## Approved

Acronyms
ATO - Authorization to Operate
CAC - Common Access Card
FISMA - Federal Information Security Management Act
ISA - Information Sharing Agreement
HHS - Department of Health and Human Services
MOU - Memorandum of Understanding
NARA - National Archives and Record Administration
OMB - Office of Management and Budget
PIA - Privacy Impact Assessment
PII - Personally Identifiable Information
POC - Point of Contact
PTA - Privacy Threshold Assessment
SORN - System of Records Notice
SSN - Social Security Number
URL - Uniform Resource Locator

## General Information

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| | | **PIA ID:** | 1334670 |
| **PIA Name:** | HRSA - 340B OPAIS - QTR2 - 2021 - HRSA739861 | **Title** | HRSA - 340B OPA Information System |
| **OpDiv** | HRSA | | |

## PTA

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| **PTA - 1A:** | Identify the Enterprise Performance Lifecycle Phase of the system | Operations and Maintenance |
| **PTA - 1B:** | Is this a FISMA-Reportable system? | Yes |
| **PTA - 2:** | Does the system include a website or online application? | Yes |
| **PTA - 2A:** | Are any of the URLs listed accessible by the general public (to include publicly accessible log in and internet websites/online applications)? | |

### URL Details

| Type of URL | List Of URL |
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| Other | https://datawarehouse.hrsa.gov https://findahealthcenter.hrsa.gov https://muafind.hrsa.gov https://granteefind.hrsa.gov https://hpsafind.hrsa.gov https://stateprofiles.hrsa.gov https://hrsainyourstate.hrsa.gov https://opotxfind.hrsa.gov https://findanetwork.hrsa.gov https://findhivcare.hrsa.gov https://maps.hrsa.gov https://gis.hrsa.gov |
| Publicly accessible website with log in | https://340bopais.hrsa.gov |
| Publicly accessible | https://340bregistration.hrsa.gov |

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| website with log in | https://340bpricing.hrsa.gov | |
| | https://340bpricingsubmissions.hrsa.gov | |
| Internet (publicly available) | https://340bopais.hrsa.gov | |
| **PTA - 3:** | Is the system or electronic collection, agency or contractor operated? | Contractor |
| **PTA - 3A:** | Is the data contained in the system owned by the agency or contractor? | Agency |
| **PTA - 5:** | Does the system have or is it covered by a Security Authorization to Operate (ATO)? | Yes |
| **PTA - 5A:** | If yes, Date of Authorization | 12/3/2018 |
| **PTA - 5B:** | If no, Planned Date of ATO | |
| **PTA - 6:** | Indicate the following reason(s) for this PTA. Choose from the following options. | PIA Validation (PIA Refresh) |
| **PTA - 7:** | Describe in further detail any changes to the system that have occurred since the last PIA | We upgraded the OPA Compliance Tool (OPACT) servers to the new servers and integrate those servers into 340B OPAIS Security boundary. |
| **PTA - 8:** | Please give a brief overview and purpose of the system by describing what the functions of the system are and how the system carries out those functions? | The OPA is responsible for the administration of the 340B Program. The OPA has established the 340B OPAIS in order to respond to the needs created by the 340B Drug Program; the 340B OPAIS is a two-part system containing a public access web site for program registration data and a confidential pricing module that contains proprietary |

information used to compute discounted drug prices.

The purpose of the system is two-fold; first, the system tracks Covered Entities (Covered Entities are healthcare providers such as certain types of Hospitals, Ryan White AIDS clinics, Community Health Centers, etc.) who participate in the 340B drug program. It is the official federal repository for information on the health care organizations, contracted pharmacies and pharmaceutical manufacturers that are participating in the 340B Drug program. The system has a registration module, where Covered Entities can register (apply) to participate in the 340B program, make changes to their data, and perform annual recertification of their data. The registration system makes the Covered Entities' membership status available to the public. Drug manufacturers use this data to determine who is eligible to receive 340B Drug program discounts. Drug manufacturers also enter similar data (contacts, addresses) into the registration module. The registration module creates user accounts based upon the Covered Entity and the Manufacturer data. Second, the system will serve as the sole federal source of 340B drug pricing data. This data is only available to 340B Covered Entities. The pricing module includes functions to reconcile pricing data from CMS and data from drug manufacturers in order to come up with correct 340B drug prices including ceiling prices.

