Supporting Statement A

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 Control No. 0915-0327

Terms of Clearance: For revisions

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Health Resources and Services Administration (HRSA) currently has approval under Office of Management and Budget (OMB) Control No. 0915-0327, to collect information in support of 340B covered entity recertification and registration, as well as registration of contract pharmacy arrangements and the pharmaceutical pricing agreement. HRSA is requesting comments on an additional information collection in response to the pricing verification requirements mandated by the provisions in the Affordable Care Act (ACA).

The ACA introduced a number of program integrity-related pricing requirements. This enhancement will afford HRSA the opportunity to implement the statutory requirements. More specifically, the Act requires:

(*i) The development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities, which shall include the following […] Comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary.*

[...]

(iii) The provision of access through the Internet website of the Department of Health and Human Services to the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary in accordance with this section, in a manner (such as through the use of password protection) that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure.

HRSA is developing a ceiling price validation system, mandated by section 7102(b) of the Affordable Care Act and this price verification computer system will allow HRSA to verify and adjudicate prices for approximately 40,000 unique national drug codes (NDCs). Without the use of technology, HRSA will not be able to meet the aforementioned mandate. The respondents are already required to calculate the statutorily defined 340B ceiling price and must use the requested variables in this information collection request (ICR) to arrive at that price, so that 340B covered entities are not overcharged.

HRSA is also requesting renewal of the existing currently approved registration and recertification forms that are mandated under Section 340B of the Public Health Service Act (PHSA) for covered entity compliance; changes from the existing versions of these forms are

primarily related to the transition from hardcopies to their online equivalents. (HRSA previously maintained separate hospital registration forms with type-specific references to statutory eligibility provisions; the registration database currently inserts appropriate language based on the hospital type selected by the user.)

In addition, HRSA is issuing an addendum to the current Pharmaceutical Pricing Agreement (PPA) in response to manufacturer integrity provisions implemented in the ACA. Section 7102(b) of the ACA amends section 340B(a)(1) of the PHS Act to add two new requirements to the Secretary's PPA with the manufacturer. The first requirement is for manufacturer submission of ceiling price data to the Secretary and the second requirement is that the manufacturer offer each covered entity covered drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price ("must offer" provision). *Note – Except for condensing 4 IC titles into 2 IC titles, this addendum is the only change from the previously approved package.*

2. Purpose and Use of Information Collection

HRSA's Healthcare Systems Bureau, Office of Pharmacy Affairs (OPA) has previously obtained approval for information collections in support of 340B covered entity recertification and registration, as well as registration of contract pharmacy arrangements and the PPA. OPA is requesting comments on an additional information collection request in response to the above pricing verification requirements and manufacturer program integrity provisions in the ACA (i.e., the PPA addendum). In particular, the PPA addendum, once implemented will serve as a separately signed document that does not impact the validity of the existing PPA between the Secretary and manufacturers.

Under Section 340B(d)(2)(B) of the Public Health Service Act (PHSA), covered entities are required to register for participation in the 340B Drug Pricing Program and complete an annual recertification to verify eligibility. To register, covered entities must fill out an application with administrative information such as the name and address of the covered entity, Medicaid participation, Medicare Cost Report data, and obtain certifying information and signatures from authorizing officials within the organization who can legally bind the organization into an agreement with the Federal government. This information is verified by HRSA staff to determine eligibility and is stored into the 340B database. HRSA requires that covered entities submit any modifications to the administrative information during registration and have an ongoing responsibility to notify HRSA of any changes to their eligibility status. To maintain accurate records, HRSA requires that covered entities must annually re-certify the accuracy of the information provided to HRSA, the maintenance of their eligibility, and to comply with statutory mandates of the program.

Section 340B(d)(1)(B)(i) of the PHSA requires the development of a system to enable the Secretary to verify the accuracy of 340B ceiling prices calculated by manufacturers under subsection (a)(1) and the drug prices charged to covered entities. The collection of information for this ICR will fulfill requirements mandated by the ACA, including:

(I) Developing and publishing through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices under such subsection;

(II) Comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary;

(III) Performing spot checks of sales transactions by covered entities; and

(IV) Inquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, such corrective action as is appropriate in response to such price discrepancies.

