coordinates, and evaluates extramural research activities in cooperation with centers, divisions, and offices within the Coordinating Center for Health Promotion. In carrying out its mission, the ERPO: (1) Coordinates, monitors, and directs the extramural research program which is designed to address center priorities; (2) provides scientific leadership in the processes supporting extramural research of the center; (3) works with National Centers to prepare and promote initiatives to stimulate extramural research in relevant priority areas; (4) coordinates and conducts in-depth external peer review and secondary program relevance review of extramural research applications by use of consultant expert panels; (5) makes recommendations to the center directors on award selections on the basis of secondary reviews; (6) staff members serve as the program officials and work with CDC grants management officers, and the Procurement and Grants Office to implement and monitor the scientific, technical, and administrative aspects of awards; (7) facilitates scientific collaborations between external and internal investigators; (8) evaluates extramural research progress and impact and disseminates findings; and (9) assists Office of the Chief Science Officer, CDC, in developing extramural research policies and oversees the implementation of those policies within the center.

Dated: June 28, 2007.

William H. Gimson,

Chief Operating Officer, Centers for Disease Control and Prevention (CDC).

[FR Doc. 07–3427 Filed 7–12–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10137, CMS–10237 and 10214, CMS–10242, CMS–379 and CMS–10102]

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:* 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; *Use:* Collection of this information is mandated in Part D of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The application requirements are codified in Subpart K of 42 CFR 423. Coverage for the prescription drug benefit is provided through prescription drug plans (PDPs) that offer drug-only coverage, or through Medicare Advantage (MA) organizations that offer integrated prescription drug and health care coverage (MA–PD plans). PDPs must offer a basic drug benefit. Medicare Advantage Coordinated Care Plans (MA–CCPs) must offer either a basic benefit or may offer broader coverage for no additional cost. Medicare Advantage Private Fee for Service Plans (MA–PFFS) 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.

The information will be collected under the solicitation of proposals from PDP, MA–PD, Cost Plan, and Employer Group Waiver Plans applicants. The collected information will be used by CMS to: (1) Insure that applicants meet CMS requirements, and (2) support the determination of contract awards.

Refer to the ''High-Level Summary of Changes in Employer Group Waiver Plan Part D Applications'' and ''High-Level Summary of All Part D Application Revisions from 2008 Solicitation for the 2009 Solicitation'' documents to review changes from 2008 to 2009; *Form Number:* CMS–10137 (OMB#: 0938–0936); *Frequency:* Reporting: Once; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 455; *Total Annual Responses:* 455; *Total Annual Hours:* 11,890.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Advantage (MA) Applications—Part C; *Use:* An entity seeking a contract as an MA organization must be able to provide Medicare's basic benefits plus meet the organizational requirements set out in regulations at 42 CFR part 422. An applicant must demonstrate that it can meet the benefit and other requirements within the specific geographic area it is requesting. The application forms are designed to give CMS the information they need about the health plan to determine compliance with Federal regulations at 42 CFR part 422 in an efficient manner. The cited regulations outline the MA application process that begins with submission of an application in the form and manner that the Secretary provides. The MA application forms will be used by CMS to determine whether an entity is eligible to enter into a contract to provide services to Medicare beneficiaries. Refer to the ''2009 Medicare Advantage Application Changes'' document to review a list of the 2009 changes. *Form Number:* CMS–10237 and 10214 (OMB#: 0938–0935); *Frequency:* Reporting: Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 241; *Total Annual Responses:* 241; *Total Annual Hours:* 5,858.

3. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Revisions to Payment Policies Under the Physician Fee Schedule, Other Changes to Payment Under Part B, and Revisions to Payment Policies for Ambulance Services for CY 2008 (42 CFR 424.36—Signature Requirements); *Use:* 42 CFR 424.33(a)(3) states that all claims must be signed by the beneficiary or the beneficiary's representative (in accordance with 42 CFR 424.36(b)). 42 CFR 424.36(a) states that the beneficiary's signature is required on a claim unless the beneficiary has died or the provisions of § 424.36(b), (c), or (d) apply. The statutory authority requiring a beneficiary's signature on a claim submitted by a provider is located in section 1835(a) and in 1814(a) of the

