

## TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

| Form name  | Number of respondents | Number of responses per respondent | Total responses | Hours per respondent | Total burden hours |
|--|-----------------------|------------------------------------|-----------------|----------------------|--------------------|
| <b>Hospital Enrollment, Additions &amp; Recertifications</b>   |                       |                                    |                 |                      |                    |
| 340B Program Registrations & Certifications for Hospitals  | 194                   | 1                                  | 194             | 2                    | 388                |
| Certifications to Enroll Hospital Outpatient Facilities .....  | 697                   | 8                                  | 5576            | 0.5                  | 2788               |
| Hospital Annual Recertifications .....   | 2134                  | 6                                  | 12804           | 0.25                 | 3201               |
| <b>Registrations and Recertifications for Entities Other Than Hospitals</b>                                  |                       |                                    |                 |                      |                    |
| 340B Registrations for Community Health Centers .....  | 427                   | 3                                  | 1281            | 1                    | 1281               |
| 340B Registrations for STD/TB Clinics .....  | 647                   | 1                                  | 647             | 1                    | 647                |
| 340B Registrations for Various Other Eligible Entity Types   | 405                   | 1                                  | 405             | 1                    | 405                |
| Community Health Center Annual Recertifications .....  | 1204                  | 5                                  | 6020            | 0.25                 | 1505               |
| STD & TB Annual Recertifications .....   | 3123                  | 1                                  | 3123            | 0.25                 | 780.75             |
| Annual Recertification for entities other than Hospitals, Community Health Centers, and STD/TB Clinics ..... | 4899                  | 1                                  | 4899            | 0.25                 | 1224.75            |
| <b>Contracted Pharmacy Services Registration &amp; Recertifications</b>                                      |                       |                                    |                 |                      |                    |
| Contracted Pharmacy Services Registration .....  | 1758                  | 5                                  | 8790            | 1                    | 8790               |
| <b>Other Information Collections</b>   |                       |                                    |                 |                      |                    |
| Submission of Administrative Changes for any Covered Entity .....  | 9396                  | 1                                  | 9396            | 0.5                  | 4698               |
| Submission of Administrative Changes for any Manufacturer .....  | 350                   | 1                                  | 350             | 0.5                  | 175                |
| Manufacturer Data Required to Verify 340B Ceiling Price Calculations .....                                   | 600                   | 4                                  | 2400            | 0.5                  | 1200               |
| Pharmaceutical Pricing Agreement .....   | 200                   | 1                                  | 200             | 1                    | 200                |
| Pharmaceutical Pricing Agreement (PPA) Addendum .....  | 620                   | 1                                  | 620             | 0.5                  | 310                |
| Total .....  | 26,554                | .....                              | 56,705          | .....                | 27593.5            |

HRSA specifically requests comments on (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.

**Jackie Painter,**

*Director, Division of the Executive Secretariat.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

[Document Identifier: HHS-OS-0945-0002-60D]

### Agency Information Collection Activities; Proposed Collection; Public Comment Request

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

**ACTION:** Notice.

**SUMMARY:** In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for extending the use of the approved information collection assigned OMB control number 0945-0002, which expires on 12/31/2015. Prior to submitting the ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on the ICR must be received on or before December 21, 2015.

**ADDRESSES:** Submit your comments to *Information.CollectionClearance@hhs.gov* or by calling (202) 690-6162.

**FOR FURTHER INFORMATION CONTACT:** Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690-6162.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the document identifier HHS-OS-0945-0002-60D for reference.

*Proposed Project:* Complaint Forms for Discrimination; Health Information Privacy Complaints.

OMB No. 0945-0002—Extension—Office of Civil Rights.

*Abstract:* The Office for Civil Rights is seeking an extension on an approval for a 3-year clearance on a previous collection. Individuals may file written complaints with the Office for Civil Rights when they believe they have been discriminated against by programs or entities that receive Federal financial assistance from the Health and Human Service or if they believe that their right to the privacy of protected health information has been violated. Annual Number of Respondents frequency of submission is record keeping and reporting on occasion.

ESTIMATED ANNUALIZED BURDEN TABLE

| Forms                                      | Type of respondent                                      | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|--|---|-----------------------|------------------------------------|-----------------------------------|--------------------|
| Civil Rights Complaint Form .....          | Individuals or households, Not-for-profit institutions. | 3493                  | 1                                  | 45/60                             | 2620               |
| Health Information Privacy Complaint Form. | Individuals or households, Not-for-profit institutions. | 10,286                | 1                                  | 45/60                             | 7715               |
| Total .....                                | .....   | .....                 | .....                              | .....                             | 10,335             |

OS specifically requests comments on (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.

