

30 minutes. The self-administered questionnaire will be completed by the focus group participants and the adolescent participants of the semi-structured interviews, and will take

about 6 minutes to complete. The total burden for all participants is estimated to be 134 hours.

Exhibit 2 shows the estimated annualized cost burden for the

respondent's time to participate in the project. The total cost is estimated to be \$2,001.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Data collection mode	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Screening form	124	1	3/60	6
Self-administered questionnaire	84	1	6/60	8
Focus group with parents of children 68 years of age (4 groups of 8 participants)	32	1	1.5	48
Focus group with adults (4 groups of 8 participants)	32	1	1.5	48
Semi-structured interviews with adolescents (13 to 20 years of age)	20	1	30/60	10
Semi-structured interview with primary care physicians	20	1	20/60	7
Semi-structured interviews with pharmacists	20	1	20/60	7
Total	332			134

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Data collection mode	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Screening form	124	6	\$10.30	\$62
Self-administered questionnaire	84	8	10.30	82
Focus groups with parents of children 68 years of age (4 groups of 8 participants)	32	48	10.30	494
Focus groups with adults (4 groups of 8 participants)	32	48	10.30	494
Semi-structured interviews with adolescents (13 to 20 years of age)	20	10	10.30	103
Semi-structured interviews with primary care physicians	20	7	61.10	428
Semi-structured interviews with pharmacists	20	7	48.22	338
Total	332	134		2,001

* Patient average hourly wage based on the average per capita income of \$21,435 (computed into an hourly wage rate of \$10.30) in Harris County, Texas where the study will take place. Provider hourly wage based on the following estimates from National Compensation Survey: Occupational wages in the United States 2006, U.S. Department of Labor, Bureau of Labor Statistics: primary care physician = \$61.10/hour; pharmacist = \$48.22/hour.

Estimates of Annualized Cost to the Government

Exhibit 3 shows the estimated cost to the Federal government for this six-month project. The total cost is \$164,440. This amount includes all direct and indirect costs of the design, data collection, analysis, and reporting phase of the study.

EXHIBIT 3—ESTIMATED COST

Cost component	Total cost
Project Development	\$13,250
Data Collection Activities	61,699
Data Processing and Analysis ...	14,080
Publication of Results	750
Project Management	17,000
Overhead	57,661
Total	164,440

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, quality improvement and 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 OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: April 23, 2009.

Carolyn M. Clancy,
Director.

[FR Doc. E9-10407 Filed 5-5-09; 8:45 am]

BILLING CODE 4160-90-M

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 (OMB) 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.

DATES: Comments on this notice must be received by July 6, 2009.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by e-mail at doris.lefkowitz@ahrq.hhs.gov.

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 that 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, childrens 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 stays, outpatient department or emergency room care, but who bill separately from the hospital, is collected in this questionnaire.

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 MEPS-HC core requires an average response time of 1

and Y2 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-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 collection. 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	ia	20,077
Grand Total	92,613	na	ia	82,767

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form mode	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

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Form mode	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
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	3,900	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 providers 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
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 (in million)	Annualized cost (in million)
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 OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: April 27, 2009.

Carolyn M. Clancy,

Director.

[FR Doc. E9-10406 Filed 5-5-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2007-D-0487] (formerly Docket No. 2007D-0260)

Compliance Policy Guide; "Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a Compliance Policy Guide (CPG) entitled "Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002." The CPG provides written guidance to FDA's and