The OPAIS pricing module is the sole official federal source for "340B ceiling prices", which are the highest prices that manufacturers and wholesalers can legally charge an eligible health care entity that has been accepted into the program (also called a "covered entity"). The pricing module is an external application that calculates "ceiling prices" based on information supplied by pharmaceutical manufacturers, the CMS, and a commercial data broker. The calculated ceiling prices are accessible to covered entities participating in the program only; this is due to the confidential nature of some of the underlying data and proprietary information, and access is limited to those with a need to know.

The Compliance module is to provide the latest known compliance information about a Covered Entity (CE), pharmaceutical manufacturer, or pharmacy in an integrated and organized fashion so that OPA staff can provide the best service to the customer, to the public, and to the government. The other objective of the system is to significantly increase customer satisfaction, increase the quality of HRSA decisions, and considerably reduce the time necessary to resolve customer issues. All of this leads to process automation of the following work-flows: 1. HRSA CE Audit 2. HRSA Manufacturer Audit 3. Manufacturer CE Audit 4. Self-Disclosure/Allegation Audit 5. Correspondence Response PHI/PII is not requested while performing 340B audits of covered entities and manufacturers. Some patient PHI, a form of PII, is inadvertently collected or contained in drug audit information.

**PTA - 9:** List and/or describe all the types of information that are collected (into), maintained, and/or shared in the system regardless of whether that information is PII and how long that information is stored.

The 340B OPAIS system will collect email addresses, work telephone numbers, and authorizing official and contact person's names in the registration module as well as information about the Hospitals, Clinics, and other Covered Entities, such as shipping addresses and Hospital financial data. The system also collects the equivalent data - email addresses, work telephone numbers, and physical addresses, from Manufacturers. The system uses PII information to create user accounts for those that

will be accessing the registration module to enter changes to Covered Entity data, such as shipping addresses, Contract Pharmacies, etc., and to grant both Manufacturers and Covered Entities access to the pricing module.

The registration module collects the Covered entity and Manufacturer data listed in the paragraph above. HRSA uses the data in the registration module to determine whether or not a Covered Entity is eligible to participate in the 340B program.

The registration module uses HRSA's Active Directory and HHS' Access Management System user data to Identify Authenticate, and Authorize (via Personal Identity Verification - PIV - card) access to HRSA - specific functions in the system for Office of Pharmacy Affairs (OPA) (i.e. non-public) users. The system does not collect any OPA user PII that is not required for PIV card use.

The Pricing module will also collect the following data from the drug manufacturer-Average Manufacturer Price, Unit Rebate Amount, package size, National Drug Code, drug name, Wholesale Acquisition Cost, Date of First sale and manufacturer-determined ceiling prices. The system stores HHS employees or contractors users activity in the system for audit purposes.

The Compliance module will collect the following data: 1. Covered Entity (CE) or Manufacturer ID - Name, address contact person info, which includes name, business email address and business phone number 2. Workflow status and documents associated with the workflow. Workflow includes audit document receipt, response to the document, and final audit letter from the OPA Director to the audited entity. 3. Electronic Signature of OPA Director (Note: Other OPA user information is used from Active Directory). 4. At present OPA grants access to the OPACT system to Federal employees of HRSA only. 5. The system uses HRSA's Active Directory to grant access to the system. Additionally, the system will enforce PIV card login by September 2017. The System administrator, a Federal employee of OPA, grants roles to each user account to control access to the various functions of the system. 6. CE program information including: policies and procedures, Medicare cost report, lists of 340B drug dispenses, individual health records, proof of CE staff employment, lists of CE's wholesalers and 340B drug purchase orders including price paid, lists of contract pharmacies and the current contracts, lists of all accounts used to purchase drugs, lists of Medicaid billing numbers and NPI numbers, contracts with a State or local government to provide health care services to low income individuals, Notice of Grant Award (NGA) or sub-grantee documentation. No PHI data is contained in an audit report. Medical record numbers are collected in order to identify a drug dispensed to a patient on a given date in the covered entity's Electronic Health Records (EHR).