**Darius Taylor,**  
*Information Collection Clearance Officer.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

**Privacy Act of 1974; System of Records Notice**

**AGENCY:** Office of the Secretary (OS), Department of Health and Human Services (HHS).

**ACTION:** Notice to establish a new Privacy Act system of records.

**SUMMARY:** In accordance with the requirements of the Privacy Act of 1974, as amended (5 U.S.C. 552a), the Office of Medicare Hearings and Appeals (OMHA) within the Office of the Secretary of Health and Human Services (HHS) is establishing a new system of records, System No. 09-90-1501, entitled "Administrative Law Judge (ALJ) Working File, Office of Medicare Hearings and Appeals," to cover OMHA ALJ working files previously maintained as part of the Social Security Administration's (SSA) ALJ Working File system of records 60-0005 (last published at 74 FR 19617). The working files covered under new System of Records Notice (SORN) 09-90-1501 are created and used by OMHA ALJs and members of their staffs for internal purposes, to document actions taken by OMHA at the hearing level in each Medicare appeal case that OMHA reviews. The working files are separate

from the official case files, which are covered under other SORNs (*i.e.*, HHS SORN 09-70-0566 covers case files on Medicare claims appeals, and SSA SORN 60-0089 covers case files on Medicare entitlement appeals).

**DATES:** This system notice is effective immediately, with the exception of the routine uses. The routine uses will be effective 30 days after publication, unless HHS receives comments that warrant a revision to this Notice.

**ADDRESSES:** Send public comments by mail or email to: Andrea Monson, Director, Division of Information Management and Systems, 1700 North Moore Street, Suite 1800, Arlington, VA 22209, 703-235-0635, *andrea.monson@hhs.gov*. Comments will be available for public inspection and copying at the above location.

**FOR FURTHER INFORMATION CONTACT:** Andrea Monson, Director, Division of Information Management and Systems, 1700 North Moore Street, Suite 1800, Arlington, VA 22209, 703-235-0635, *andrea.monson@hhs.gov*.

**SUPPLEMENTARY INFORMATION:**

**I. Background on New System of Records**

The Medicare claims appeals process consists of four levels of administrative review within HHS, and a fifth level of review with the federal district courts after administrative remedies within HHS have been exhausted. The first two levels of review are administered by the Centers for Medicare & Medicaid Services (CMS) and conducted by Medicare contractors. The third level of review is administered by OMHA and is conducted by ALJs. Subsequent reviews are conducted at the fourth level of appeal within the Departmental Appeals Board (DAB), and at the fifth level by the federal district courts.

The Medicare entitlement and premium appeals process consists of three levels of administrative review, and a fourth level of review with the federal district courts after administrative remedies have been exhausted. The first level is the reconsideration level conducted by

SSA. The second level of review is administered by OMHA and is conducted by ALJs. Subsequent reviews are conducted at the third level of appeal within the DAB and at the fourth level by the federal district courts.

The Department established OMHA in June, 2005, pursuant to section 931 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) (MMA), which required the transfer of responsibility for the ALJ hearing function of the Medicare claims and entitlement appeals process from SSA to HHS. The MMA requires a unified case tracking system that facilitates the maintenance and transfer of case-specific data across both the fee-for-service and managed care components of the Medicare program. HHS' CMS operates the unified case tracking system required by MMA, which is covered by CMS System of Record Notice No. 09-70-0566, entitled "Medicare Appeals System" (MAS SORN).

OMHA's adjudication process uses a "case file" comprising the official agency record, and an ALJ working file. The case file will continue to be covered by CMS' MAS SORN for Medicare claims appeals. The case file for Medicare entitlement and premium appeals will continue to be covered by the SSA Claims Folders System, Social Security Administration Claims Folders System, Social Security Administration, Office of the General Counsel, Office of Public Disclosure (60-0089). The case file is used throughout the administrative appeals process by the various levels of review.

Only OMHA's ALJ working files will now be covered in the new system of records established by this Notice, to reflect that they are used only by OMHA.

**II. The Privacy Act**

The Privacy Act (5 U.S.C. 552a) governs the means by which the U.S. Government collects, maintains, and uses information about individuals in a system of records. A "system of records" is a group of any records under the control of a federal agency from