

Background and Brief Description

Subtitle A of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, (42 U.S.C. 262a), requires the United States Department of Health and Human Services (HHS) to regulate the possession, use, and transfer of biological agents or toxins that have the potential to pose a severe threat to public health and safety (select agents and toxins). Subtitle B of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (which may be cited as the Agricultural Bioterrorism Protection Act of 2002), (7 U.S.C. 8401), requires the United States Department of Agriculture (USDA) to regulate the possession, use, and transfer of biological agents or toxins that have the potential to pose a severe threat to animal or plant health, or animal or plant products (select agents

and toxins). Accordingly, HHS and USDA have promulgated regulations requiring individuals or entities that possess, use, or transfer select agents and toxins to register with the CDC or the Animal and Plant Health Inspection Service (APHIS). See 42 CFR part 73, 7 CFR part 331, and 9 CFR part 121 (the select agent regulations). The Federal Select Agent Program (FSAP) is the collaboration of the CDC, Division of Select Agents and Toxins (DSAT) and the APHIS Agriculture Select Agent Services (AgSAS) to administer the select agent regulations in a manner to minimize the administrative burden on persons subject to the select agent regulations. The FSAP administers the select agent regulations in close coordination with the Federal Bureau of Investigation's Criminal Justice Information Services (CJIS). Accordingly, CDC and APHIS have adopted an identical system to collect

information for the possession, use, and transfer of select agents and toxins.

CDC is requesting OMB approval to continue to collect information under the select agent regulations for the next three years. Information will be collected via fax, email and hard copy mail from respondents.

The revisions to the data collection are primarily changes to the forms to clarify instructions, correct editorial errors from previous submission, and reformat the structure of the forms based on the day-to-day processing of these forms. Changes were made to the following forms: Report of Identification of a Select Agent or Toxin, Request for Exemption, Application for Registration, Request to Transfer Select Agents and Toxins, and Administrative Review.

There is no cost to respondents other than their time. The total estimated annualized burden hours are 8,527.

ESTIMATED ANNUALIZED BURDEN HOURS

Regulation sections	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
73.3 & 73.4	Request for Exclusions	3	1	1
73.5 & 6	Report of Identification of a Select Agent or Toxin.	303	3	1
73.5 & 73.6	Request for Exemption	1	1	1
73.7	Application for Registration	5	1	5
73.7	Amendment to a Certificate of Registration ...	277	7	1
73.9	Documentation of self-inspection	277	1	1
73.10	Request for Expedited Review	1	1	30/60
73.11	Security Plan	277	1	5
73.12	Biosafety Plan	277	1	5
73.13	Request Regarding a Restricted Experiment	20	2	1
73.14	Incident Response Plan	277	1	5
73.15	Training	277	1	1
73.16	Request to Transfer Select Agents and Toxins.	156	2	1
73.17	Records	277	1	30/60
73.19	Notification of Potential Theft, Loss, or Release.	215	2	1
73.20	Administrative Review	5	4	1

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 Chief, Information Collection Review Office,
 Office of Scientific Integrity, Office of the
 Associate Director for Science, Office of the
 Director, Centers for Disease Control and
 Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-437A & CMS-437B and CMS-10488]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect

information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: The necessity and utility of the proposed information collection for the proper performance of the agency's functions; the accuracy of

the estimated burden; ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by August 24, 2015.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 or Email: OIRA_submission@omb.eop.gov.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently

approved collection. *Title of Information Collection:* State Agency Sheets for Verifying Exclusions from the Inpatient Prospective Payment System and Supporting Regulations; *Use:* For first time verification requests for exclusion from the Inpatient Prospective Payment System (IPPS), a hospital/unit must notify the Regional Office (RO) servicing the State in which it is located that it believes it meets the criteria for exclusion from the IPPS. Currently, all new inpatient rehabilitation facilities (IRFs) must provide written certification that the inpatient population it intends to serve will meet the requirements of the IPPS exclusion criteria for IRFs. They must also complete the Form CMS-437A if they are a rehabilitation unit or complete Form CMS-437B if they are a rehabilitation hospital. This information is submitted to the State Agency (SA) no later than 5 months before the date the hospital/unit would become subject to IRF-PPS.

