the allocated time may be limited. Individuals who are associated with groups or have similar interests may be requested to combine their comments and present them through a single representative. No audiovisual presentations are permitted. For additional information or questions on public comments, please contact Lisa Vasquez, Maternal and Child Health Bureau, Health Resources and Services Administration; email: *lvasquez@hrsa.gov*.

Contact Person: Anyone interested in obtaining other relevant information should contact Debi Sarkar, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18W68, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; email: *dsarkar@hrsa.gov*.

More information on the Advisory Committee is available at *http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders*.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–26524 Filed 10–19–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than December 21, 2015.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program and Collection of Manufacturer Data to Verify 340B Drug Pricing Program Ceiling Price Calculations.

OMB No. 0915–0327—Revision.

Abstract: Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted as Section 340B of the Public Health Service Act (PHS Act; ''Limitation on Prices of Drugs Purchased by Covered Entities''), provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a Pharmaceutical Pricing Agreement (PPA) with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula (''ceiling price''). A manufacturer subject to a PPA must offer all covered outpatient drugs at no more than the ceiling price to a covered entity listed in the 340B Program database. The manufacturer shall rely on the information in the 340B database to determine if the covered entity is participating in the 340B Program or for any notifications of changes to eligibility that may occur within a quarter. By signing the PPA, the manufacturer agrees to comply with all applicable statutory and regulatory requirements.

The purpose of this revision is to include an addendum to the PPA to incorporate the administrative requirement for manufacturer integrity provisions directly addressed in the Affordable Care Act.

Need and Proposed Use of the Information: HRSA is proposing revisions to the current PPA to include an addendum in response to manufacturer integrity provisions implemented in the Affordable Care Act. Section 7102(b) of the Affordable Care Act amends section 340B(a)(1) of the Public Health Service Act (PHSA) to add two new requirements for inclusion in the PPA with manufacturers of covered outpatient drugs:

I. ''Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the ''ceiling price'') and

II. ''. . . shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.''

These requirements shall be included in the PPA addendum to be signed by manufacturers participating in the 340B Program to ensure that the provisions of the 340B statute requiring inclusion in the PPA are satisfied. The execution of the addendum by manufacturers will fulfill the administrative requirement of the statute that these provisions be included in the PPA. The burden imposed on manufacturers by the proposed requirement of the PPA is minimal because the addendum does not impose requirements beyond review and a signature by the manufacturer.

Likely Respondents: Drug Manufacturers.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Hours per respondent	Total burden hours
Hospital Enrollment, Additions & Recertifications					
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
Registrations and Recertifications for Entities Other Than Hospitals					
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
Contracted Pharmacy Services Registration & Recertifications					
Contracted Pharmacy Services Registration	1758	5	8790	1	8790
Other Information Collections					
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.

[FR Doc. 2015–26522 Filed 10–19–15; 8:45 am]

BILLING CODE 4165–15–P

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.