Under this ICR, on a quarterly basis, manufacturers will submit 340B pricing data into a pricing system, which will then verify and compare the manufacturer's pricing data with HRSA's 340B pricing data. The system will note any discrepancies with the pricing data and notify the manufacturers of the potential price discrepancies. Manufacturers will have an opportunity to review and reconcile any price discrepancies. HRSA will then review and verify the 340B pricing data and the final 340B ceiling price will be posted in the pricing system. Covered entities will be able to access the system and view the HRSA-verified 340B ceiling price to ensure that they are receiving covered outpatient drugs at or below the statutorily mandated 340B ceiling price. The forms that will accompany the pricing system that are part of this ICR include the following: "Manufacturer Data Required to Verify 340B Ceiling Price Calculations" and other related forms including the "Pharmaceutical Pricing Agreement" and the "Pharmaceutical Pricing Agreement Addendum (PPA Addendum)."

3. Use of Improved Information Technology and Burden Reduction
   Information collection via the new drug pricing instrument will be done strictly online. The respondents can either manually enter the requested information into the newly created secure pricing platform or upload their file into the system. The upload capability of the system reduces the burden on the user and reduces the errors that might occur from manually entering multiple lines of data.

4. Efforts to Identify Duplication and Use of Similar Information
   HRSA is responsible for calculating the 340B ceiling price. Although two of the variables requested in this ICR can be obtained from the Centers Medicare & Medicaid Services (CMS), we have found inconsistences and discrepancies with the files received from CMS. The file from CMS is also not all encompassing of all the labeler codes or products that are required to participate in the 340B Program. For example, the file does not contain new products and manufacturers that participate in the 340B Program but not in the Medicaid Drug Rebate Program (MDRP). Therefore, this information collection does not duplicate any other effort.

5. Impact on Small Businesses or Other Small Entities
   The collection of drug manufacturer data may impact up to 100 small businesses or other small entities, based on data from a past voluntary pilot. The new pricing system OPA is

creating will help these firms more easily and accurately report their data than was possible under the previous data collection method. The pricing system will be free and will help manufacturers detect and correct potential data errors so that the government will have concurrence from the manufacturer for its calculations.

6. Consequences of Collection the Information Less Frequently
   Pricing data submissions from manufacturers will occur on a quarterly basis as per CMS requirements for submissions of Average Manufacturer Price (AMP) data, which HRSA uses to calculate the 340B ceiling price.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
   The ACA required that manufacturers submit drug data on a quarterly basis to HRSA.

8. Comments in Response to the Federal Register Notice/Outside Consultation

Section 8A

HRSA issued a 60-day *Federal Register* notice on October 20, 2015, Vol. 80, No. 202, pp. 63560-63561. This revision includes an addendum to the PPA to incorporate the administrative requirement for manufacturer integrity provisions directly addressed in the ACA. Eight comments were received from various pharmaceutical manufacturers and industry stakeholders. See Attachment II for a summary of the comments.

Comments received were regarding the statutory language used to describe the quarterly pricing provided. Commenters suggested that HRSA revise the language to reflect the statutory language that describes the obligation of manufacturers to sign a pharmaceutical pricing agreement. HRSA has revised its draft instrument to reflect these comments. Commenters also question that the burden estimates associated with this revision were too low. HRSA determined that the burden estimates were sufficiently accounted for. Other comments received related to pricing elements, the appropriate effective date applicable to the PPA addendum, and the meaning of the "must-offer" language in the statute were outside the scope of this proposed revision and were, therefore, not addressed.

Section 8B

Consultation and review of the registration and recertification materials was conducted by HRSA's contractor, the 340B Prime Vendor, which is the point of contact for all questions related to 340B registration and recertification. The 340B Prime Vendor analyzed data from several covered entities that utilized their call center with questions related to registration and recertification and determined that the current burden analysis is an accurate estimate of time that covered entities spend to complete the registration and/or recertification process.

