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

guidance. Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: *For information regarding Study Group 1*: Ginette Y. Michaud, Chairperson, GHTF, Study Group 1, Office of Device Evaluation Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3700.

For information regarding Study Group 5: Herbert Lerner, GHTF, Study Group 5, Office of Device Evaluation, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3641.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has participated in a number of activities to promote the international harmonization of regulatory requirements. In September 1992, a meeting was held in Nice, France by senior regulatory officials to evaluate international harmonization. This meeting led to the development of the organization now known as the Global Harmonization Task Force (GHTF) to facilitate harmonization. Subsequent meetings have been held on a yearly basis in various locations throughout the world.

The GHTF is a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. Since its inception, the GHTF has been comprised of representatives from five founding members grouped into three geographical areas: Europe, Asia-Pacific, and North America, each of which actively regulates medical devices using their own unique regulatory framework.

The objective of the GHTF is to encourage convergence at the global level of regulatory systems of medical devices to facilitate trade while preserving the right of participating members to address the protection of public health by regulatory means considered most suitable. One of the ways this objective is achieved is by identifying and developing areas of international cooperation to facilitate progressive reduction of technical and regulatory differences in systems established to regulate medical devices. In an effort to accomplish these objectives, the GHTF formed five study groups to draft documents and carry on other activities designed to facilitate global harmonization. This notice is a result of documents that have been developed by two of the Study Groups (1 and 5).

Study Group 1 was initially tasked with the responsibility of identifying differences between various regulatory systems. In 1995, the group was asked to propose areas of potential harmonization for premarket device regulations and possible guidance that could help lead to harmonization. As a result of its efforts, this group has developed proposed documents SG1(PD)/N045R12:2007 and SG1(PD)/N046R3:2007.

SG1(PD)/N045R12:2007 (proposed document) entitled ''Principles of In Vitro Diagnostic (IVD) Medical Devices Classification'' assists a manufacturer to allocate its IVD Medical Device to an appropriate risk class using a set of harmonized classification principles based on an IVD Medical Device's intended use. This document applies to IVD Medical Devices.

SG1(PD)/N046R3:2007 (proposed document) entitled ''Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices'' provides an overview of conformity assessment elements to demonstrate conformity to GHTF final document entitled ''Essential Principles of Safety and Performance for Medical Devices.'' ''Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices'' applies to IVD Medical Devices. It describes the evidence and procedures that may be used by the manufacturer to demonstrate that a medical device is safe and performs as intended by the manufacturer, and the process by which a Regulatory Authority, or Conformity Assessment Body, may confirm that the procedures are properly applied by the manufacturer.

Study Group 5 was initially tasked with the responsibility of developing guidance documents on the content and format for clinical investigation reports and on how to conduct and document a clinical evaluation. As a result of its efforts, this group has developed documents SG5/N1R8:2007 and SG5/N2R8:2007.

SG5/N1R8:2007 (final document) entitled ''Clinical Evidence—Key Definitions and Concepts'' introduces the concepts of clinical evaluation and clinical evidence, and examines the relationship between clinical investigation, clinical data, clinical evaluation, and clinical evidence. SG5/N2R8:2007 (final document) entitled ''Clinical Evaluation'' provides guidance on how to conduct the clinical evaluation of a medical device as part of the conformity assessment procedure prior to placing a medical device on the market, as well as to support its ongoing marketing.

II. Significance of Guidance

These documents represent recommendations from the GHTF study groups and do not describe regulatory requirements. FDA is making these documents available so that industry and other members of the public may express their views and opinions.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. The Center for Devices and Radiological Health (CDRH) maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. Information on the GHTF may be accessed at *http://www.ghtf.org*. The CDRH web site may be accessed at *http://www.fda.gov/cdrh*.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding these documents. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 5, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–13664 Filed 7–12–07; 8:45 am]

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