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| **PTA -9A:** | Are user credentials used to access the system? | Yes |
| **PTA - 9B:** | Please identify the type of user credentials used to access the system. | HHS User Credentials<br><br>  HHS/OpDiv PIV Card<br><br>  Non-HHS User Credentials<br><br>  Email address<br><br>  Password<br><br>  Username |
| **PTA - 10:** | Describe why all types of information is collected (into), maintained, and/or shared with another system. This description should specify what information is collected about each category of individual | Below are the classes of users for the system and the explanation for collecting the data from them.<br>i. Covered entities – will have access to calculated and verified 340B ceiling prices. To ensure that we are granting access to the appropriate person due to the sensitivity of the data, we collect their name, work title, work phone number, and the associated |

Covered Entity (Hospital, health center, etc.) information, and Rules of Behavior form.

ii. Manufacturers – we collect the same information mentioned above for the Covered entities. Additionally, the manufacturers have to submit the following drug pricing data points which are used to compare the manufacturer's ceiling price against HRSA's calculation. The data points are- Average Manufacturer Price, Unit Rebate Amount, package size, National Drug Code, and manufacturer-determined ceiling prices.

iii. HRSA/HSB/OPA staff – will have a mechanism to accept ceiling prices submitted by manufacturers and compare them to prices calculated by OPA using Centers for Medicare and Medicaid Services (CMS) price data. When discrepancies exist, the 340B OPAIS will enable reporting functions that assist OPA with monitoring and compliance enforcement. OPA staff will also have a mechanism to approve or reject Covered Entity registrations to the 340B program.

The compliance module is mainly designed to integrate and automate the following work-flow processes carried out by OPA. 1. HRSA CE Audit 2. HRSA Manufacturer Audit 3. Manufacturer CE Audit 4. Self-disclosure and Allegation Audit 5. Correspondence Request Processing The system maintains information like: 1. Audit/Compliance information: a. Covered Entity (CE) or Manufacturer ID: we need to track what entity is being audited. b. Type of Audit: we need to know the type of audit being conducted so that we can use the appropriate business process. c. Status of the Audit: we need to know where we are in the audit process. d. Documents associated with audits: we need the documentation to analyze the audit results. 2. Identification information for any given CE or Manufacturer or Pharmacy. a. CE/Manufacturer name and address: we need to know how to contact the entity. b. Authorizing Officer's contact information: we need to know who is responsible for attesting to the accuracy of data given to us by the entity. We also need to contact them if there are issues. c. Contact Person's contact information: We need to know with whom to work at the entity as we do the audit. 3. Internal User Information a. Name, Email address from Active Directory: the system sends emails to users when they are given a task in the system. b. Electronic Signature of OPA Director: the system generates audit letters that must be signed by the OPA Director. c. The system also stores the roles that each user (person) has in it. Roles determine what the user can do and see in the system. The system requires and tracks user credentials.

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| PTA - 10A: | Are records in the system retrieved by one or more PII data elements? | No |
| PTA - 11: | Does the system collect, maintain, use or share PII? | Yes |

## PIA

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| PIA - 1: | Indicate the type of PII that the system will collect or maintain | Social Security Number |
| | | Name |
| | | E-Mail Address |
| | | Phone numbers |
| | | Medical records (PHI) |
| | | Date of Birth |
| PIA - 2: | Indicate the categories of individuals about whom PII is collected, maintained or shared | Business Partners/Contacts (Federal, state, local agencies) |
| | | Employees/ HHS Direct Contractors |
| | | Grantees |
| | | Patients |
| | | Vendors/Suppliers/Third-Party Contractors (Contractors other than HHS Direct Contractors) |
| | | Other |
| PIA - 3: | Indicate the approximate number of individuals whose PII is maintained in the system | Above 2000 |
| PIA - 4: | For what primary purpose is the PII used? | Names, work email and work telephone numbers for covered entity (CE) and manufacturer contacts/authorizing officials for Registration and Pricing modules. These modules are used to create user accounts for those accessing both the pricing and registration systems for business purposes only.<br><br>The primary purpose of PII for the Compliance module is to identify and or provide contact information for OPA staff. Additionally, contact information for CE's, Drug Manufactures, and contract pharmacies may be used to determine eligibility for the 340B Drug Program. |
| PIA - 5: | Describe any secondary uses for which the PII will be used (e.g. testing, training or research) | Not Applicable |
| PIA - 6: | Describe the function of the SSN/Taxpayer ID | At times an SSN may be inadvertently submitted during an audit of a covered entity or drug manufacturer due to information not being redacted prior to uploading documents into the compliance module of the 340B OPAIS. OPA does not programmatically use SSN for any purposes. |
| PIA - 6A: | Cite the legal authority to use the SSN | We do not use the SSNs. |
| PIA - 7: | Identify legal authorities, governing information use and disclosure | Section 340B(d)(1)(B)(iii) of the Public Health Service Act requires the "provision of access through Department of Health and Human Services to the applicable ceiling prices for covered outpatient |

