prescription drugs under the Medicare Part D benefit to Medicare beneficiaries. The data is used primarily for payment, and is used for claim validation as well as for other legislated functions such as quality monitoring, program integrity and oversight.

Form Number: CMS–10174 (OMB#: 0938–0982).

Frequency: Reporting—Monthly.

Affected Public: Business or other for-profits and not-for-profit institutions.

Number of Respondents: 747.

Total Annual Responses: 947,881,770.

Total Annual Hours: 1896.

(For policy questions regarding this collection contact Bobbie Knickman at 410–786–4161. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* New collection.

Title of Information Collection: Medicare Quality of Care Complaint Form.

Use: In accordance with Section 1154(a)(14) of the Social Security Act, Quality Improvement Organizations (QIOs) are required to conduct appropriate reviews of all written complaints submitted by beneficiaries concerning the quality of care received. The Medicare Quality of Care Complaint Form will be used by Medicare beneficiaries to submit quality of care complaints. This form will establish a standard form for all beneficiaries to utilize and ensure pertinent information is obtained by QIOs to effectively process these complaints.

Form Number: CMS–10287 (OMB#: 0938–New).

Frequency: Reporting—on occasion.

Affected Public: Individuals or households.

Number of Respondents: 3,500.

Total Annual Responses: 3,500.

Total Annual Hours: 583.

(For policy questions regarding this collection contact Tom Kessler at 410–786–1991. For all other issues call 410–786–1326.)

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

Title of Information Collection: External Quality Review Protocols.

Use: The results of Medicare reviews, Medicare accreditation services, and Medicaid external quality reviews will be used by States in assessing the quality of care provided to Medicaid beneficiaries by managed care organizations and to provide information on the quality of care provided to the general public upon request.

Form Number: CMS–R–305 (OMB#: 0938–0786).

Frequency: Reporting—Yearly.

Affected Public: State, Local or Tribal Governments.

Number of Respondents: 40.

Total Annual Responses: 40.

Total Annual Hours: 520,000.

(For policy questions regarding this collection contact Gary B. Jackson at 410–786–1218. For all other issues call 410–786–1326.)

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 by the OMB desk officer at the address below, no later than 5 p.m. on *September 21, 2009:*

OMB, Office of Information and Regulatory Affairs, *Attention:* CMS Desk Officer, *Fax Number:* (202) 395–6974, *E-mail: OIRA_submission@omb.eop.gov.*

Dated: August 14, 2009.

Michelle Shortt,

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

[FR Doc. E9–20127 Filed 8–20–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10198]

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:* Extension without change of a currently approved collection; *Title of Information Collection:* Creditable Coverage Disclosure to CMS On-Line Form and Instructions; *Use:* Most entities that currently provide prescription drug benefits to any Medicare Part D eligible individual must disclose to the CMS whether the prescription drug benefit that they offer is creditable. The disclosure is required to be provided annually and upon any change that affects whether the coverage is creditable prescription drug coverage. CMS released a Disclosure to CMS Guidance Paper and a disclosure to CMS notification on-line form in January 2006.

Section 1860D–1 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and implementing regulations at 42 CFR 423.56 requires that entities that offer prescription drug benefits under any of the types of coverage described in 42 CFR 423.56(b) provide a disclosure of creditable coverage to CMS informing us whether such coverage meets the actuarial requirements specified in guidelines provided by CMS. *Form Number:* CMS–10198 (OMB#: 0938–1013); *Frequency:* Reporting—Yearly and Semi-annually; *Affected Public:* Federal Government, Business or other for-profits and not-for-profit institutions, and State, Local, or Tribal Governments; *Number of Respondents:* 87,500; *Total Annual Responses:* 87,500; *Total Annual Hours:* 7,291.7. (For policy questions regarding this collection contact James Mayhew at 410–786–9244. For all other issues call 410–786–1326.)

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

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration,

comments and recommendations must be submitted in one of the following ways by *October 20, 2009:*

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, *Attention:* Document Identifier/OMB Control Number (CMS–10198), Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: August 14, 2009.

