its oversight review, ORI found that Norma Couvertier, former Research Assistant II, APT Foundation in New Haven, Connecticut, engaged in research misconduct in research supported by National Institute of Drug Abuse (NIDA), National Institutes of Health (NIH), award R37 DA015969.

Specifically, ORI found that Ms. Couvertier engaged in research misconduct by falsifying and fabricating data that were reported on Participant Urine Monitoring and Breathalyzer Result Forms (CRFs) completed by the Respondent for thirty two (32) of the enrolled study participants in the computer Based Training in Cognitive Behavioral Therapy (CBT4CBT) research study. A total of 253 alcohol breathalyzer (BALS) results were recorded for the 32 participants as being 0.000 indicating no alcohol detected, rather than the code 999 used when no breathalyzer test was done.

ORI also found that Ms. Couvetier, on 253 occasions, with 32 different study participants, falsified alcohol breathalyzer test results and knowingly and consistently entered a false negative test (indicated by 0.000) rather than identifying the result as a missing data collection (indicated by code 999).

ORI acknowledges Ms. Couvetier's verbal admissions and willingness to cooperate and assist during the APT Foundation's investigation.

Ms. Couvertier has entered into a Voluntary Settlement Agreement in which she has voluntarily agreed, for a period of three (3) years, beginning on September 18, 2009:

(1) To exclude herself from serving in any advisory capacity to the U.S. Public Health Service (PHS), including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant;

(2) that any institution that submits an application for PHS support for a research project on which the Respondent's participation is proposed or that uses her in any capacity on PHS-supported research or that submits a report of PHS-funded research in which she is involved must concurrently submit a plan for supervision of her duties to ORI. The supervisory plan must be designed to ensure the integrity of her research contribution. Respondent agreed that she will not participate in any PHS-supported research until such a supervisory plan is approved by ORI.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852. (240) 453–8800.

John Dahlberg,

Director, Division of Investigative Oversight, Office of Research Integrity.

[FR Doc. E9–24392 Filed 10–8–09; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10142, CMS–R–262, CMS–10300, CMS–10298 and CMS–10294]

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:* Revision of a currently approved collection; *Title of Information Collection:* CY 2011 Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); *Use:* Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), and implementing regulations at 42 CFR, Medicare Advantage organizations (MAO) and Prescription Drug Plans are required to submit an actuarial pricing ''bid'' for each plan offered to Medicare beneficiaries for approval CMS.

MAOs and PDPs use the Bid Pricing Tool (BPT) software to develop their actuarial pricing bid. The information provided in the BPT is the basis for the plan's enrollee premiums and CMS payments for each contract year. The tool collects data such as medical expense development (from claims data and/or manual rating), administrative expenses, profit levels, and projected plan enrollment information. By statute, completed BPTs are due to CMS by the first Monday of June each year.

CMS reviews and analyzes the information provided on the Bid Pricing Tool. Ultimately, CMS decides whether to approve the plan pricing (*i.e.,* payment and premium) proposed by each organization. Refer to the supporting document attachment ''C'' for a list of changes. *Form Number:* CMS–10142 (OMB#: 0938–0944); *Frequency:* Reporting—Yearly; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 550; *Total Annual Responses:* 6,050; *Total Annual Hours:* 42,350. (For policy questions regarding this collection contact Diane Spitalnic at 410–786–5745. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* CY 2011 Plan Benefit Package (PBP) Software and Formulary Submission *Use:* Under the Medicare Modernization Act (MMA), Medicare Advantage (MA) and Prescription Drug Plan (PDP) organizations are required to submit plan benefit packages for all Medicare beneficiaries residing in their service area. The plan benefit package submission consists of the PBP software, formulary file, and supporting documentation, as necessary. MA and PDP organizations use the PBP software to describe their organization's plan benefit packages, including information on premiums, cost sharing, authorization rules, and supplemental benefits. They also generate a formulary to describe their list of drugs, including information on prior authorization, step therapy, tiering, and quantity limits. Additionally, CMS uses the PBP and formulary data to review and approve the plan benefit packages proposed by each MA and PDP organization.

CMS requires that MA and PDP organizations submit a completed PBP and formulary as part of the annual bidding process. During this process, organizations prepare their proposed plan benefit packages for the upcoming contract year and submit them to CMS for review and approval. Based on operational changes and policy clarifications to the Medicare program and continued input and feedback by the industry, CMS has made the necessary changes to the plan benefit package submission. Refer to the supporting document ''Appendix B'' for

a list of changes. *Form Number:* CMS–R–262 (OMB#: 0938–0763); *Frequency:* Reporting—Yearly; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 475; *Total Annual Responses:* 4988; *Total Annual Hours:* 12,113. (For policy questions regarding this collection contact Sara Walters at 410–786–3330. For all other issues call 410–786–1326.)