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| | specific to the system and program | Secretary in accordance with this section, in a manner (such as through the use of password prote covered entities and adequately assures security and protection of privileged pricing data from una |
| | | We established and continue to maintain the 340B database based on the following provisions: 340B(a)(9) Notice to Manufacturers: The Secretary shall notify manufacturers of covered outpatier under section 1902(a)(5) of the Social Security Act of the identities of covered entities ur der this p longer meet the requirements of paragraph (5) or that are no longer certified pursuant to paragrap identifiable information is limited only to collecting contact information only in their busine ss capac and manufacturers. Section 340B of the Public Health Service Act has numerous requirements including the registratic information about the covered entities and signing of Pharmaceutical Pricing Agreement: by Manu identification of an authorized official who has authority to register and change data in the database accuracy of the information and has ongoing verification of the information contained in our databas information are included on forms approved by OMB. Section 340B (a)(5) (C) requires covered entities to submit to audits, section 340B (d)(1) B)(v) auth manufacturers and wholesalers, section 340B (d)(3) requires the establishment of a proc ess of for OPA cannot perform any of these functions without collecting audit and contact data. |

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| **PIA - 9:** | Identify the sources of PII in the system | Directly from an individual about whom the information pertains |

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| In-person |
| Hard Copy Mail/Fax |
| Email |
| Online |
| Government Sources |
| Within the OPDIV |
| Other HHS OPDIV |
| Other Federal Entities |
| Non-Government Sources |
| Members of the Public |
| Private Sector |

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| **PIA - 9A:** | Identify the OMB information collection approval number or explain why it is not applicable. | OMB Number: 0915-0327 |
| **PIA - 9B:** | Identify the OMB information collection expiration date. | 11/30/2022 |
| **PIA - 10:** | Is the PII shared with other organizations outside the system's Operating Division? | No |
| **PIA - 11:** | Describe the process in place to notify individuals that their personal information will be collected. If no prior notice is given, explain the reason | The 340B Drug Program covered entity registration process is the mechanism by which registrant being accepted into the program. The PII OPA collects during the registration process is the name Primary Contacts, their phone numbers and email addresses. This is done as part of the administr |

program and maintaining system integrity

For the Compliance module, there is no process in place to notify individuals that their personal in
capacity nor stored in any government IT system. The PII information used by the system only ide
organization; and this is public information. All the PII collected by this system is voluntary and an
why their information is used when accessing the 340B OPAIS.

The names, addresses and emails of contact persons of the covered entity and Manufacturer are p

Also all the information collected in the system that includes Name, Address, Email ID for an OPA
directory maintained by HHS. The only PII information collected in the Compliance is the signature
and not considered mandatory.

Some patient PHI, a form of PII, is inadvertently collected or contained in drug audit information. T
patients when PHI has been collected. The goal of OPA is to not collect any PII from patients in ou
directly with the auditor to request new data that does not include PII; however, not all PII collected
identified. If the information is accidentally collected, it will not be shared with any other entities and

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| **PIA - 12:** | Is the submission of PII by individuals voluntary or mandatory? | Voluntary |
| **PIA - 13:** | Describe the method for individuals to opt-out of the collection or use of their PII. If there is no option to object to the information collection, provide a reason | The method for the covered entities (i.e. health centers, hospitals, etc.) to change/terminate from th termination request. Consequently (per entities request) their point of contact and or authorizing of number, etc.) will be updated and or removed from OPA's website. The email addresses are used participating stakeholders to assist them in performing the functions required by law. If they object address, this will prevent them from performing this requirement. The same process is applicable t exception to the termination process which is specified in the pharmaceutical pricing agreement. The PII Compliance module collects the signature of the individual participating in the program wh The individual responsible for programmatic implementation of the 340B Drug program is the Direc The OPA Director's signature is used on all correspondence to communicate with drug manufactu in the program. The user can opt out of using the automatic digital signature and instead sign all upload documents into the system. The Director of Pharmacy Affairs must click a button in order t containing his/her digitized signature. He/ She can, instead, print an "unsigned" letter and sign it m additional collection of PII/PHI is unintentional and incidental. |
| **PIA - 14:** | Describe the process to notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of original collection). Alternatively, describe why they cannot be notified or have their consent obtained | There is no process in place to notify and obtain consent from individuals when major changes occur to the system because the PII information that the application uses is publicly available and accessible to the general public. For the Compliance module, the collection of any patient PII/PHI incidentally is unintentional and therefore no mechanism has been set up to obtain consent or provide notification as this PHI is not used or shared. |
| **PIA - 15:** | Describe the process in place to resolve an individual's concerns when they believe their PII has been inappropriately obtained, used, or disclosed, or that the PII is inaccurate. If no process exists, explain why not | The authorizing official (AO) and Primary Contacts (PC) are the only persons for the 340B covered telephone number and email to register their organization. The AO and PC can submit an OMB ap correct inaccurate information in the 340B database. There is no formal process in place to addres believe that their PII has been inappropriately obtained, used, or disclosed. All PII is publicly availa their PII is publicly available and thus can be accessed, used, or disclosed by any member of the p |

