

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.

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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, health 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.

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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