Dated: July 31, 2008.

**William H. Gimson,**

*Chief Operating Officer, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifier: CMS–R–138, CMS–10147, CMS–10146, CMS–10064, and CMS–10225]**

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

*Agency:* Centers for Medicare & 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 & 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:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Geographic Classification Review Board (MGCRB) Procedures and Criteria and Supporting Regulations in 42 CFR, Section 412.256 & 412.230; *Use:* Section 1886(d)(10) of the Social Security Act established the MGCRB, an entity that has the authority to accept short-term hospital inpatient prospective payment system (IPPS) hospital applications requesting geographic reclassification for wage index or standardized payment amounts and to issue decisions on these requests. Since it is important to ensure the accuracy of the MGCRB decisions and remain apprised of potential payment impacts, the regulations note that CMS should also receive a copy of any hospital's application to the MGCRB. The information submitted by the hospitals is used by CMS staff to determine the validity of the hospitals' requests and the discretion used by the MGCRB in reviewing and making decisions regarding hospitals' requests for geographic reclassification. Since CMS wrote the guidelines for the MGCRB, it is essential that CMS staff monitor this process. *Form Number:* CMS–R–138 (OMB# 0938–0573); *Frequency:* Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 300; *Total Annual Responses:* 300; *Total Annual Hours:* 300.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Prescription Drug Coverage and Your Rights; *Use:* Section 42 CFR 423.562, requires each Part D plan sponsor to arrange with its network pharmacies to post or distribute the Medicare Prescription Drug Coverage and Your Rights notice to Part D plan enrollees at each pharmacy visit when the enrollee disagrees with the information provided by the pharmacist. The purpose of this notice is to provide enrollees with information about how to contact their Part D plans to request a coverage determination, including a request for an exception to the Part D plan's formulary. *Form Number:* CMS 10147 (OMB# 0938–0975); *Frequency:* Daily; *Affected Public:* Business or other for-profits; *Number of Respondents:* 40,000; *Total Annual Responses:* 30,000,000; *Total Annual Hours:* 500,000.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Notice of Denial of Medicare Prescription Drug Coverage; *Use*: Section 1860D–4(g)(1) of the Social Security Act, requires Part D plan sponsors that deny prescription drug coverage to provide a written notice of the denial to the enrollee. The written notice must include a statement, in clear language, of the reasons for the denial and a description of the appeals process. *Form Number:* CMS 10146 (OMB# 0938–0976); *Frequency:* Daily; *Affected Public:* Business or other for-profits; *Number of Respondents:* 758; *Total Annual Responses:* 290,344; *Total Annual Hours:* 145,172.

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Minimum Data Set (MDS) for Swing Bed Hospitals and Supporting Regulations in 42 CFR 413.114(a)(2) and 413.343(a); *Use:* Exercising CMS' authority under section 1888(e)(7) of the Social Security Act to determine the most appropriate manner in which to implement the Skilled Nursing Facility Prospective Payment System (SNF PPS) for swing bed hospitals, CMS designed a 2-page MDS instrument for use by swing bed hospitals that includes all resident assessment data needed to reimburse swing bed hospitals for SNF-level care furnished to Medicare beneficiaries and to provide CMS with the basic demographic and utilization data for future planning and analysis. *Form Number:* CMS–10064 (OMB# 0938–0872); *Frequency:* Occasionally; *Affected Public:* Business or other for-profits, Not-for-profit institutions and State, Local, or Tribal Governments; *Number of Respondents:* 481; *Total Annual Responses:* 50,505; *Total Annual Hours:* 328,283.

5. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Disclosures to Patients by Certain Hospitals and Critical Access Hospitals and Supporting Regulations in 42 CFR 489.20; *Form Number:* CMS–10225 (OMB#: 0938–1035); *Use:* This information request relates to proposed required third party disclosures by certain Medicare-participating hospitals and critical access hospitals (CAHs) to their patients. The policy is contained in the FY 2009 Inpatient Prospective Payment System Final Rule. Because this information request is closely related to the previously approved collection burden under 0938–01034, we have included a discussion of both the approved provisions and the new provisions in the supporting statement document.

In addition to the two existing collections previously approved under 0938–1034, we are revising § 489.3 to define a physician-owned hospital as a hospital in which a physician, or an immediate family member of a physician has an ownership or investment interest in the hospital. Because of this change to the definition of a physician-owned hospital, new § 489.20(u)(1) will require that hospitals with ownership or investment interests by a physician or immediate family member disclose this information to all their patients. Additionally, we revised § 489.20(u) by creating § 489.20(u)(1) that requires any physician-owned hospital to furnish patients with written notice that the hospital is physician-owned and provide the list of physician owners (including immediate family members) to the patient at the time the patient or someone on the patient's behalf requests it.