Social Security Act (the Act), for Part B and Part A services, respectively. The authority requiring a beneficiary's signature for supplier claims is implicit in sections 1842(b)(3)(B)(ii) and in 1848(g)(4) of the Act. Because it is very difficult to obtain a beneficiary's signature (or the signature of a person authorized to sign on behalf of the beneficiary) on a claim when the beneficiary is being transported by ambulance in emergency situations, CMS is proposing that, for emergency ambulance transport services, an ambulance provider or supplier may submit the claim without a beneficiary's signature, as long as certain documentation requirements are met. The information collected will be used by CMS contractors (both, fiscal intermediaries and carriers) that process and pay emergency ambulance transport claims. *Form Number:* CMS–10242 (OMB#: 0938–New); *Frequency:* Reporting: Hourly, Daily, Weekly, Monthly and Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 9,000; *Total Annual Responses:* 6,500,000; *Total Annual Hours:* 541,667.

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Financial Statement of Debtor and Supporting Regulations in 42 CFR 405.376; *Use:* 42 CFR 405.376(g) requires that, ''* * * In determining whether a claim will be compromised, or collection action terminated, CMS will consider the following factors: * * * age and health of the debtor, present and potential income, inheritance prospects, possible concealment or fraudulent transfer of assets * * *'' Sections 1842(a)(1)(B) and (C) of the Social Security Act and 42 CFR 405.376(g) provide the authority for collection of this information.

In some instances a physician/supplier who is notified of a debt may allege inability to immediately repay the debt in full and may request an extended repayment schedule. Alternatively, the debtor may request a compromise settlement for less than the full amount due. Before establishing an extended repayment schedule or compromise settlement, the CMS's Regional Offices and the carrier must evaluate the provider's capacity to pay the debt. Accordingly, the provider is requested to complete a ''Financial Statement of Debtor'' form, CMS–379. *Form Number:* CMS–379 (OMB#: 0938–0270); *Frequency:* Reporting: Yearly; *Affected Public:* Business or other for-profit; *Number of Respondents:* 500; *Total Annual Responses:* 500; *Total Annual Hours:* 1000.

5. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* National Implementation of Hospital Consumer Assessment of Health Providers and Systems (HCAHPS); *Use:* The intent of the HCAHPS initiative is to provide a standardized survey instrument and data collection methodology for measuring patients' perspectives on hospital care. While many hospitals collect information on patient satisfaction, there is no national standard for collecting or publicly reporting this information that would enable valid comparisons to be made across all hospitals. In order to make ''apples to apples'' comparisons to support consumer choice, it is necessary to introduce a standard measurement approach. Hospital Consumer Assessment of Healthcare Providers and Systems, also known as the CAHPS Hospital Survey (HCAHPS) can be viewed as a core set of questions that hospitals can combine with their customized items. HCAHPS was developed and is being implemented under the auspices of the Hospital Quality Alliance, a private/public partnership that includes hospital associations, consumer groups, payors and government agencies that share a common interest in reporting on hospital quality.

Beginning in July 2007, participation in HCAHPS can affect the annual payment update for the inpatient prospective payment system (IPPS) hospitals participating in the Reporting Hospital Quality Data Annual Payment Update (RHQDAPU) program; *Form Number:* CMS–10102 (OMB#: 0938–0981); *Frequency:* Reporting: Monthly; *Affected Public:* Individuals or households; *Number of Respondents:* 2,820,000; *Total Annual Responses:* 2,820,000; *Total Annual Hours:* 329,940.

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 September 11, 2007.

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: July 3, 2007.

Michelle Shortt,

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

[FR Doc. E7–13412 Filed 7–12–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0265]

Global Harmonization Task Force, Study Groups 1 and 5; New Proposed and Final Documents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of several proposed and final documents that have been prepared by Study Groups 1 and 5 of the Global Harmonization Task Force (GHTF). These documents represent a harmonized proposal and recommendation from the GHTF Study Groups that may be used by governments developing and updating their regulatory requirements for medical devices. These documents are intended to provide information only and do not describe current regulatory requirements; elements of these documents may not be consistent with current U.S. regulatory requirements. FDA is requesting comments on these documents.

DATES: Submit written or electronic comments by October 11, 2007. After the 90 day period, written comments or electronic comments may be submitted at any time to the contact persons listed in this document.

ADDRESSES: Submit written requests for single copies of the guidance documents to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the