Michelle Shortt,

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

[FR Doc. E9–20128 Filed 8–20–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0391]

Clinical Investigator Training Course

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Office of Critical Path Programs and the Clinical Trials Transformation Initiative (CTTI) are co-sponsoring a 3-day training course for clinical investigators on scientific, ethical, and regulatory aspects of clinical trials. This training course is intended to provide investigators with expertise in the design, conduct, and analysis of clinical trials; improve the quality of clinical trials; and enhance the safety of trial participants. Senior FDA staff will communicate directly with clinical investigators on issues of greatest importance for successful clinical research.

DATES: The training course will be held on November 16 and 17, 2009, from 8 a.m. to 5 p.m. and on November 18, 2009, from 8 a.m. to 3:30 p.m.

ADDRESSES: The course will be held at the National Labor College, 10000 New Hampshire Ave., Silver Spring, MD 20903.

FOR FURTHER INFORMATION CONTACT: Devota DeMarco, Office of Critical Path Programs (HF–18), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3605, *Devota.DeMarco@fda.hhs.gov*; or

Nancy Stanisic, Office of Critical Path Programs (HF–18), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1660, *Nancy.Stanisic@fda.hhs.gov*.

Registration: Register by November 2, 2009, at the registration/information Web site at *https://www.trials transformation.org/fda-clinical-investigator-training-course/* or by fax at 919–660–1769. Registration materials, payment procedures, accommodation information, and a detailed description of the course can be found at the registration/information Web site. The registration fee is $300 per person. The fee includes course materials and onsite lunch. Early registration is recommended because seating is limited. There will be no onsite registration. If you need special accommodations due to a disability, please contact one of the persons listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

SUPPLEMENTARY INFORMATION:

I. Background

Clinical trial investigators play a critical role in the development of medical products. They bear the responsibility for ensuring the safe and ethical treatment of study subjects and for acquiring adequate and reliable data to support regulatory decisions. This course is intended to assist clinical investigators in understanding what preclinical and clinical information is needed to support the investigational use of medical products, as well as the scientific, regulatory, and ethical considerations involved in the conduct of clinical trials. The course will cover a wide variety of key topics, including material on novel safety concerns, adverse event monitoring, compliance with the legal and ethical obligations of clinical research, and acceptable scientific and analytic standards in the design and conduct of clinical studies. The faculty will include a diverse representation of senior FDA staff, enabling FDA to communicate directly with clinical investigators on issues of greatest importance for successful clinical research.

II. Description of the Training Course

A. Purpose

The training course is designed to provide clinical investigators with an overview of the following topics:

- The essential toxicological, pharmacological, and manufacturing data to support investigational use in humans;
- Fundamental issues in the design and conduct of clinical trials;
- Statistical and analytic considerations in the interpretation of trial data;
- Appropriate safety evaluation during studies; and
- The ethical considerations and regulatory requirements for clinical trials.

In addition, the course should:

- Foster a cadre of clinical investigators with knowledge, experience, and commitment to investigational medicine;
- Promote communication between clinical investigators and FDA;
- Enhance investigators' understanding of FDA's role in experimental medicine; and
- Improve the quality of data while enhancing subject protection in the performance of clinical trials.

B. Proposed Agenda

The course will be conducted over 3 days and will comprise approximately 26 lectures, each lasting between 30 and 45 minutes. Two sessions of case studies will be included for which participants will be expected to do preparatory reading and answer questions. The course will be presented mainly by senior FDA staff, with guest lecturers presenting selected topics.

On day one, the course will address the role of FDA in clinical studies, regulatory considerations for clinical trials, and review of the material generally appearing in an ''investigator's brochure,'' i.e., the preclinical information (toxicology, animal studies, and chemistry/manufacturing information) that supports initial clinical trials in humans. Presentations will also discuss the role of clinical pharmacology in early clinical studies and how this information is used in the design of subsequent studies. Day two will include discussions of scientific, statistical, ethical, and regulatory aspects of clinical studies. Day three will include discussions of safety assessment in clinical trials, including hepatic and cardiovascular safety, approaches to special populations (e.g., pregnant women and pediatrics), and the role of personalized medicine and new scientific techniques in medical product development.