Kimberly S. Lane,

Deputy Director, Office of Science Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–643 and CMS–10185]

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 without change of a currently approved collection. *Title of Information Collection:* Hospice Survey and Deficiencies Report Form and Supporting Regulations. *Use:* CMS uses the information collected as the basis for certification decisions for hospices that wish to obtain or retain participation in the Medicare and Medicaid programs. The information is used by CMS regional offices, which have the delegated authority to certify Medicare facilities for participation, and by State Medicaid agencies, which have comparable authority under Medicaid. The information on the Hospice Survey and Deficiencies Report Form is coded for entry into the OSCAR system. The data is analyzed by the CMS regional offices and by the CMS central office components for program evaluation and monitoring purposes. The information is also available to the public upon request. *Form Number:* CMS–643 (OCN 0938–0379). *Frequency:* Yearly. *Affected Public:* State, Local, or Tribal Governments. *Number of Respondents:* 3,644. *Total Annual Responses:* 1,217. *Total Annual Hours:* 1,217. (For policy questions regarding this collection contact Kim Roche at 410–786–3524. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Revision of a currently approved collection;

Title of Information Collection: Medicare Part D Reporting Requirements and Supporting Regulations; *Use:* Title I of 42 CFR, Part 423, § 423.514, requires each Part D Sponsor to have an effective procedure to provide statistics indicating: the cost of its operations, the patterns of utilization of its services, the availability, accessibility, and acceptability of its services, information demonstrating it has a fiscally sound operation and other matters as required by CMS. In addition, § 423.505 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), establishes as a contract provision that Part D Sponsors must comply with the reporting requirements for submitting drug claims and related information to CMS. Data collected via Medicare Part D Reporting Requirements is an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries. The data collected will be validated, analyzed, and utilized for trend reporting.

The revisions for the CY 2013 include the removal, addition or both of data elements for the Prompt Payment by Part D Sponsors, Grievances, Fraud, Waste, and Abuse Compliance Programs, and Plan Oversight of Agents reporting sections; however, these changes resulted in no changes to the burden for these sections. In addition, we added data elements and revised data elements for the Medication Therapy Management Programs and the Coverage Determinations and Exceptions reporting sections, which resulted in an increase in burden hours for both sections. Lastly, we removed the following reporting sections and decreased burden estimates associated with these sections because these data are no longer necessary for monitoring through these reporting requirements: Access to Extended Day Supplies at Retail Pharmacies; and Pharmacy Support of E-prescribing. *Form Number:* CMS–10185 (OMB#: 0938–0992); *Frequency:* Yearly, Quarterly, Semi-Annually; *Affected Public:* Private Sector, business or other for-profit; *Number of Respondents:* 3,180; Total *Annual Responses:* 48,152; *Total Annual Hours:* 76,240. (For policy questions regarding this collection contact LaToyia Grant at 410–786–5434. For all other issues call 410–786–1326.)

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 Email 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 *August 17, 2012.*

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, Email: *OIRA_submission@omb.eop.gov.*

Dated: July 12, 2012.

Martique Jones,

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

[FR Doc. 2012–17380 Filed 7–17–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–2567]

Agency Information Collection Activities: Proposed Collection; 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) 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 without change of a currently approved collection. *Title of Information Collection:* Deficiencies and Plan of Correction (CMS–2567) and Supporting Regulations contained in 42 CFR 488.18, 488.26, and 488.28. *Use:* Section 1864(a) of the Social Security Act requires that the Secretary use State survey agencies to conduct surveys to determine whether health care facilities meet Medicare and Clinical Laboratory Improvement Amendments participation requirements. The CMS–2567 form is the means by which the survey findings are documented. This section of the law further requires that compliance findings resulting from these surveys be made available to the public within 90 days of such surveys. The CMS–2567 from is the vehicle for this disclosure. The regulations at 42 CFR 488.18 require that State survey agencies document all deficiency findings on a statement of deficiencies and plan of correction, which is the CMS–2567. 42 CFR 488.26 and 488.28 further delineate how compliance findings must be recorded and that CMS prescribed forms must be used.

The form is also used by health care facilities to document their plan of correction and by CMS, the States, facilities, purchasers, consumers, advocacy groups, and the public as a source of information about quality of care and facility compliance.

Form Number: CMS–2567 (OCN 0938–0391). *Frequency:* Yearly and occasionally. *Affected Public:* Private Sector (Business or other for-profit and not-for-profit institutions). *Number of Respondents:* 62,000. *Total Annual Responses:* 62,000. *Total Annual Hours:* 134,540. (For policy questions regarding this collection contact Angela Mason-Elbert at 410–786–8279. For all other issues call 410–786–1326.)

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 Email 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 17, 2012.*

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: July 12, 2012.

Martique Jones,

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

[FR Doc. 2012–17378 Filed 7–17–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0011]

Establish a Patient-Based Registry To Evaluate the Association of Gadolinium Based Contrast Agents Exposure and Nephrogenic Systemic Fibrosis

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of the development of a patient-based registry to evaluate the association of gadolinium based contrast agents (GBCAs) exposure and nephrogenic systemic fibrosis (NSF). The goal of the GBCA project is to study the safety of the GBCAs when used as indicated.

DATES: Important dates are as follows:

1. The application due date is August 1, 2012.
2. The anticipated start date is September 13, 2012.
3. The opening date is July 2, 2012.
4. The expiration date is August, 2, 2012.

ADDRESSES: Submit the paper application to: Vieda Hubbard, Grants Management (HFA–500), 5630 Fishers Lane, Rockville, MD 20857, and a copy to Ira Krefting, Center for Drug Evaluation and Research, Division of Medical Imaging Products, 10903 New Hampshire Ave., Bldg. 22, rm. 2100, Silver Spring, MD 20993. For more information, see section III of the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT: Ira Krefting, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2100, Silver Spring, MD 20993, 301–796–1135, Email: *ira.krefting@fda.hhs.gov;* or

Vieda Hubbard, Office of Acquisitions and Grants Services (HFA–500), Food and Drug Administration, 5630 Fishers Lane, rm. 2034, Rockville, MD 20857, 301–827–7177, Email: *vieda.hubbard@fda.hhs.gov.*

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at: *http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM311309.pdf.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–12–029
93.103

A. Background

Annually, millions of patients undergo magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA) procedures employing GBCAs. Postmarketing data indicate that six of the eight GBCAs approved for use in the United States have been directly implicated in the development of NSF, a newly characterized, potentially fatal systemic fibrotic skin and internal organ condition. Among the factors that may increase the risk for NSF are repeated or higher than recommended doses of GBCA and degree of renal impairment at the time of exposure; imaging patients with severe renal failure appear to be at highest risk. In one, early retrospective study of 370 patients with severe renal failure who received gadodiamide the estimated risk for development of NSF was 4 percent (Ref. 1). In a recent retrospective chart review study by Wang of 52,954 contrast MR examinations with restrictive guidelines for GBCA in patients with renal failure no new cases of NSF were found (Ref. 2).