We also require three new collections which are the primary focus of this supporting statement. First, we have added new § 489.20(u)(2) to require a hospital to require all physicians who are members of the hospital's medical staff to agree, as a condition of continued medical staff membership or admitting privileges, to disclose in writing to all patients they refer to the hospital any ownership or investment interest in the hospital held by themselves or by an immediate family member. The burden associated with this requirement is two-fold and pertains to both hospitals and physicians. First, hospitals are required to update by-laws and policies and procedures to reflect that as a condition of medical staff membership or admitting privileges, physicians must agree to disclose ownership or investment interests to patient. In addition, physicians are required to develop disclosure notices, distribute them to patients and maintain these disclosures in the patients' medical records.

Finally, we are including new language under § 489.20(v) to provide for an exception to the disclosure requirements for a physician-owned hospital that does not have at least one referring physician who has an ownership or investment interest in the hospital (or who has an immediate family member with an ownership or investment interest in the hospital), provided that the hospital attests, in writing, to that effect and maintains such attestation in its files. The burden associated with this requirement is limited to those physician-owned hospitals that do not have physician owners who refer patients to the hospital.

The intent of the disclosures is to increase the transparency of the hospital's ownership and operations to patients as they make decisions about receiving care at the hospital. *Frequency:* Reporting—Occasionally; *Affected Public:* Business or other for-profit; *Number of Respondents:* 2,697; *Total Annual Responses:* 49,735,828; *Total Annual Hours:* 840,318.

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,* 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 September 8, 2008.

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

Dated: July 31, 2008.

**Michelle Shortt,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2008–N–0429]**

### Food Labeling; Current Trends in the Use of Allergen Advisory Labeling: Its Use, Effectiveness, and Consumer Perception; Public Hearing; Request for Comments

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

**ACTION:** Notice of public hearing; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public hearing on the use of advisory labeling of allergens in foods. FDA is developing a long-term strategy to assist manufacturers in using allergen advisory labeling that is truthful and not misleading, conveys a clear and uniform message, and adequately informs food-allergic consumers and their caregivers. To that end, FDA is soliciting comments and information to assist the agency in determining how manufacturers currently use advisory labeling, how consumers interpret different advisory labeling statements, and what wording is likely to be most effective in communicating to consumers the likelihood that an allergen may be present in a food. The agency is also interested in receiving comments about whether consumers find advisory labeling helpful for making food purchasing decisions. This public hearing is the first step in closing existing knowledge gaps in developing our long-term strategy.

**DATES:** The public hearing will be held on September 16, 2008, from 9 a.m. to 4:30 p.m. The closing date for registration is September 8, 2008. See section V of this document for other dates associated with participation in the hearing. Submit written or electronic comments (i.e., submissions other than notices of participation and written material associated with an oral presentation) by January 14, 2009. The administrative record of the hearing will remain open until January 14, 2009.

**ADDRESSES:** *Public hearing.* The public hearing will be held at the Harvey W. Wiley Federal Building, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, (Metro stop: College Park on the Green Line).

*Registration.* Submit electronic notices of participation for the hearing to *http://www.cfsan.fda.gov/register.html.* We encourage you to use this method of registration, if possible. Submit written notices of participation by mail, fax, or e-mail to Isabelle Howes, U.S. Department of Agriculture Graduate School, 600 Maryland Ave., SW., suite 330, Washington, DC 20024–2520, FAX: 202–479–6801, or e-mail: *Isabelle_Howes@grad.usda.gov.* You may also submit oral notices of participation by phone to Isabelle Howes, U.S. Department of Agriculture Graduate School (see **FOR FURTHER INFORMATION CONTACT**).

*Written material associated with an oral presentation.* Submit written material associated with an oral presentation by mail, fax, or e-mail to Isabelle Howes.

*Comments.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov.* For additional information on submitting comments, see section VI in this document.

**FOR FURTHER INFORMATION CONTACT:**

*For questions about registration or written material associated with an oral presentation, or to register orally*: Isabelle Howes, 202–314–4713.

*For all other questions about the hearing or if you need parking or special accommodations due to a disability*: Juanita Yates, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 301–436–1731, e-mail: *Juanita.Yates@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

#### I. Background

Food allergies affect approximately two percent of adults and about five