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 *December 8, 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, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: October 1, 2009.

Michelle Shortt,

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

[FR Doc. E9–24236 Filed 10–8–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10287]

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:* 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.)

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 November 9, 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: October 1, 2009.

Michelle Shortt,

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

[FR Doc. E9–24233 Filed 10–8–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (0MB) approve the proposed information collection project: ''Medical Expenditure Panel Survey (MEPS) Household Component and the MEPS Medical Provider Component through 2012.'' In accordance with the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)), AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on May 6, 2009 and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by November 9, 2009.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by e-mail at *OIRA_submissionomb.eop.gov* (attention: AHRQ's desk officer).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by e-mail at *doris.lefkowitz@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

''Medical Expenditure Panel Survey (MEPS) Household Component and the MEPS Medical Provider Component Through 2012''

AHRQ seeks to renew the Medical Expenditure Panel Survey Household Component (MEPS–HC) and the MEPS Medical Provider Component (MEPS–MPC) through the year 2012. For over thirty years, the results of the MEPS and its predecessor surveys (the 1977 National Medical Care Expenditure Survey, the 1980 National Medical Care Utilization and Expenditure Survey and

the 1987 National Medical Expenditure Survey) have been used by OMB, DHHS, Congress and a wide number of health services researchers to analyze health care use, expenses and health policy. AHRQ is authorized to conduct the MEPS pursuant to 42 U.S.C. 299b–2.

Major changes continue to take place in the health care delivery system. The MEPS is needed to provide information about the current state of the health care system as well as to track changes over time. The current MEPS design, unlike the previous periodic surveys, permits annual estimates of use of health care and expenditures and sources of payment for that health care. It also permits tracking individual change in employment, income, health insurance and health status over two years. The use of the National Health Interview Survey (NHIS) as a sampling frame expands the surveys' analytic capacity by providing another data point for comparisons over time.

The MEPS–HC and MEPS–MPC are two of three components of the MEPS:

- MEPS–HC is a sample of households participating in the National Health Interview Survey (NHIS) in the prior calendar year and are interviewed 5 times over a 2½ year period. These 5 interviews yield two years of information on use of and expenditures for health care, sources of payment for that health care, insurance status, employment, health status and health care quality.
- MEPS–MPC collects information from medical and financial records maintained by hospitals, physicians, pharmacies, health care institutions, and home health agencies named as sources of care by household respondents.
- Insurance Component (MEPS–IC): The MEPS–IC collects information on establishment characteristics, insurance offerings and premiums from employers. The MEPS–IC is conducted by the Census Bureau for AHRQ and is cleared separately.

This request is for the MEPS–HC and MEPS–MPC only.

Method of Collection

The MEPS is designed to meet the need for information to estimate health expenses, insurance coverage, access, use and quality. Households selected for participation in the MEPS are interviewed five times in person. These rounds of interviewing are spaced about 5 months apart. The interview will take place with a family respondent who will report for him/herself and for other family members.

After a preliminary mail contact containing an advance letter, households will be mailed MEPS record keeping materials (a calendar) and a DVD and brochure. After the advance contact, households will be contacted for the first of five in-person interviews. The interviews are conducted as a computer assisted personal interview (CAPI). The CAPI instrument is organized as a core instrument that will repeat unchanged in each of the rounds. Additional sections are asked only once a year and provide greater depth. Dependent interviewing methods in which respondents are asked to confirm or revise data provided in earlier interviews will be used to update information such as employment and health insurance data after the round in which such data are usually collected. The main data collection modules for the MEPS–HC are as follows:

Household Component Core Instrument. The core instrument collects data about persons in sample households. Topical areas asked in each round of interviewing include condition enumeration, health status, health care utilization including prescribed medicines, expense and payment, employment, and health insurance. Other topical areas that are asked only once a year include access to care, priority conditions, income, assets, satisfaction with health plans and providers, children's health, adult preventive care. While many of the questions are asked about the entire reporting unit (RU), which is typically a family, only one person normally provides this information.