We propose to continue to use the Criteria Worksheets (Forms CMS-437A and CMS-437B) for verifying first-time exclusions from the IPPS, for complaint surveys, for its annual 5 percent validation sample, and for facility self-attestation. These forms are related to the survey and certification and Medicare approval of the IPPS-excluded rehabilitation units and rehabilitation hospitals.

For rehabilitation hospitals and rehabilitation units already excluded from the IPPS, annual onsite re-verification surveys by the SA are not required. These hospitals and units will be provided with a copy of the appropriate CMS-437 Worksheet at least 5-months prior to the beginning of its cost reporting period, so that the hospital/unit official may complete and sign an attestation statement and complete and return the appropriate CMS-437A or CMS-437B at least 5-months prior to the beginning of its cost reporting period. Fiscal Intermediaries will continue to verify, on an annual basis, compliance with the 60 percent rule (42 CFR 412.29(b)(2)) for rehabilitation hospitals and rehabilitation units through a sample of medical records and the SA will verify the medical director requirement.

The SA will maintain the documents unless instructed otherwise by the RO. The SA will notify the RO at least 60 days prior to the end of the rehabilitation hospital's/unit's cost reporting period of the IRF's compliance or non-compliance with the payment requirements. The information collected on these forms, along with other information submitted by the IRF is necessary for determining exclusion

from the IPPS. Hospitals and units that have already been excluded need not reapply for exclusion. These facilities will automatically be reevaluated yearly to determine whether they continue to meet the exclusion criteria. *Form Number:* CMS-437A and CMS-437B (OMB Control Number: 0938-0986); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 478; *Total Annual Responses:* 478; *Total Annual Hours:* 120. (For policy questions regarding this collection contact James Cowher at 410-786-1948)

2. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Consumer Experience Survey Data Collection; *Use:* Section 1311(c)(4) of the Affordable Care Act (ACA) requires the Department of Health and Human Services (HHS) to develop an enrollee satisfaction survey system that assesses consumer experience with qualified health plans (QHPs) offered through an Exchange. It also requires public display of enrollee satisfaction information by the Exchange to allow individuals to easily compare enrollee satisfaction levels between comparable plans. The HHS established the Marketplace Survey and the QHP Enrollee Experience Survey (QHP Enrollee Survey) to assess consumer experience with the Marketplaces and the QHPs offered through the Marketplaces. The surveys include topics to assess consumer experience with the Marketplace such as enrollment and customer service, as well as experience with the health care system such as communication skills of providers and ease of access to health care services. The CMS developed the surveys using the Consumer Assessment of Health Providers and Systems (CAHPS®) principles (<http://www.cahps.ahrq.gov/about.htm>) and established an application and approval process for survey vendors who want to participate in collecting QHP enrollee experience data.

The Marketplace Survey will provide (1) actionable information that the Marketplaces can use to improve performance, (2) information that CMS and state regulatory organizations can use for oversight, and (3) a longitudinal database for future marketplace research. The CAHPS® family of instruments does not have a survey that assesses entities similar to Marketplaces, so the Marketplace Survey items were generated by the project team. The QHP Enrollee Survey, which is based on the CAHPS® Health Plan Survey, will (1) help consumers choose among competing health plans,

(2) provide actionable information that the QHPs can use to improve performance, (3) provide information that regulatory and accreditation organizations can use to regulate and accredit plans, and (4) provide a longitudinal database for consumer research.

We are completing two rounds of developmental testing for the surveys. The 2014 survey psychometric tests helped determine psychometric properties and provided an initial measure of performance for Marketplaces and QHPs to use for quality improvement. Based on psychometric test results, CMS further refined the questionnaires and sampling designs to conduct the 2015 beta test of each survey. We are requesting clearance for the national implementation of the QHP Enrollee Survey, beginning in 2016. *Form Number:* CMS-10488 (OMB control number: 0938-1221); *Frequency:* Annually; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions), Public sector (Individuals and Households); *Number of Respondents:* 120,015; *Total Annual Responses:* 120,015; *Total Annual Hours:* 29,623. (For policy questions regarding this collection contact Nidhi Singh-Shah at 301-492-5110.)

