

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—C, Attention: Bonnie L. Harkless, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: June 14, 2007.

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–R–290, CMS–10221, and CMS–2728]

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 Program: Process for Making National Coverage Determinations; *Form Number:* CMS–R–290 (OMB#: 0938–0776); *Use:* On September 26, 2003 (68 FR 55634), we published a notice that described how we revised the process we use to make Medicare coverage decisions including decisions regarding whether new technology and services can be covered. In accordance with section IV.B of the aforementioned notice, CMS' Revised Process for

Making National Coverage Determinations, we require an individual or entity to make a formal request for a national coverage determination. Upon receipt of a formal request and adequate supporting documentation, we will make a determination based on the evidence presented, to cover the device or service or not to cover the device or service where it is not supported by the medical evidence. We are resubmitting this information collection request (ICR) to the Office of Management and Budget as an extension of the currently approved collection. We have not made any material modifications to the ICR since the last submission. *Frequency:* Recordkeeping and Reporting—On occasion; *Affected Public:* Business or other-for-profit, Not-for-profit institutions; *Number of Respondents:* 200; *Total Annual Responses:* 200; *Total Annual Hours:* 8,000.

2. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Worksheet for Recording Results of Medicare Site Visits of Independent Diagnostic Testing Facilities (IDTFs) Form; *Form Number:* CMS–10221 (OMB#: 0938–New); *Use:* Prior to enrolling in Medicare, independent diagnostic testing facilities (IDTFs) must undergo a site visit as required under 42 CFR 410.33. The purpose of the site visit is to ensure that the IDTF is in compliance with the provisions of 42 CFR 410.33, as well as all other applicable Federal, State and local laws and regulations. It is also used to verify the information the IDTF furnished on its CMS–855B enrollment application.

Section 410.33 contains a significant number of standards that IDTFs must meet in order to enroll in Medicare. Compliance with the standards further ensures that only qualified and legitimate IDTFs can bill Medicare. This is especially important in light of concerns about recent fraudulent activity by some IDTFs. We are submitting the “Worksheet for Recording Results of Medicare Site Visits of Independent Diagnostic Testing Facilities (IDTFs),” for OMB approval. The purpose of this document is to ensure that the individuals performing IDTF site visits take into account both new and existing IDTF standards in a consistent fashion. *Frequency:* Reporting—On occasion; *Affected Public:* Business or other-for-profit, Not-for-profit institutions; *Number of Respondents:* 2,000; *Total Annual Responses:* 2,000; *Total Annual Hours:* 4,000.

3. *Type of Information Collection Request:* Extension of a currently

approved collection; *Title of Information Collection:* End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration; *Form Number:* CMS–2728 (OMB#: 0938–0046); *Use:* The End Stage Renal Disease Medical Evidence (CMS–2728) is completed for all ESRD patients either by the first treatment facility or by a Medicare-approved ESRD facility when it is determined by a physician that the patient's condition has reached that stage of renal impairment that a regular course of kidney dialysis or a kidney transplant is necessary to maintain life.

The data reported on the CMS–2728 is used by the Federal Government, ESRD Networks, treatment facilities, researchers and others to monitor and assess the quality and type of care provided to end stage renal beneficiaries. The data collection captures the specific medical information required to determine the Medicare medical eligibility of End Stage Renal Disease claimants. It also collects data for research and policy on this population. *Frequency:* Reporting—Once; *Affected Public:* Individuals or households, Business or other-for-profit, Not-for-profit institutions; *Number of Respondents:* 100,000; *Total Annual Responses:* 100,000; *Total Annual Hours:* 75,000.

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.

Written comments and recommendations for the proposed information collections must be mailed or faxed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503, *Fax Number:* (202) 395–6974.

Dated: June 14, 2007.

Michelle Shortt,

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

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