3. *Type of Information Collection Request:* New collection; *Title of Information Collection:* State Plan Amendment Templates for Additional State Plan Option for Providing Premium Assistance under Title XIX and XXI; *Use:* Section 301 of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA), Public Law 111–3, adds Section 2105(c)(10) of the Social Security Act effective April 1, 2009, to offer States a new option to provide premium assistance subsidies to enroll targeted low-income individuals under age 19, and their parents in qualified employer-sponsored coverage. To elect this option, a State Children's Health Insurance Program agency will complete the template pages and submit it for approval as part of a State plan amendment. *Form Number:* CMS–10300 (OMB#: 0938–New); *Frequency:* Reporting—Once and On occasion; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 51; *Total Annual Responses:* 51; *Total Annual Hours:* 255. (For policy questions regarding this collection contact Stacey Green at 410–786–6102. For all other issues call 410–786–1326.)

4. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Data Collection For Developing Outpatient Therapy Payment Alternatives (DOTPA) ; *Use:* In Section 545 of the Benefits Improvement and Protection Act (BIPA) of 2000, the Congress required the Secretary of the Department of Health and Human Services to report on the development of standardized assessment instruments for outpatient therapy. Currently, CMS does not collect these data. The purposes of this project are to identify, collect, and analyze therapy-related information tied to beneficiary need and the effectiveness of outpatient therapy services that is currently unavailable to CMS. The ultimate goal is to develop payment method alternatives to the current financial cap on Medicare outpatient therapy services. *Form Number:* CMS–10298 (OMB#: 0938–New); *Frequency:* Reporting—Yearly; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 190; *Total Annual Responses:* 38,632; *Total Annual Hours:* 13,658. (For policy questions regarding this collection contact David Bott at 410–786–0249. For all other issues call 410–786–1326.)

5. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Program Evaluation of the Eighth and Ninth Scope of Work Quality Improvement Organization Program; *Use:* The statutory authority for the Quality Improvement Organization (QIO) Program is found in Part B of Title XI of the Social Security Act, as amended by the Peer Review Improvement Act of 1982. The Social Security Act established the Utilization and Quality Control Peer Review Organization Program, now known as the QIO Program. The statutory mission of the QIO Program, as set forth in Title XVIII—Health Insurance for the Aged and Disabled, Section 1862(g) of the Social Security Act—is to improve the effectiveness, efficiency, economy, and quality of services delivered to Medicare beneficiaries. The quality strategies of the Medicare QIO Program are carried out by specific QIO contractors working with health care providers in their state, territory, or the District of Columbia. The QIO contract contains a number of quality improvement initiatives that are authorized by various provisions in the Act. As a general matter, Section 1862(g) of the Act mandates that the secretary enter into contracts with QIOs for the purpose of determining that Medicare services are reasonable and medically necessary and for the purposes of promoting the effective, efficient, and economical delivery of health care services and of promoting the quality of the type of services for which payment may be made under Medicare. CMS interprets the term ''promoting the quality of services'' to involve more than QIOs reviewing care on a case-by-case basis, but to include a broad range of proactive initiatives that will promote higher quality. CMS has, for example, included in the SOW tasks in which the QIO will provide technical assistance to Medicare-participating providers and practitioners in order to help them improve the quality of the care they furnish to Medicare beneficiaries. Additional authority for these activities appears in Section 1154(a)(8) of the Act, which requires that QIOs perform such duties and functions, assume such responsibilities, and comply with such other requirements as may be required by the Medicare statute. CMS regards survey activities as appropriate if they will directly benefit Medicare beneficiaries. In addition, Section 1154(a)(10) of the Act specifically requires that the QIOs ''coordinate activities, including information exchanges, which are consistent with economical and efficient operation of programs among appropriate public and private agencies or organizations, including other public or private review organizations as may be appropriate.'' CMS regards this as specific authority for QIOs to coordinate and operate a broad range of collaborative and community activities among private and public entities, as long as the predicted outcome will directly benefit the Medicare program.

The purpose of the study is to design and conduct an analysis evaluating the impact on national and regional health care processes and outcomes of the Ninth Scope of Work QIO Program. The QIO Program is national in scope and scale and affects the quality of healthcare of 43 million elderly and disabled Americans. CMS will conduct an impact and process analysis using data from multiple sources: (1) Primary data collected via in-depth interviews, focus groups, and surveys of QIOs, health care providers, and other stakeholders; (2) secondary data reported by QIOs through CMS systems; and (3) CMS administrative data. The findings will be presented in a final report as well as in other documents and reports suitable for publication in peer-review journals. This request relates to the following data collections: (1) Survey of QIO directors and theme leaders; (2) Survey of hospital QI directors and nursing home administrators; (3) focus groups with Medicare beneficiaries; and (4) in-person and telephone discussions with QIO staff, partner organizations, health care providers, and community health leaders. Form Number: CMS–10294 (OMB# 0938–New); *Frequency:* Occasionally; *Affected Public:* Business or other for-profits, and Medicare beneficiaries; *Number of Respondents:* 3,343; *Total Annual Responses:* 3,343; *Total Annual Hours:* 1,707. (For policy questions regarding this collection contact Robert Kambic at 410–786–1515. 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 *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