

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-8003, CMS-10268, and CMS-855(A,B,I,R)]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Home and Community Based Waiver Requests and Supporting Regulations in 42 CFR 440.180 and 441.300-310; *Use:* Under a Secretarial waiver, States may offer a wide array of home and community-based services to individuals who would otherwise require institutionalization. States requesting a waiver must provide certain assurances, documentation and cost and utilization estimates which are reviewed, approved and maintained for the purpose of identifying/verifying States' compliance with such statutory and regulatory requirements. *Form Number:* CMS-8003 (OMB# 0938-0449); *Frequency:* Occasionally; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 50; *Total Annual Responses:* 136; *Total Annual Hours:* 8,010.

2. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Consolidated Renal Operations in a Web Enabled Network (CROWNWeb) Third-party Submission Authorization Form; *Use:*

The Consolidated Renal Operations in a Web Enabled Network (CROWNWeb) Third-Party Submission Authorization form is to be completed by "Facility Administrators" (administrators of CMS-certified dialysis facilities) if they intend to authorize a third party (a business with which the facility is associated, or an independent vendor) to submit data to CMS to comply with the recently revised Conditions for Coverage of dialysis facilities. The CROWNWeb system is the system used as the collection point of data necessary for entitlement of ESRD patients to Medicare benefits and for Federal Government monitoring and assessing of the quality and types of care provided to renal patients. The information collected through the CWTPSA form will allow CMS and its contractors to receive data from authorized parties acting on behalf of CMS-certified dialysis facilities. CMS anticipates that roughly 3000 signed forms will be received by February 2009, and that the total number of forms may reach 5100 by February 2012. *Form Number:* CMS-10268 (OMB# 0938-New); *Frequency:* Monthly; *Affected Public:* Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 5,100; *Total Annual Responses:* 5,100; *Total Annual Hours:* 425.

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Enrollment Application; *Form Number:* CMS-855 (A, B, I, R)(OMB#: 0938-0685); *Use:* The primary function of the Medicare enrollment application is to gather information from a provider or supplier that tells us who it is, whether it meets certain qualifications to be a health care provider or supplier, where it practices or renders its services, the identity of the owners of the enrolling entity, and information necessary to establish correct claims payments. We are revising this currently approved information collection. The goal of the revisions to this information collection request (ICR) is to adjust the burden associated with this ICR to account for the removal of the CMS-855(S) application. *Frequency:* Recordkeeping and Reporting—On occasion; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 400,000; *Total Annual Responses:* 400,000; *Total Annual Hours:* 785,702.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or e-

mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by September 2, 2008:

1. *Electronically.* You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: June 26, 2008.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease Among Men and Women in Agriculture (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on April 30, 2008 (Vol. 73, No. 84, p. 23473), and allowed 60 days for public comment. No public comments or questions were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an

information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease Among Men and Women in Agriculture (NCI) (OMB#: 0925-0406). **Type of Information Collection Request:** Renewal. **Need and Use of Information Collection:** The purpose of this information collection is to continue and complete updating the occupational and environmental exposure information as well as medical history information for respondents

enrolled in the Agriculture Health Study. This represents a request to continue and complete phase III (2005-2008) of the study. Due to reduced annual budgets for research, a delay in data collection has resulted and there has not been enough time to complete the data collection on the number of respondents that had been originally requested in the 2005 OMB submission. The primary objectives of the study are to determine the health effects resulting from occupational and environmental exposures in the agricultural environment. The data will be collected by using a computer assisted telephone interview (CATI) system. A small

percentage of the respondents will also be asked to participate in a buccal cell collection which is a sample of loose cells from the respondent's mouth. The findings will provide valuable information concerning the potential link between agricultural exposures and cancer and other chronic diseases among agricultural Health Study cohort members, and this information may be generalized to the entire agricultural community. **Frequency of Response:** Once. **Affected Public:** Private sector, farms. **Type of Respondents:** Licensed pesticide applicators and their spouses. The annual reporting burden is as follows:

ESTIMATES OF ANNUAL BURDEN HOURS

Type of respondent	Instrument	Estimated number of respondents	Frequency of response	Average time per response (Minutes/hour)	Annual burden hours
Private Applicators	Interview Only	2,920	1.00	35/60	1,703.33
	Interview & buccal cells	83	1.00	60/60	83.00
Spouses	Interview Only	2,680	1.00	35/60	1,563.33
	Interview & buccal cells	165	1.00	60/60	165.00
Commercial Applicators	Interview Only	930	1.00	35/60	542.50
	Interview & buccal cells	83	1.00	60/60	83.00
Totals	6,861	4,140.17

The annualized cost to respondents is estimated at \$109,652, which amount to a total cost of \$1,348,000 over three years. There are no capital costs, operating costs, and/or maintenance costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, 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.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Attention: NIH Desk Officer, Office of

Management and Budget, at *OIRA_submission@omb.eop.gov* or by fax to 202-395-6974. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Michael Alavanja, Dr.P.H, Occupational and Environmental Epidemiology Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute, NIH, Executive Plaza South, Room 8000, 6120 Executive Blvd., Rockville, MD 20892 or call 301-496-9093 or e-mail your request, including your address to: *alavanjm@mail.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: June 25, 2008.

Vivian Horovitch-Kelley,
NCI Project Clearance Liaison Office,
National Institutes of Health.
 [FR Doc. E8-15072 Filed 7-2-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.