## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifier: CMS–R–220, CMS–R–273, CMS–10151, CMS–10152, CMS–R–10, CMS–R–79]**

### 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:* Extension of a currently approved collection; *Title of Information Collection:* HIPAA Standard Unique Employer Identifier and Supporting Regulations in 45 CFR Parts 160 and 162; *Form Nos.:* CMS–R–220(OMB # 0938–0874); *Use:* Section 1173b of Subtitle F of Title II of the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191) requires the Secretary of the Department of Health and Human Services to adopt standards for unique health identifiers for individuals, employers, health plans, and health care providers. The use of this standard improves the Medicare and Medicaid programs, other Federal health programs and private health programs, by simplifying the administration of the system and enabling the efficient electronic transmission of certain health information; *Frequency:* Other—one-time; *Affected Public:* Business or other for-profit, Not-for-profit institutions, Federal Government, and State, Local or Tribal Government; *Number of Respondents:* 2,550,000; *Total Annual Responses:* 2,550,000; *Total Annual Hours:* 1.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Community Mental Health Center Site Visit Assessment Tool and Supporting Regulations in 42 CFR 410.2; *Form No.:* CMS–R–273 (OMB # 0938–0770); *Use:* This collection instrument aids CMS in its efforts to ensure that new and existing Community Mental Health Centers (CMHC) are compliant with Medicare provider requirements, and all applicable Federal and State requirements. The collection pertains to CMHC's provision of pre-admission screening to State mental health facilities and to expanding the collection tool's use into other program areas as a means to screen applicants, enrollees, and existing providers/suppliers to ensure their legitimacy to participate in the Medicare Program; *Frequency:* Reporting-Other, upon initial application or re-enrollment into the Medicare program; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and State, Local or Tribal Government; *Number of Respondents:* 4,731; *Total Annual Responses:* 4,731; *Total Annual Hours:* 20,372.

3. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Data Collection for Medicare Beneficiaries Receiving Implantable Cardioverter-defibrillators for Primary Prevention of Sudden Cardiac Death; *Form Nos.:* CMS–10151(OMB # 0938–NEW); *Use:* CMS provides coverage for implantable cardioverter-defibrillators (ICDs) for secondary prevention of sudden cardiac death based on extensive evidence showing that use of ICDs among patients with a certain set of physiologic conditions are effective. Accordingly, CMS considers coverage for ICDs reasonable and necessary under Section 1862 (a)(1)(A) of the Social Security Act. However, evidence for use of ICDs for primary prevention of sudden cardiac death is less compelling for certain patients. To encourage responsible and appropriate use of ICDs, CMS issued a Decision Memo for Implantable Defibrillators on January 27, 2005, indicating that ICDs will be covered for primary prevention of sudden cardiac death if the beneficiary is enrolled in either an FDA-approved category B Investigational Device Exemption (IDE) clinical trial (see 42 CFR § 405.201), a trial under the CMS Clinical Trial Policy (see NCD Manual § 310.1) or a qualifying prospective data collection system (either a practical clinical trial or prospective systematic data collection, which is sometimes referred to as a registry).; *Frequency:* Other—as needed; *Affected Public:* Business or other for-profit, Individuals or Households, and Not-for-profit institutions; *Number of Respondents:* 1217; *Total Annual Responses:* 50,000; *Total Annual Hours:* 4167.

4. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Data Collection for Medicare Beneficiaries Receiving FDG Positron Emissions Tomography (PET) for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung and Testicular Cancers; *Form Nos.:* CMS–10152(OMB # 0938–NEW); *Use:* In the Decision Memo #CAG–00181N issued on January 27, 2005, CMS determined that the evidence is sufficient to conclude that for Medicare beneficiaries receiving FDG positron emission tomography (PET) for brain, cervical, ovarian, pancreatic, small cell lung, and testicular cancers is reasonable and necessary only when the provider is participating in and patients are enrolled in a systematic data collection project. CMS will consider prospective data collection systems to be qualified if they provide assurance that specific hypotheses are addressed and they collect appropriate data elements. The data collection should include baseline patient characteristics; indications for the PET scan; PET scan type and characteristics; FDG PET results; results of all other imaging studies; facility and provider characteristics; cancer type, grade, and stage; long-term patient outcomes; disease management changes; and anti-cancer treatment received.; *Frequency:* Other—as needed; *Affected Public:* Business or other for-profit, Individuals or Households, and Not-for-profit institutions; *Number of Respondents:* 2,000; *Total Annual Responses:* 50,000; *Total Annual Hours:* 4167.

5. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements Contained in BPD–718: Advance Directives (Medicare and Medicaid) and Supporting Regulations in 42 CFR Sections 417.436, 417.801, 422.128, 430.12, 431.20, 431.107, 438.6, 440.170, 483.10, 484.10, and 489.102; *Form No.:* CMS–R–10 (OMB# 0938–0610); *Use:* Steps have been taken at both the Federal and State level, to afford greater opportunity for the individual to participate in decisions made concerning the medical treatment to be received by an adult patient in the event that the patient is unable to communicate to others, a

preference about medical treatment. The individual may make his preference known through the use of an advance directive, which is a written instruction prepared in advance, such as a living will or durable power of attorney. This information is documented in a prominent part of the individual's medical record. Advance directives as described in the Patient Self-Determination Act (enacted in 1991) have increased the individual's control over decisions concerning medical treatment. The advance directives requirement was enacted because Congress wanted individuals to know that they have a right to make health care decisions and to refuse treatment even when they are unable to communicate.; *Frequency:* On occasion; *Affected Public:* Business or other for-profit; *Number of Respondents:* 33,096; *Total Annual Responses:* 33,096; *Total Annual Hours:* 924,120.

6. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Payment Adjustment for Sole Community Hospitals and Supporting Regulations in 42 CFR Section 412.92; *Form No.:* CMS–R–79 (OMB# 0938–0477); *Use:* This collection provides that if a hospital that is classified as a sole community hospital (SCH) experiences, due to circumstances beyond its control, a decrease of more than 5 percent in its total number of discharges compared to the immediately preceding cost reporting period, the hospital may apply for a payment adjustment. To qualify for this adjustment to its payment rate an SCH must submit documentation, including cost information as requested by CMS, to the intermediary; *Frequency:* On occasion; *Affected Public:* Not-for-profit institutions, Business or other for-profit, and State, Local or Tribal Government; *Number of Respondents:* 40; *Total Annual Responses:* 40; *Total Annual Hours:* 160.

To obtain copies of the supporting statement and any related forms for these paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/regulations/pra/,* 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.

Written comments and recommendations for these information collections will be considered if they are mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Christopher Martin, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: July 29, 2005.

**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

### Privacy Act of 1974; Report of a New System of Records

**AGENCY:** Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS).

**ACTION:** Notice of a New System of Records.

**SUMMARY:** In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new system titled ''Federal Reimbursement of Emergency Health Services Furnished to Undocumented Aliens (Section 1011),'' System No. 09–07–0546. The system will contain enrollment and payment request information, in support of a short-term program which pays hospitals, certain physicians, and ambulance providers (including Indian Health Service (IHS) facilities whether operated by the IHS or by an Indian Tribe or tribal organization) for their otherwise un-reimbursed costs of services provided under the provisions of section 1867 (Emergency Medical Treatment and Labor Act) (EMTALA) of the Social Security Act (the Act) and related hospital inpatient and outpatient services and ambulance services furnished to undocumented aliens, aliens paroled into the United States (U.S.) at a U. S. port of entry for the purposes of receiving such services, and Mexican citizens permitted temporary entry to the U.S. for not more than 30 days under the authority of a biometric machine readable border crossing identification card (also referred to as a ''laser visa'') issued in accordance with the requirements of regulations prescribed under the Immigration and Nationality Act. This system is being established under provisions of Section 1011 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 Modernization Act of 2003 (MMA).

The primary purpose of the system is to maintain information collected on individuals who submit an enrollment application and make payment requests associated with Section 1011 of the MMA, and other information designed to support the enrollment, claims payment, and research reporting functions of the Section 1011 program. Information retrieved from this system will also be disclosed to: (1) Support regulatory, payment activities, and policy functions performed within the agency or by a designated contractor or consultant; (2) combat fraud and abuse in certain health benefits programs; (3) assist another Federal or state agency with information to enable such agency to administer a Federal health benefits program, or to enable such agency to fulfill a requirement of a Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal; (4) funds support constituent requests made to a Congressional representative; and, (5) support litigation involving the agency. We have provided background information about the new system in the **SUPPLEMENTARY INFORMATION** section below. Although the Privacy Act requires only that the ''routine use'' portion of the system be published for comment, CMS invites comments on all portions of this notice. See **DATES** section for comment period.

**DATES:** CMS filed a new system report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on July 21, 2005. In any event, we will not disclose any information under a routine use until 40 days after publication. We may defer implementation of this system or one or more of the routine use statements listed below if we receive comments that persuade us to defer implementation.

**ADDRESSES:** The public should address comments to: CMS Privacy Officer, Division of Privacy Compliance Data Development (DPCDD), CMS, Mail Stop N2–04–27, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.–3 p.m., eastern time zone.

**FOR FURTHER INFORMATION CONTACT:** Section 1011 Project Officer, Center for Medicare Management, CMS, Mailstop C4–10–07, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

**SUPPLEMENTARY INFORMATION:** Sections 1866(a)(1)(I), 1866(a)(1)(N), and 1867 of the Act impose specific obligations on