On November 17, 2014, representatives from HRSA's OPA met with members of the 340B Pharmaceutical Company Operational Work Group (340B OWG) to obtain manufacturer operational input on the submission of pricing data. HRSA addressed the workgroup's questions regarding the calculation of the 340B ceiling price, handling pricing discrepancies, data

elements, timing of submissions, security and confidentiality of pricing data.

Input from the following representatives was obtained:

Name	Title	Company	Phone Number	E-mail
Megan Thompson	340B Call Center Specialist	Apexus	888-340-2787	ApexusAnswers@340bpvp.com
Mark Coin	Director, Federal Legislative Affairs	Baxter Healthcare	202-508-8200	mark_coin@baxter.com
Phillip Matheny	Operations Manager Federal Accounts	Genentech	402-891-8053	pmatheny@gene.com
Ken Nelson	Director, Government Pricing Analytics	Johnson & Johnson	732-562-3000	knelson8@its.jnj.com
Colleen Menges	Director of Government Contracts	Johnson & Johnson	732-562-3348	CMenges@its.jnj.com
Frank Prybeck	Director Federal Government Pricing and Contracting	Celgene	908-673-9000	fprybeck@celgene.com
Kathleen Black	Director, Government Strategy	Pfizer	610-902-1200	Kathleen.Black@pfizer.com
David Buckley	Contract Operations Manager	GlaxoSmithKline	919-315-3329	david.k.buckley@gsk.com
Christopher Schott	Associate	Hogan Lovells	202-637-5467	christopher.schott@hoganlovells.com
Heather Dixson	Advisor Government Price Reporting	Eli Lilly	317-276-8626	dixson_heather_a@lilly.com
Paula Martins	Manager, Government Contracts	Daiichi Sankyo, Inc.	973-630-2686	PMartins@dsi.com
Justin Wutti	Government Pricing Specialist	Teva Pharmaceutical Industries	215-591-3000	Justin.Wutti@tevapharm.com
Alice Valder Curran	Partner	Hogan Lovells	202-637-5997	alice.valder.curran@hoganlovells.com
Chris Hatwig	President	Apexus	972-910-6616	chatwig@340bpvp.com

9. Explanation of any Payment/Gift to Respondents

Respondents will not receive any payments or gifts.

10. Assurance of Confidentiality Provided to Respondents

Application and eligibility information regarding covered entities that is collected for this submission does not contain any personal identifiers and, therefore, does not apply to the Privacy Act.

Confidentiality of manufacturer ceiling price calculations has been assured in accordance with section 340B(d)(1)(B)(iii) of the PHSA.

11. Justification for Sensitive Questions

This data collection does not request sensitive information from the respondent.

12. Estimates of Annualized Hour and Cost Burden

12A. 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 and Recertifications					
340B Program Registrations and Certifications for Hospitals	194	1	194	2	388
Certifications to Enroll Hospital Outpatient Facilities	697	8	5,576	0.5	2,788
Hospital Annual Recertifications	2,134	6	12,804	0.25	3,201
Registrations and Recertifications for Entities Other Than Hospitals					
340B Registrations for Community Health Centers	427	3	1.281	1	1,281
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	1,204	5	6,020	0.25	1,505
STD & TB Annual Recertifications	3,123	1	3,123	0.25	780.75

Annual Recertification for Entities Other Than Hospitals, Community Health Centers, and STD/TB Clinics	4,899	1	4,899	0.25	1,224.75
Contracted Pharmacy Services Registration and Recertifications					
Contracted Pharmacy Services Registration	1,758	5	8,790	1	8,790
Other Information Collections					
Submission of Administrative Changes for Any Covered Entity	9,396	1	9,396	0.5	4,698
Submission of Administrative Changes for Any Manufacturer	350	1	350	0.5	175
Manufacturer Data Required to Verify 340B Ceiling Price Calculations	600	4	2,400	0.5	1,200
Pharmaceutical Pricing Agreement	200	1	200	1	200
Pharmaceutical Pricing Agreement (PPA) Addendum	620	1	620	0.5	310
Total	**26,654**		**56,705**		**27,593.5**

340B Program Registrations & Certifications for Hospitals: Refers to an electronic process by which eligible hospitals register for the program and obtain certifications of government ownership/operation or government contracts, as appropriate. It is estimated that approximately 194 new respondents per year take 2 hours to gather the information and complete these forms to register in the program, resulting in a total annual burden of 388 hours (194x 2 = 388 hours) for hospitals.

