DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: OS–4040–0005] [30-Day Notice]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection 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.

Type of Information Collection Request: Revision.

Title of Information Collection: SF–424 Individual.

Form/OMB No.: OS–4040–0005.

Use: The SF–424 (individual) is a simplified, alternative government-wide data set and application cover page for use by Federal grant-making agencies that award grants to individuals. The form will include one change to one field—the Social Security Number (SSN). The SSN field will remain optional. The SSN field will be changed to pre-populate the first five digits with ''000–00–'' The applicant will only enter the last four digits of the SSN. This change ensures the entire SSN will not be collected or stored. This change will not increase the collection burden to the applicant.

Frequency: Recordkeeping on Occasion.

Affected Public: Individuals or Households.

Annual Number of Respondents: 5827.

Total Annual Responses: 6949.

Average Burden per Response: 25 minutes.

Total Annual Hours: 2895.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov* , or call the Reports Clearance Office on (202) 690–6162. Written comments and recommendations for the proposed information collections must be received within 30 days of this notice directly to the Desk Officer at the address below:

OMB Desk Officer: John Kraemer, OMB Human Resources and Housing Branch, *Attention:* (OMB #4040–0005), New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: April 5, 2007.

Mary Oliver-Anderson,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. E7–7004 Filed 4–12–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10227, CMS–1561 and 1561A, CMS–2728, CMS–10221, CMS–R–290, and CMS–R–26]

Agency Information Collection Activities: Proposed Collection; 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) 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:* Existing collection in use without an OMB Control Number; *Title of Information Collection:* PACE State Plan Amendment Pre-print; *Form Number:* CMS–10227 (OMB#: 0938–New); *Use:* The Balanced Budget Act of 1997 created section 1934 of the Social Security Act that established the Program for the All-Inclusive Care for the Elderly (PACE). The legislation established the PACE program as a Medicaid State plan option serving the frail and elderly in the home and community. In accordance with the rule published in the November 24, 1999 **Federal Register** (64 FR 66271), if a State elects to offer PACE as an optional Medicaid benefit, it must complete a State Plan Amendment described as Enclosures #3, 4, 5, 6 and 7. In State Medicaid Director letters dated March 23, 1998 and November 9, 2000, CMS advised States that it had provided a suggested pre-print and supplemental pages for a State to express its intention to elect PACE as an option to its State plans. As pre-print packet Enclosures #3–7 were suggested and not required, CMS did not believe at the time that a suggested form required clearance from OMB. The PACE regulation 42 CFR part 460 was first published in the **Federal Register** as an interim final rule on November 24, 1999. The final PACE rule was published on December 8, 2006. CMS is seeking OMB approval to use Enclosures #3, 4, 5, 6 and 7. The information is used by CMS to affirm that the State elects to offer PACE an optional State plan service and the specifications of eligibility, payment and enrollment for the program; *Frequency:* Reporting—Once; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56 possible responses but we have only received 20 thus far; *Total Annual Hours:* 1,120.

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Health Insurance Benefit Agreement and Supporting Regulations at 42 CFR 489; *Form Numbers:* CMS–1561 and 1561A (OMB#: 0938–0832); *Use:* Applicants to the Medicare program are required to agree to provide services in accordance with Federal requirements. The CMS–1561 and 1561A are essential for CMS to ensure that applicants are in compliance with the requirements. Applicants will be required to sign the completed form and provide operational information to CMS to assure that they continue to meet the requirements after approval; *Frequency:* Reporting—Other: all new applicants must complete; *Affected Public:* State, Local or Tribal Governments, Business or Other for profit and Not-for-profit institutions; *Number of Respondents:* 3300; *Total*

Annual Responses: 3300; *Total Annual Hours:* 275.

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.

4. *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.

5. *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.

6. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Information Collection Requirements (ICRs) Contained in the Clinical Laboratory Improvement Amendments (CLIA) Regulations 42 CFR part 493.801, 493.803, 493.1232, 493.1233, 493.1234, 493.1235, 493.1236, 493.1239, 493.1241, 493.1242, 493.1249, 493.1251, 493.1252, 439.1253, 493.1254, 493.1255, 493.1256, 493.1261, 493.1262, 493.1263, 493.1269, 493.1273, 493.1274, 493.1278, 493.1283, 493.1289, 493.1291, and 493.1299; *Form Numbers:* CMS–R–26 (OMB#: 0938–0612); *Use:* The ICRs referenced in 42 CFR part 493 outline the requirements necessary to determine an entity's complicance with CLIA. CLIA requires laboratories that perform testing on human beings to meet performance requirements (quality standards) in order to be certified by the Department of Health and Human Services (HHS). HHS conducts inspections to determine a laboratory's compliance with CLIA requirements. CLIA implements the certificate, laboratory standards and inspection requirements; *Frequency:* Reporting—As needed; *Affected Public:* State, Local or Tribal Governments, Federal Government, Business or Other for profit and Not-for-profit institutions; *Number of Respondents:* 168,688; *Total Annual Responses:* 756,241; *Total Annual Hours:* 11,363,680.

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 at the address below, no later than 5 p.m. on June 12, 2007.

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

Dated: April 6, 2007.

Michelle Shortt,

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

[FR Doc. E7–6990 Filed 4–12–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0015]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adoption of the Food and Drug Administration Food Code by Local, State, and Tribal Governments

AGENCY: Food and Drug Administration, HHS.