Adult Self Administered Questionnaire. A brief self-administered questionnaire (SAQ), administered once a year in rounds 2 and 4, will be used to collect self-reported (rather than through household proxy) information on health status, health opinions and satisfaction with health care for adults 18 and older.

Diabetes Care SAQ. A brief self administered questionnaire on the quality of diabetes care is administered once a year in rounds 3 and 5 to persons identified as having diabetes.

Permission forms for the MEPS–MPC. As in previous panels of the MEPS, we will ask respondents for permission to obtain supplemental information from their medical providers (hospitals, physicians, health care institutions, home health agencies and pharmacies).

MEPS–MPC Instruments

The main objective of the MEPS–MPC is a collection of data from medical providers that will serve as an imputation source of medical expenditure and source of payment data reported by household respondents. This data will supplement, replace and verify information provided by household respondents about the charges, payments, and sources of payment associated with specific health care encounters. The questionnaires used in the MEPS–MPC vary according to type of provider. The data collection instruments are as follows:

Home Care for Health Care Providers Questionnaire. This questionnaire is used to collect data from home health care agencies which provide medical care services to household respondents. Information collected includes type of personnel providing care, hours or visits provided per month, and the charges and payments for services received.

Home Care Provider Questionnaire for Non-Health Care Providers. This is used to collect information about services provided in the home by non-health care workers to household respondents because of a medical condition; for example, cleaning or yard work, transportation, shopping, or child care.

Office-based Providers Questionnaire. This questionnaire is for the office-based physician sample, including doctors of medicine (MDs) and osteopathy (DOs), as well as providers practicing under the direction or supervision of an MO or DO (*e.g.,* physician assistants and nurse practitioners working in clinics). Providers of care in private offices as well as staff model HMOs are included.

Separately Billing Doctors Questionnaire. Information from physicians identified by hospitals as providing care to sampled persons during the course of inpatient, outpatient department or emergency room care, but who bill separately from the hospital, is collected in this questionnaires.

Hospitals Questionnaire. This questionnaire is used to collect information about hospital events, including inpatient stays, outpatient department, and emergency room visits. Hospital data are collected not only from the billing department, but from medical records and administrative records departments as well. Medical records departments are contacted to determine the names of all the doctors who treated the patient during a stay or visit. In many cases, the hospital administrative office also has to be contacted to determine whether the doctors identified by medical records billed separately from the hospital itself.

Institutions Questionnaire. This questionnaire is used to collect data from health care institutions providing care to sampled persons and includes nursing homes, assisted living facilities, rehabilitation facilities, as well as any

other health care facilities providing health care to a sampled person.

Pharmacies Questionnaire. This questionnaire requests the prescription name, NDC code, date prescription was filled, payments by source, prescription strength, form and quantity, and person for whom the prescription was filled. Most pharmacies have the requested information available in electronic format and respond by providing a computer generated printout of the patient's prescription information. If the computerized form is unavailable, the pharmacy can report their data to a telephone interviewer.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in the MEPS–HC and MEPS–MPC. The MEPS–HC Core Interview will be completed by 15,000 ''family level'' respondents, also referred to as RU respondents. Since the MEPS–HC consists of 5 rounds of interviewing covering a full two years of data, the annual average number of responses per respondent is 2.5 responses per year. The MEPSHC core requires an average response time of 1½ hours to administer. The Adult SAQ will be completed once a year by each person in the RU that is 18 years old and older, an estimated 21,000 persons. The Adult SAQ requires an average of 7 minutes to complete. The Diabetes care SAQ will be completed once a year by each person in the RU identified as having diabetes, an estimated 1,800 persons and takes about 3 minutes to complete. Permission forms for the MEPS–MPC will be completed once for each medical provider seen by any RU member. Each of the 15,000 RUs in the MEPS–HC will complete an average of 5.2 forms, which require about 3 minutes each to complete. The total annual burden hours for the MEPS–HC is estimated to be 62,690 hours.