Certifications to Enroll Hospital Outpatient Facilities: Refers to an electronic process by which eligible hospitals additionally register offsite outpatient facilities. It is estimated that 697 hospitals will each register approximately 8 outpatient facilities, taking 0.50 hours per facility to gather the information and complete the enrollment process, resulting in a total annual burden of 2,788 hours ((697 x 8) x 0.50 = 2,788 hours).

Hospital Annual Recertification: Refers to an electronic process where hospitals verify their information in the 340B public database and attest that they continue to be eligible and in compliance with statutory requirements of the program. It is estimated that 2,134 hospitals will each recertify approximately 6 participating locations. Gathering the necessary information and

completing the recertification process will take 0.25 hours per location , resulting in a total annual burden of 3,201 hours ((2,134 x 6) x 0.25 = 3,201 hours).

340B Registrations for All Over Covered Entities: Refers to an electronic process by which other eligible grant recipients (e.g. Black Lung Clinics, Consolidated Community Health Centers, Federal Qualified Health Center Lookalikes, Comprehensive Hemophilia Treatment Centers, Native Hawaiian Health Centers, Ryan White Programs, Tribal Contract/Compact Health Centers, Urban Indian Health Centers, Family Planning clinics, and STD/TB clinics) register for the program. It is estimated that 1479 entities take 1 hour to gather the information and complete this form to register in the program, resulting in a total annual burden of 2,958 hours for these entities (1,479 x 2 = 2,958 hours).

Annual Recertification for Community Health Centers: Refers to an electronic process where participating community health centers verify their information in the 340B public database and attest that they continue to be eligible and in compliance with statutory requirements of the program. It is estimated that 1,204 community health centers will have 5 sites to recertify. Gathering the necessary information and completing the recertification process will take 0.25 hours per location, resulting in a total annual burden of 1,505 hours ((1,204 x 5 = 6,020) x 0.25 = 1,505 hours).

Annual Recertification for STD & TB: Refers to an electronic process where participating STD and/or TB clinics verify their information in the 340B public database and attest that they continue to be eligible and in compliance with statutory requirements of the program. It is estimated that 3,123 STD/TB clinics take 0.25 hours to gather the information and recertify, resulting in a total annual burden of 780.75 hours (3,123 x 0.25 = 780.75 hours).

Annual Recertification for Entities Other than Hospitals, Community Health Centers, and STD/TB Clinics: Refers to an electronic process where participating covered entities verify their information in the 340B public database and attest that they continue to be eligible and in compliance with statutory requirements of the program. It is estimated that 4,899 covered entities other than Hospitals, Community Health Centers, and STD/TB Clinics take 0.25 hours to gather the information and recertify, resulting in a total annual burden of 1,224.75 hours (4,899 x 0.25 = 1,224.75 hours).

Contract Pharmacy Self Certification: Refers to an electronic process where covered entities can record their contract pharmacy arrangements in the 340B public database. It is estimated that 1,758 entities will each register approximately 5 contract pharmacy locations, taking 1 hour to gather the information and complete this process, resulting in a total annual burden of 8,790 hours ((1,758 x 5) x 1 = 8,790 hours).

Administrative Change Form: Refers to an electronic process by which 340B covered entities request changes to their records in the 340B public database. It is estimated that 9,396 entities take 0.50 hours each to gather the information and complete this form to request change in the 340B public database, resulting in a total annual burden of 4,698 hours (9,396 x 0.50 = 4,698 hours).

Administrative Changes for Any Manufacturer: Refers to the current hardcopy form by which participating drug manufacturers request changes to their records in the 340B public database. It is estimated that 350 manufacturers take 0.50 hours each to gather the information and complete this form to request a change in the 340B public database, resulting in a total annual burden of 175 hours (350 x 0.50 = 175 hours).

Manufacturer Data Required to Verify 340B Ceiling Price Calculations: Refers to the drug product and pricing data that manufacturers must submit to the online 340B pricing database on a quarterly basis. It is estimated that 600 manufacturers will take 0.50 hours each to gather and upload or otherwise submit their information to the database on a quarterly basis, resulting in a total annual burden of 1,200 hours ((600 x 4) x 0.5 = 1,200 hours).

Pharmaceutical Pricing Agreement (PPA): Pursuant to the PHSA, manufacturers that participate in the Medicaid program sign the PPA agreeing to charge 340B covered entities at or below a specified maximum price known as the 340B ceiling price for covered outpatient drugs. It is estimated that 200 manufacturers take 1 hour to read and complete a PPA, resulting in a total annual burden of 200 hours (200 x 1= 200 hours).

Pharmaceutical Pricing Agreement Addendum (PPA Addendum): Pursuant to the PHSA, manufacturers that participate in the Medicaid program sign the PPA agreeing to charge 340B covered entities at or below a specified maximum price known as the 340B ceiling price for covered outpatient drugs. It is estimated that 620 manufacturers take 0.5 hours to read and complete a PPA addendum, resulting in a total annual burden of 310 hours (620 x 0.5= 310 hours).

12B.

Type of Respondent	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
Hospital Authorizing Official (CEO, CFO, Executive Director, President, VP) (Chief Executive median hourly wage from BLS- http://www.bls.gov/oes/current/oes111011.htm)	9,074.5	$80	$725,960
Non-Hospital Authorizing Official and Hospital 340B Primary Contact (Program Manager, Director, etc.) (General and Operations Managers median hourly wage from BLS - http://www.bls.gov/oes/current/oes111021.htm)	7,613.5	$50	$380,675
Contract Pharmacy Authorizing Official (Pharmacist median hourly wage from BLS http://www.bls.gov/oes/current/oes291051.htm)	8,790	$60	$527,400
Manufacturer Authorizing Official (General and Operations Managers median hourly wage from BLS - http://www.bls.gov/oes/current/oes111021.htm)	1,575	$50	$78,750

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
TOTAL:	27,053		$1,712,785

13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs
There are no capital, start-up, or maintenance costs for the respondents.

14. Annualized Cost to Federal Government
This is an ongoing information collection request. The estimated average federal cost to implement the manufacturer and covered entity requirements in the 340B pricing and registration systems will be approximately $3.58 million per year. The HRSA contractor will develop and maintain the system on an annual basis.

Description	Time	Salary	Annual Cost
Pricing & Registration Database Maintenance/Enhancement Contract	Yearly	N/A	$3,221,135
Public Health Analyst (hospital registrations) - GS-13/1	75% of time	$90,823	$68,117
Public Health Analyst (hospital registrations) – GS-13/1	75% of time	$90,823	$68,117
Public Health Analyst (hospital registrations) – GS-13/1	75% of time	$90,823	$68,117
Public Health Analyst (non-hospital registrations) – GS-13/1	75% of time	$90,823	$68,117
Public Health Analyst (non-hospital registrations) – GS-13/1	75% of time	$90,823	$68,117
Public Health Analyst (recertifications) – GS-13/1	75% of time	$90,823	$68,117
Program Management Officer (pricing) – GS-13/1	75% of time	$90,823	$68,117
Branch Chief – GS-14/1	50% of time	$107,325	$53,663
Total per year:			**$3,751,617**

15. Explanation for Program Changes or Adjustments
Currently, there are 27,054 total reporting and record keeping burden hours in the Office of Management and Budget (OMB) inventory. HRSA is requesting 27,593.5 burden hours, an increase of 539.5 hours. The increase is associated in part with the addition of the Pharmaceutical Pricing Agreement (PPA) Addendum.

16. Plans for Tabulation, Publication, and Project Time Schedule
    A 3 year clearance is being requested for this recurring data collection. There are no plans for tabulation, statistical analysis or publication of the information collected.

17. Reason(s) Display of OMB Expiration Date is Inappropriate
    No exemption is being requested. The expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions
    There are no exceptions to the certification.