Dated: July 21, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Privacy Act of 1974, as Amended by Public Law 100-503; Computer Matching Program

SUBJECT: Notice of a computer matching program.

AGENCY: Office of Financial Services (OFS), Office of Administration (OA), ACF, HHS.

ACTION: Request for public comment on the Public Assistance Reporting Information System (PARIS) notice of a computer matching program between the Department of Veterans Affairs and State Public Assistance Agencies (SPAAAs).

C.F.D.A. Number: 93.647.

Statutory Authority: Privacy Act of 1974, as amended by Pub. L. 100-503.

SUMMARY: In compliance with the Privacy Act of 1974, as amended by Public Law 100-503, the Computer Matching and Privacy Protection Act of 1988, ACF is publishing a notice of a computer matching program. The purpose of this computer match is to identify specific individuals who receive benefits from the Department of Veterans Affairs (VA) and also receive payments pursuant to various benefit programs administered by both the Department of Health and Human Services (HHS) and the Department of Agriculture. ACF will facilitate this program on behalf of SPAAAs that participate in PARIS for verification of continued eligibility for public assistance. The match will utilize VA and SPAA records.

DATES: Submit written comments on or before August 24, 2015.

ACF will file a report of the subject matching program with the Committee on Homeland Security and Governmental Affairs of the Senate and the Committee on Oversight and Government Reform of the House of Representatives and the Office of Information and Regulatory Affairs within the Office of Management and Budget (OMB). The dates for the matching program will be effective as indicated in "E. Inclusive Dates of the Matching Program" in this notice.

ADDRESSES: Interested parties may comment on this notice by writing to the Director, Office of Financial Services, Office of Administration, 370 L'Enfant Promenade SW., Washington, DC 20047. All comments received will be available for public inspection at this address.

FOR FURTHER INFORMATION CONTACT: Director, Office of Financial Services, Office of Administration, 370 L'Enfant Promenade SW., Washington, DC 20047. Telephone: (202) 401-7237.

SUPPLEMENTARY INFORMATION: The Privacy Act of 1974, as amended by Public Law 100-503, the Computer Matching and Privacy Protection Act of 1988, (5 U.S.C. 552a), adds certain protections for individuals applying for and receiving Federal benefits. The law regulates the use of computer matching by Federal agencies when records in a system of records are matched with other Federal, State, and local government records.

Federal agencies that provide or receive records in computer matching programs must:

1. Negotiate written agreements with source agencies;
2. Provide notification to applicants and beneficiaries that their records are subject to matching;

3. Verify match findings before reducing, suspending, or terminating an individual's benefits or payments;

4. Furnish detailed reports to Congress and OMB; and

5. Establish a Data Integrity Board that must approve matching agreements.

This computer matching program meets the requirements of Public Law 100-503.

Robert Noonan,

Deputy Assistant Secretary for Administration, ACF.

Notice of Computer Matching Program

A. Participating Agencies

VA and SPAAAs.

B. Purpose of the Match

To identify specific individuals who receive benefits from the VA and also receive payments pursuant to HHS and Department of Agriculture benefit programs, and to verify their continued eligibility for such benefits. SPAAAs will contact affected individuals and seek to verify the information resulting from the match before initiating any adverse actions based on the match results.

C. Authority for Conducting the Match

The authority for conducting the matching program is contained in section 402(a)(6) of the Social Security Act [42 U.S.C. 602(a)(6)].

D. Records To Be Matched

VA will disclose information from the system of records identified as Compensation, Pension, Education, and Vocational Rehabilitation and Employment Records-VA (58VA21/22/28) published at 74 FR 29275, (June 19, 2009), last amended at 77 FR 42593, (July 19, 2012). VA's disclosure of information for use in this computer match is listed as a routine use in this system of records.

VA, as the source agency, will prepare electronic files containing the names and other personal identifying data of eligible veterans receiving benefits. These records are matched electronically against SPAA files consisting of data regarding monthly Medicaid, Temporary Assistance for Needy Families, general assistance, and Supplemental Nutrition Assistance Program beneficiaries.

1. The electronic files provided by the SPAAAs will contain client names and Social Security numbers (SSNs).

2. The resulting output returned to SPAAAs will contain personal identifiers, including names, SSNs, employers, current work or home addresses, etc.