The MEPS–MPC uses 7 different questionnaires; 6 for medical providers and 1 for pharmacies. Each questionnaire is relatively short and requires 3 to 5 minutes to complete.

The total annual burden hours for the MEPS–MPC is estimated to be 20,077 hours. The total annual burden hours for the MEPS–HC and MPC is estimated to be 82,767 hours.

Exhibit 2 shows the estimated annual cost burden associated with the respondents' time to participate in this information. The annual cost burden for the MEPS–HC is estimated to be $1,226,216; the annual cost burden for the MEPS–MPC is estimated to be $285,965.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
MEPS–HC				
MEPS–HC Core Interview	15,000	2.5	1.5	56,250
Adult SAQ	21,000	1	7/60	2,450
Diabetes care SAQ	1,800	1	3/60	90
Permission forms for the MEPS–MPC	15,000	5.2	3/60	3,900
Subtotal for the MEPS–HC	52,800	na	na	62,690
MEPS–MPC				
Home care for health care providers questionnaire	441	6.5	5/60	239
Home care for non-health care providers questionnaire	23	6.6	5/60	13
Office-based providers questionnaire	13,665	5.8	5/60	6,605
Separately billing doctors questionnaire	12,450	2	3/60	1,245
Hospitals questionnaire	5,402	6.5	5/60	2,926
Institutions (non-hospital) questionnaire	72	1.5	5/60	9
Pharmacies questionnaire	7,760	23.3	3/60	9,040
Subtotal for the MEPS–MPC	39,813	na	na	20,077
Grand Total	92,613	na	na	82,767

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
MEPS–HC				
MEPS–HC Core Interview	15,000	56,250	$19.56	$1,100,250
Adult SAQ	21,000	2,450	19.56	47,922
Diabetes care SAQ	1,800	90	19.56	1,760
Permission forms for the MEPS–MPC	15,000	62,690	19.56	76,284
Subtotal for the MEPS–HC	52,800	62,690	na	1,226,216
MEPS–MPC				
Home care for health care providers questionnaire	441	239	14.24	3,403
Home care for non-health care questionnaire	23	13	19.56	254
Office-based providers questionnaire	13,665	6,605	14.24	94,055
Separately billing doctors questionnaire	12,450	1,245	14.24	17,729
Hospitals questionnaire	5,402	2,926	14.24	41,666

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Form name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Institutions (non-hospital) questionnaire	72	9	14.24	128
Pharmacies questionnaire	7,760	9,040	14.24	128,730
Subtotal for the MEPS–MPC	39,813	20,077	na	285,965
Grand Total	92,613	82,767	na	1,512,181

*Based upon the mean of the average wages for Healthcare Support Workers, All Other (31–9099) and All Occupations (00–0000), Occupational Employment Statistics, May 2007 National Occupational Employment and Wage Estimates United States, U.S. Department of Labor, Bureau of Labor Statistics. *http://www.bls.gov/oes/current/oes_nat.htm#b29–0000.*

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the total and annualized cost of this information collection. The cost associated with the design and data collection of the MEPS–HC and MEPS–MPC is estimated to be $47.6 million in each of the next three fiscal years.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost Component	Total cost (millions)	Annualized cost (millions)
Sampling Activities	$2.79	$0.93
Interviewer Recruitment and Training	8.52	2.84
Data Collection Activities	86.7	28.9
Data Processing	21.39	7.13
Production of Public Use Data Files	19.53	6.51
Project Management	3.93	1.31
Total	142.8	47.6

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for 0MB approval of the proposed information collection. All comments will become a matter of public record.

Dated: September 16, 2009.

Carol M. Clancy,

Director.

[FR Doc. E9–24305 Filed 10–8–09; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2009–E–0073 and FDA–2009–E–0015]

Determination of Regulatory Review Period for Purposes of Patent Extension; ENTEREG; U.S. Patent Nos. 5,250,542 and 5,434,171

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ENTEREG and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of patents which claim that human drug product.

ADDRESSES: Submit written comments and petitions 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*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug