| Forms (if necessary) | Type of respondent | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|---|---|---|---|---|
| Total | | | | | 1,116 |

**Seleda Perryman,**

*Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.*

[FR Doc. E9–24470 Filed 10–8–09; 8:45 am]

**BILLING CODE 4150–37–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

**[Document Identifier 0990–0346]**

### Agency Information Collection Request; 60-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed information collection request 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. To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov,* or call the Reports Clearance Office on (202) 690–6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above e-mail address within 60 days.

*Proposed Project:* HITECH Act Breach Notification—OMB No. 0990–0346–Extension—Office of Civil Rights.

*Abstract:* The Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5) requires the Office for Civil Rights to collect information regarding breaches discovered by covered entities and their business associates under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule (45 C.F.R. Part 160 and Subparts A and E of Part 164). ARRA was enacted on February 17, 2009. The Department of Health and Human Services (HHS) issued interim final regulations on August 24, 2009 (74 FR 42740), which became effective September 23, 2009, to require HIPAA covered entities and their business associates to provide notification in the case of breaches of unsecured protected health information. Section 164.404 of this interim final regulation requires HIPAA covered entities to notify affected individuals of a breach of their unsecured protected health information and, in some cases, to notify the media of such breaches pursuant to § 164.406. Section 164.408 requires covered entities to provide the Secretary with immediate notice of all breaches of unsecured protected health information involving more than 500 individuals. Additionally, the Act requires covered entities to provide the Secretary with an annual log of all breaches of unsecured protected health information that involve less than 500 individuals. Finally, business associates must notify the covered entity of any breaches that occur subject to § 164.410.

**Estimated Annualized Burden Table**

| Type of respondent | Number of respondents | Average number of responses per respondent | Average burden hours per response | Total burden hours |
|---|---|---|---|---|
| Individual Notice—Written and E-mail Notice (drafting, preparing, sending, and documenting notification) | 106 | 1 | 206 | 21,836 |
| 500 or More Affected Individuals (investigating and documenting breach) | 56 | 1 | 44 | 2,464 |
| Less than 500 Affected Individuals (investigating and documenting breach) | 50 | 1 | 8 | 400 |
| Individual Notice—Substitute Notice (posting or publishing) | 70 | 1 | 1 | 70 |
| Individual Notice—Substitute Notice (toll-free number) | 70 | 1 | 3,438 | 240,660 |
| Media Notice | 56 | 1 | 1 | 56 |
| Notice to Secretary (notice for breaches affecting 500 or more individuals and annual notice and maintenance of annual log) | 106 | 1 | 140/60 | 247 |
| TOTAL | | | | 265,733 |

**Seleda Perryman,**

*Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.*

[FR Doc. E9–24471 Filed 10–8–09; 8:45 am]

**BILLING CODE 4153–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

### Findings of Research Misconduct

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the Office of Research Integrity (ORI) and the Assistant Secretary for Health have taken final action in the following case:

*Norma Couvertier, APT Foundation:* Based on the report of an investigation conducted by the APT Foundation and additional analysis conducted by ORI in

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