

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.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. This is necessary to ensure compliance with an initiative of the Administration. We cannot reasonably comply with the normal clearance procedures because the use of normal clearance procedures is reasonably likely to cause a statutory deadline to be missed.

For the 2008 contract year, CMS is taking several steps to reduce the person-hours necessary to complete the Part D solicitations. These steps include automating the majority of the Part D and Employer Group Waiver Plan solicitations within CMS' Health Plan Management System (HPMS), incorporating the Pharmacy Access Submission document into the underlying Part D solicitation, and streamlining key information that was previously requested by attachments into attestations in time to qualify applicants prior to the first Monday in June of 2006.

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

Title of Information Collection: Application for Prescription Drug Plans (PDP); Application for Medicare Advantage Prescription Drug (MA-PD); Application for Cost Plans to Offer Qualified Prescription Drug Coverage; Application for Employer Group Waiver Plans to Offer Prescription Drug Coverage; Service Area Expansion Application for Prescription Drug Coverage.

Form Number: CMS-10137 (OMB#: 0938-0936).

Use: Collection of this information is mandated in Part D of the Medicare

Prescription Drug, Improvement, and Modernization Act of 2003. Coverage for the prescription drug benefit is provided through prescription drug plans (PDP's) that offer drug-only coverage, or through Medicare Advantage organizations that offer integrated prescription drug and health care coverage. PDPs must offer a basic drug benefit. Medicare Advantage Coordinated Care Plans must offer either a basic benefit or may offer broader coverage for no additional cost. Medicare Advantage Private Fee for Service Plans may choose to offer a Part D benefit. Cost Plans that are regulated under Section 1876 of the Social Security Act, and Employer Group Plans may also provide a Part D benefit. If any of the contracting organizations meet basic requirements, they may also offer supplemental benefits through enhanced alternative coverage for an additional premium. This collection will be used by CMS to: (1) Insure that applicants meet CMS requirements and (2) support the determination of contract awards.

Frequency: Reporting—Once.

Affected Public: Business or other for-profit and Not-for-profit institutions

Number of Respondents: 216.

Total Annual Responses: 216.

Total Annual Hours: 5,316.

CMS is requesting OMB review and approval of this collection by *December 15, 2006*, with a 180-day approval period. Written comments and recommendation will be considered from the public if received by the individuals designated below by December 1, 2006.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's 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.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below by December 1, 2006: Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Room C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850, Attn: Bonnie L Harkless, and, OMB Human Resources and Housing Branch, Attention: Carolyn

Lovett, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395-6974.

November 9, 2006.

Michelle Shortt,

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

[FR Doc. E6-19428 Filed 11-16-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10088 and CMS-R-13]

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:* Revision of a currently approved collection; *Title of Information Collection:* Notification of Fiscal Intermediaries (FIs) and CMS of Co-located Medicare Providers and Supporting Regulations in 42 CFR 412.22 and 412.533; *Use:* Many long term care hospitals (LCTHs) are co-located with other Medicare providers (acute care hospitals, inpatient rehabilitation facilities, skilled nursing facilities, and psychiatric facilities), which leads to potential gaming of the Medicare system based on patient shifting. CMS is requiring LTCHs to notify fiscal intermediaries (FIs) and CMS of co-located providers. In

addition, CMS has established policies to limit payment abuse that will be based on FIs tracking patient movement among these co-located providers. *Form Number:* CMS-10088 (OMB#: 0938-0897; *Frequency:* Reporting—as needed; *Affected Public:* Business or other for profit and Not-for-profit institutions; *Number of Respondents:* 200; *Total Annual Responses:* 200; *Total Annual Hours:* 50.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Conditions of Coverage for Organ Procurement Organizations (OPOs) and Supporting Regulations in 42 CFR 486.301-348; *Use:* Organ Procurement Organizations are required to submit accurate data to CMS through the Organ Procurement and Transplantation Network (OPTN). The data concerns the organ procurement activities, as well as various OPO business activities, including information on its designated service area; structure; various policies, procedures, and protocols; and its quality assessment and performance improvement (QAPI) program. This information is necessary to assure maximum effectiveness in the procurement and distribution of organs. *Form Number:* CMS-R-13 (OMB#: 0938-0688; *Frequency:* Reporting—Every 4 years and as needed; *Affected Public:* Not-for-profit institutions; *Number of Respondents:* 58; *Total Annual Responses:* 58; *Total Annual Hours:* 21,427.

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: November 7, 2006.

Michelle Shortt,

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

[FR Doc. E6-19430 Filed 11-16-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-235]

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 of a currently approved collection; *Title of Information Collection:* Data Use Agreement Information Collection Requirements, Model Language and Supporting Regulations in 45 CFR part 5b. *Use:* The Data Use Agreement (DUA) is needed as part of the review of each CMS data request to ensure compliance with the requirements of the Privacy Act for disclosure of data that contain individually-identifiable information. In addition, the DUA is used to maintain appropriate accounting and tracking of disclosures of records from Privacy Act systems of records. *Form Number:* CMS-R-235 (OMB#: 0938-0734); *Frequency:* Reporting-On occasion; *Affected Public:* Not-for-profit institutions; *Number of Respondents:* 1,500; *Total Annual Responses:* 1,500; *Total Annual Hours:* 750.

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 *January 16, 2007*.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—B, Attention: William N. Parham, III, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: November 7, 2006.

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

Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 6, 2006, from 8 a.m. to 4:30 p.m.

Location: Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Veronica J. Calvin, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd.,