Information Collection: National Medicare & You Education Program (NMEP) Survey of Medicare Beneficiaries *Use:* The Centers for Medicare and Medicaid Services is requesting a reinstatement of this information collection request to continue to collect information from Medicare beneficiaries, caregivers, health care providers, and health information providers. The collection of information was inadvertently discontinued in December 2008; however, as stated earlier, we are currently seeking a reinstatement with change as we have revised the collection instrument. It is critical for this agency to obtain feedback from the aforementioned groups so that the agency can accurately assess the needs of the Medicare audience. Using random digit dial and/or an administrative sample, members of the Medicare audience will be called and asked to complete the survey via telephone. The results of this survey will be compiled and studied so that communication may be amended to benefit Medicare's audience. The survey has the following objectives: to assess satisfaction with and knowledge of the Medicare program; to gather information on health behaviors and quality of health care; to determine the most used source for Medicare information; and to gather information from health care provider and health information providers. *Form Number:* CMS–R–254 (OMB# 0938–0738); *Frequency:* Once; *Affected Public:* Individuals and Households, Private Sector—Business or other for-profits; *Number of Respondents:* 7,000; *Total Annual Responses:* 7,000; *Total Annual Hours:* 1,750.

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 by the OMB desk officer at the address below, no later than 5 p.m. on September 14, 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 7, 2009.

Michelle Shortt,

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

[FR Doc. E9–19537 Filed 8–13–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–284 and CMS–10190]

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 without change of a currently approved collection; *Title of Information Collection:* Medicaid Statistical Information System; *Use:* State data are reported by the Federally mandated electronic process, known as (MSIS) Medical Statistical Information System. These data are the basis of actuarial forecasts for Medicaid service utilization and costs; of analysis and cost savings estimates required for legislative initiatives relating to Medicaid and for responding to requests for information from CMS components, the Department, Congress and other customers.

Form Number: CMS–R–284 (OMB#: 0938–0345); *Frequency:* Reporting—Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 204; *Total Annual Hours:* 2,040. (For policy questions regarding this collection contact Denise Franz 410–786–6117. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Section 1901 of the Act (42 U.S.C. 1396) requires that States must establish a State plan for medical assistance that are approved by the Secretary to carry out the purposes of title XIX. The DRA provides States with numerous flexibilities in operating their State Medicaid programs. The intent of these flexibilities is to provide States with program alternatives that allow them to provide the most appropriate health care coverage that meets beneficiary needs, while at the same time curtailing State and Federal spending. Except for the documentation of citizenship requirements, States can submit SPAs to CMS to effectuate these changes to their Medicaid programs. CMS provided State Medicaid Directors letters providing guidance on these provisions and the implementation of the DRA and associated SPA templates for use by States to modify their Medicaid State plans if they choose to implement these flexibilities. Under this process, the end result is the State burden will be reduced significantly. To implement these flexibilities, a collection of information to effectuate these changes is required. Therefore, State Medicaid agencies will complete the templates to effectuate the changes. CMS will review the information to determine if the State has met all of the requirements of the DRA provisions the States choose to implement. If the requirements are met, CMS will approve the amendments to the State's Title XIX plan giving the State the authority to implement the flexibilities. For a State to receive Medicaid Title XIX funding, there must be an approved Title XIX State plan. Five templates were created to assist States in effectuating these flexibilities through modifications to the State plan. The Children's Health Insurance Program Reauthorization Act (CHIPRA) of 2009, enacted on February 4, 2009, corrected language in section 6044 (Alternative Benefit Packages) of the DRA as if these amendments were included in the DRA, and subsequently amended section 1937 ''State Flexibility for Medicaid Benefit Packages.'' We have modified the preprints to reflect these statutory changes. *Form Number:* CMS–10190 (OMB#: 0938–0993); *Frequency:* Reporting—Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 16; *Total*

Annual Hours: 699. (For policy questions regarding this collection contact Fran Crystal at 410–786–1195. 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 13, 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–R–284 and CMS–10190), Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: August 7, 2009.

Michelle Shortt,

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

[FR Doc. E9–19539 Filed 8–13–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0342]

International Conference on Harmonisation; Draft Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 10 on Polyacrylamide Gel Electrophoresis General Chapter; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 10: Polyacrylamide Gel Electrophoresis General Chapter.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance provides the results of the ICH Q4B evaluation of the Polyacrylamide Gel Electrophoresis General Chapter harmonized text from each of the three pharmacopoeias (United States, European, and Japanese) represented by the Pharmacopoeial Discussion Group (PDG). The draft guidance conveys recognition of the three pharmacopoeial methods by the three ICH regulatory regions and provides specific information regarding the recognition. The draft guidance is intended to recognize the interchangeability between the local regional pharmacopoeias, thus avoiding redundant testing in favor of a common testing strategy in each regulatory region. This draft guidance is the tenth annex to the core Q4B guidance, which was made available in the **Federal Register** of February 21, 2008 (73 FR 9575).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by October 13, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; or the Office of Communication and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling the Center for Biologics Evaluation and Research at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Submit written comments on the draft 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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Robert H. King, Sr., Center for Drug Evaluation and Research (HFD–003), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4150, Silver Spring, MD 20993–0002, 301–796–1242; or

Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–0373.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is