Medical Products, Latex Gloves)	4	16	9	2.08	300
Center for Food Safety and Applied Nutrition	Varies (e.g., Food Safety, Nutrition, Dietary Supplements, Consumer Education)	8	40	9	1.58	569
Center for Veterinary Medicine	Varies (e.g., Animal Nutrition, Supplements, Labeling of Animal Rx)	5	25	9	2.08	468
Total		28	286		1.78	4,252

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

Annually, FDA projects about 28 focus group studies using 186 focus groups lasting an average of 1.78 hours each. FDA has allowed burden for unplanned focus groups to be completed so as not to restrict the agency's ability to gather information on public sentiment for its proposals in its regulatory as well as other programs.

Dated: November 14, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05-23248 Filed 11-23-05; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Transportation Security Administration

#### Extension Agency Information Collection Activity Under OMB Review: Department of Homeland Security—Vulnerability Identification Self-Assessment Tool—Transportation (DHS-VISAT-T)

**AGENCY:** Transportation Security Administration (TSA), DHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces that TSA has forwarded the Information Collection Request (ICR) abstracted below to the Office of Management and Budget (OMB) for review and approval of an extension of the currently approved collection under the Paperwork Reduction Act. The ICR describes the nature of the information collection and its expected burden. TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on September 23, 2005, 70 FR 55915.

**DATES:** Send your comments by December 27, 2005. A comment to OMB is most effective if OMB receives it within 30 days of publication.

**ADDRESSES:** Comments may be faxed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: DHS-TSA Desk Officer, at (202) 395-5806.

**FOR FURTHER INFORMATION CONTACT:** Katrina Wawer, Information Collection Specialist, Office of Transportation Security Policy, TSA-9, Transportation Security Administration, 601 South 12th Street, Arlington, VA 22202-4220.

#### SUPPLEMENTARY INFORMATION:

#### Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 (et seq.)), an agency may not conduct or

sponsor, and a person is not required to respond to a collection of information, unless it displays a valid OMB control number. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement 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;

(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 using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

#### Information Collection Requirement

*Title:* Department of Homeland Security—Vulnerability Identification Self-Assessment Tool—Transportation (DHS-VISAT-T).

*Type of Request:* Extension of a currently approved collection.

*OMB Control Number:* 1652-0037.

*Forms(s):* Not applicable.

*Affected Public:* Various modal transportation sector owners and operators.

*Abstract:* This voluntary collection, by way of a web-based vulnerability assessment tool, allows TSA to gather security-related data and provides a cost-free service to the transportation sector. TSA designed this tool to be flexible to support the unique characteristics of each transportation mode, while still providing a common framework from which analysis and trends can be identified. Users may use the results of the assessment to develop a security plan or to identify areas of potential vulnerability. Information regarding how to access the tool is available on TSA's Web site: <http://www.tsa.gov>. Select "Industry Partners," then "Risk Management," then finally select the "DHS-VISAT" link.

*Number of Respondents:* 300,245.

*Estimated Annual Burden Hours:* An estimated 2,401,960 hours annually.

Issued in Arlington, Virginia, on November 18, 2005.

**Lisa S. Dean,**

*Privacy Officer.*

[FR Doc. 05-23243 Filed 11-23-05; 8:45 am]

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## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4971-N-60]

### Notice of Submission of Proposed Information Collection to OMB; Local Appeals to Single-Family Mortgage Limits

**AGENCY:** Office of the Chief Information Officer, HUD.

**ACTION:** Notice.

**SUMMARY:** The proposed information collection requirement described below has been 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.

Housing industry groups may appeal for increases in FHA's maximum mortgage limits for specific counties or metropolitan statistical areas (MSA's).

**DATES:** *Comments Due Date:* December 27, 2005.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval Number (2502-0302) and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Wayne Eddins, Reports Management Officer, AYO, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail [Wayne\\_Eddins@HUD.gov](mailto:Wayne_Eddins@HUD.gov); or Lillian Deitzer at [Lillian\\_L\\_Deitzer@HUD.gov](mailto:Lillian_L_Deitzer@HUD.gov) or telephone (202) 708-2374. This is not a toll-free number.

Copies of available documents submitted to OMB may be obtained from Mr. Eddins or Ms Deitzer.

**SUPPLEMENTARY INFORMATION:** This notice informs the public that the Department of Housing and Urban Development has submitted to OMB a request for approval of the information collection described below. This notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (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 agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to