ANNUAL ESTIMATED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses/ respondent	Average burden hours per response	Total burden hours
Hospital staff (Training)	6,000	1	1	6,000
Hospital staff (data collection)	6,000	102	1	612,000
State/Territory Preparedness staff (training)	62	1	1	62
State/Territory Preparedness staff (data collection)	62	102	3	18,972
Total				31,154

Seleda Perryman,

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

[FR Doc. 2010–11567 Filed 5–13–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–NEW; 30-day notice]

Agency Information Collection Request. 30-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 collection 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) 690–5683. Send written comments and recommendations for the proposed information collections within 30 days of this notice directly to the OS OMB Desk Officer; faxed to OMB at 202–395–5806.

Proposed Project: Evaluation of Medicare Personal Health Records Choice Pilot—OMB No. 0990–NEW—Office of the Assistant Secretary for Planning and Evaluation.

Abstract: Since 2003, HHS has worked toward the goal of establishing electronic, longitudinal health records for Americans that can be accessed safely, across the internet, and anytime and anywhere by patients, doctors, and other health care providers. In addition to electronic health records (EHRs), where health information is created, stored and accessed mainly by health care organizations and practitioners, personal health records (PHRs), electronic, patient-centered applications and services, are gaining increasing recognition and momentum. Current PHR business models represent broad and varied uses, from disease management to health promotion, with sponsors consisting of commercial vendors, heath plans, employers, and health care providers. We know very little about why consumers, and specifically Medicare beneficiaries, elect to use PHRs and what functionality they want from a PHR. Understanding these needs will be critical if HHS and the Centers for Medicare & Medicaid Services (CMS) are to pursue PHRs as a tool to empower consumers to manage their health and have the capability to link to their provider's EHR.

In January 2009, CMS launched a new program in Arizona and Utah, the *Medicare PHR Choice Pilot* (PHRC). This pilot encourages Medicare fee-for-service (FFS) beneficiaries to take advantage of the newer, more robust Internet-based tools for tracking their health and health care services. This is the first pilot to offer a choice of PHRs to Medicare FFS beneficiaries, including PHRs with additional functionality and direct data linkages for the consumers. Pilot participants can choose among GoogleHealth™, NoMoreClipboard™, PassportMD™, and HealthTrio™, competitors in the open PHR market.

HHS' Office of the Assistant Secretary for Planning and Evaluation (ASPE) has contracted with Mathematica Policy Research to conduct an evaluation of this pilot program, including a PHR enrollee user satisfaction survey to assess barriers, facilitators, and satisfaction with the PHRs. A self-administered paper-and-pencil instrument will be the primary data collection mode for the PHRC user satisfaction survey, with telephone followup for mail nonrespondents. The one-time data collection field period is expected to be 12 weeks in Fall 2010.

ESTIMATED ANNUALIZED BURDEN TABLE

Forms (if necessary)	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Self-administered questionnaire	Medicare beneficiaries	500	1	25/60	208
Total		500			208

Seleda Perryman,

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

[FR Doc. 2010–11568 Filed 5–13–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0545]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Biological Products: Reporting of Biological Product Deviations and Human Cells, Tissues, and Cellular and Tissue-Based Product Deviations in Manufacturing; Form FDA 3486 and Addendum 3486A

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by June 14, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0458. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Biological Products: Reporting of Biological Product Deviations and Human Cells, Tissues, and Cellular and Tissue-Based Product Deviations in Manufacturing; Form FDA 3486 and Addendum 3486A—(OMB Control Number 0910–0458)—Extension

Under section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262), all biological products, including human blood and blood components, offered for sale in interstate commerce must be licensed and meet standards, including those prescribed in the FDA regulations, designed to ensure the continued safety, purity, and potency of such products. In addition under section 361 of the PHS Act (42 U.S.C. 264), FDA may issue and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or possessions or from foreign countries into the States or possessions. Further, the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351) provides that drugs and devices (including human blood and blood components) are adulterated if they do not conform with current good manufacturing practice (CGMP) assuring that they meet the requirements of the act. Establishments manufacturing biological products including human blood and blood components must comply with the applicable CGMP regulations (parts 211, 606, and 820 (21 CFR parts 211, 606, and 820)) and current good tissue practice (CGTP) regulations (part 1271 (21 CFR part 1271)) as appropriate. FDA regards biological product deviation (BPD) reporting and human cells, tissues, and cellular and tissue-based product (HCT/P) deviation reporting to be an essential tool in its directive to protect public health by establishing and maintaining surveillance programs that provide timely and useful information.

Section 600.14, in brief, requires the manufacturer who holds the biological product license, for other than human blood and blood components, and who had control over a distributed product when the deviation occurred, to report to the Center for Biologics Evaluation and Research (CBER) or to the Center for Drugs Evaluation and Research (CDER) as soon as possible but not to exceed 45 calendar days after acquiring information reasonably suggesting that a reportable event has occurred. Section 606.171, in brief, requires a licensed manufacturer of human blood and blood components, including Source Plasma; an unlicensed registered blood establishment; or a transfusion service who had control over a distributed product when the deviation occurred, to report to CBER as soon as possible but not to exceed 45 calendar days after acquiring information reasonably suggesting that a reportable event has occurred. Similarly, § 1271.350(b), in brief, requires non-reproductive HCT/P establishments described in § 1271.10 to report to CBER all HCT/P deviations relating to a distributed HCT/P that relates to the core CGTP requirements, if the deviation occurred in the establishment's facility or in a facility that performed a manufacturing step for the establishment under contract, agreement or other arrangement. Form FDA 3486 is used to submit BPD reports and HCT/P deviation reports.

Respondents to this collection of information are the licensed manufacturers of biological products other than human blood and blood components, licensed manufacturers of blood and blood components including Source Plasma, unlicensed registered blood establishments, transfusion services, and establishments that manufacture non-reproductive HCT/Ps regulated solely under section 361 of the PHS Act as described in § 1271.10. The number of respondents and total annual responses are based on the BPD reports and HCT/P deviation reports FDA received in fiscal year (FY) 2008. The number of licensed manufacturers and total annual responses under 21 CFR 600.14 include the estimates for BPD reports submitted to both CBER and CDER. Based on the information from industry, the estimated average time to complete a deviation report is 2 hours. The availability of the standardized report form, Form FDA 3486, and the ability to submit this report electronically to CBER (CDER does not currently accept electronic filings) further streamlines the report submission process.

CBER has developed an addendum to Form FDA 3486. The Web-based addendum 3486A provides additional information when a BPD report has been reviewed by FDA and evaluated as a possible recall. The additional information requested includes information not contained in the Form FDA 3486 such as: (1) Distribution pattern, (2) method of consignee notification, (3) consignee(s) of products for further manufacture, (4) additional product information, (5) updated product disposition, and (6) industry recall contacts. This information is requested by CBER through e-mail notification to the submitter of the BPD report. This information is used by CBER for recall classification purposes. At this time Addendum 3486A is being used only for those BPD reports