

Dated: May 30, 2008.

**Michelle Shortt,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifier: CMS-10262, CMS-21  
and 21B, CMS-10143 and CMS-64]**

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

*Agency:* Centers for Medicare & Medicaid 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), Department of Health and Human Services, 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 function; (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:* New Collection; *Title of Information Collection:* Health Insurance Flexibility and Accountability (HIFA) Evaluation; *Use:* The HIFA initiative sought to increase health coverage of uninsured populations through a flexible waiver process emphasizing public subsidy of Employer-Sponsored Insurance (ESI). Testing whether that approach reduces the rate/number of uninsured is critically important to CMS. The proposed survey of HIFA enrollees in New Mexico and Oregon would provide the only data available to test certain fundamental HIFA effects, especially with reference to reduction of the uninsured population, the effectiveness of premium assistance for ESI and the possibility of crowd-out of private coverage. *Form Number:* CMS-10262

(OMB# 0938-NEW); *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 800; *Total Annual Responses:* 800; *Total Annual Hours:* 400.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Quarterly Children's Health Insurance Program Statement of Expenditures for Title XXI; *Use:* States use the form CMS-21 to report budget, expenditure, and related statistical information required for implementation of the Children's Health Insurance Program. *Form Number:* CMS-21 and 21B (OMB# 0938-0731); *Frequency:* Quarterly; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 56; *Total Annual Responses:* 448; *Total Annual Hours:* 7,840.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Monthly State File of Medicaid/Medicare Dual Eligible Enrollees; *Use:* The monthly file of dual eligible enrollees will be used to determine those duals with drug benefits for the phased down State contribution process required by the Medicare Modernization Act of 2003. These data are also used to support Part D subsidy determinations and auto-assignment of individuals to Part D plans. *Form Number:* CMS-10143 (OMB# 0938-0958); *Frequency:* Monthly; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 612; *Total Annual Hours:* 6,120.

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program; *Use:* The State Medicaid Agencies use the form CMS-64 to report their actual program benefit costs and administrative expenses to CMS. CMS uses this information to compute the Federal financial participation for the State's Medicaid Program costs. *Form Number:* CMS-64 (OMB# 0938-0067); *Frequency:* Quarterly; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 56; *Total Annual Responses:* 224; *Total Annual Hours:* 18,144.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS 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](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on July 7, 2008. OMB Human Resources and Housing Branch, Attention: Carolyn Raffaelli, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395-6974.

Dated: May 30, 2008.

**Michelle Shortt,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare and Medicaid Services

**[Document Identifier: CMS-10267]**

#### Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

*Agency:* Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services, 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.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have

submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR Part 1320(a)(2)(ii). This is necessary to ensure compliance with an initiative of the Administration. We cannot reasonably comply with the normal clearance procedures because of an unanticipated event, as stated in 5 CFR 1320.13(a)(2)(ii). The agency cannot reasonably comply with the normal clearance procedures because the application and user account registration form must have OMB clearance by September 2008 to meet the time necessary to begin CAS security administrator training and user account registration for new CROWNWeb alpha testers and CROWNWeb production users.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* CROWNWeb Authentication Service (CAS) Account Form; *Form Number:* CMS-10210 (OMB#: 0938-NEW); *Use:* The CROWNWeb Authentication Service (CAS) application must be completed by any person needing access to the CROWNWeb system which include includes CMS employees, ESRD Network Organization staff and dialysis facilities staff. The CROWNWeb system is the system used as the collection point of data necessary for entitlement of ESRD patients to Medicare benefits and Federal Government monitoring and assessing of quality and type of care provided to renal patients. The data collected in CAS will provide the necessary security measures for creating and maintaining active CROWNWeb user accounts and collection of audit trail information required by the CMS Information Security Officers (ISSO). *Frequency:* Reporting—One-time; *Affected Public:* Business or other for-profit, Not-for-profit; *Number of Respondents:* 15,600; *Total Annual Responses:* 15,600; *Total Annual Hours:* 7,800.

CMS is requesting OMB review and approval of this collection by *August 29, 2008*, with a 180-day approval period. Written comments and recommendations will be considered from the public if received by the individuals designated below by *August 5, 2008*.

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

*regulations/pr* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto: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 *August 5, 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 and,

OMB Human Resources and Housing Branch, Attention: CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395-6974.

Dated: June 2, 2008.

**Michelle Shortt,**

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

[FR Doc. E8-12681 Filed 6-5-08; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0288]

#### **Compliance Policy Guide Sec. 560.700 Processing of Imported Frozen Products of Multiple Sizes (e.g., Shrimp, Prawns, Etc.) (CPG 7119.10); Withdrawal of Guidance**

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

**ACTION:** Notice; withdrawal.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal of Compliance Policy Guide Sec. 560.700 Processing of Imported Frozen Products of Multiple Sizes (e.g., Shrimp, Prawns, Etc.) (CPG 7119.10) (CPG Sec. 560.700). CPG Sec. 560.700 is included in FDA's Compliance Policy Guides Manual, which was listed in the

Annual Comprehensive List of Guidance Documents that published on March 28, 2006.

**DATES:** The withdrawal is effective June 6, 2008.

#### **FOR FURTHER INFORMATION CONTACT:**

Robert D. Samuels, Center for Food Safety and Applied Nutrition (HFS-325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-2300.

**SUPPLEMENTARY INFORMATION:** In a notice containing a cumulative list of guidances available from the agency that published in the **Federal Register** on March 28, 2006 (71 FR 15422 at 15453), FDA included the Compliance Policy Guides Manual, which includes CPG Sec. 560.700. FDA is withdrawing CPG Sec. 560.700 because it is obsolete.

Dated: May 15, 2008.

**Margaret O' K. Glavin,**

*Associate Commissioner for Regulatory Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Proposed Collection; Comment Request; Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO) (NCI)**

**SUMMARY:** In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

*Proposed Collection: Title:* Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO). *Type of Information Collection Request:* REVISION (OMB #: 0925-0407, current expiry date 10/31/2008). *Need and Use of Information Collection:* This trial is designed to determine if screening for prostate, lung, colorectal and ovarian cancer can reduce mortality from these cancers which currently cause an estimated 254,900 deaths annually in the U.S. The design is a two-armed randomized trial of men and women aged 55 to 74 at entry. OMB first approved this study in 1993 and has approved it every 3 years since then through 2008. During the first approval period a pilot study was conducted to