The OPA Information System Security Officer (ISSO) will investigate and address any concerns ab
individual inquiry as needed. OPA does not anticipate a large number of issues, since the individu
system. The PII obtained is "Public" information - the work email address for an employee of a cov
systems administrator's data is part of the HRSA Active Directory General Support System, we inh
PII issues.

| PIA - 16: | Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy. Please address each element in your response. If no processes are in place, explain why not | The PII information collected in this application consist of name, work telephone numbers and ema applicants. This information is collected for administrative reasons only. Covered entities are enco information on the database. OPA staff verify each application for accuracy to ensure that covered is maintained. OPA staff also conduct annual recertification of all cover entities to ensure that each requirements. The recertification process also includes validation of participant's information.<br><br>For internal applications, the information of the users is cross verified with HHS active directory ev The PII associated with HRSA Active Directory accounts is covered by the HRSA GSS.<br><br>Any incidental PHI/PII is received from covered entities through Secure Email and File Transfer (S review process, the covered entity will be asked to re-submit with PHI/PII redacted. |
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| PIA - 17: | Identify who will have access to the PII in the system and the reason why they require access | Users<br><br>Administrators<br><br><br>Developers<br><br>Contractors<br><br>Others |

Provide the reason of access for each of the groups identified in PIA -17

Users - Access to limited PII (names/telephone numbers) for program operations in accordance with agency/program rules of behavior

Administrators - Access to limited PII (names/telephone numbers) for program operations in accordance with agency/program rules of behavior. Administrators also needs access in order to manage, create or delete accounts.

Developers - Access to limited PII (names/telephone numbers) for program operations in accordance with agency/program rules of behavior. Additionally they might need access for testing purposes.

Contractors - Access to limited PII (names/telephone numbers) for program operations in accordance with agency/program rules of behavior.

Others - Names and telephone numbers are available to the public.

| PIA - 17B: | Select the type of contractor | HHS/OpDiv Direct Contractor |
| --- | --- | --- |
| PIA - 18: | Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII | OPA has Identification, Authorization, and Authentication standard operating procedures for 340B OPAIS system. All users that have access to PII are internal OPA users. OPA users must sign an HHS and OPA Rules of Behavior contract and must have a user account request form signed by the system owner, the business owner, and the Information System Security Officer (ISSO) before they can access the system (via PIV |

card authentication). The user form identifies which authorized roles each user has in the system. Each role has different access rights and permissions in the system. Per NIST (and HHS) guidelines, OPA ISSO conducts quarterly audits of its internal user accounts, rules of behavior, and user request forms to ensure that user access rights are current and appropriate.

Data access is based upon roles in the system. Role assignments determine access to data. There is a user form and associated authorization process where OPA determines who gets what role.

| PIA - 19: | Describe the technical methods in place to allow those with access to PII to only access the minimum amount of information necessary to perform their job | 340B OPAIS has user roles associated with each type of user - public, Covered Entity, Manufactur Administrators, etc. Each user role has limited rights to see data and perform functions in the syste of their job. Covered Entities only have access to their own data as each covered entity account is entity. Similarly, Manufacturers only have access to their own data. Public users only have access must sign an HHS and OPA Rules of Behavior and must have a user account request form signed owner, and the Information System Security Officer (ISSO) before they can access the system (via form identifies which roles each user is authorized to have in the system. Each role has different ac system. Per NIST (and HHS) guidelines, OPA conducts quarterly audits of its internal user accoun request forms to ensure that user access rights are current and appropriate.

340B OPAIS system has role based access control in place. The information accessible by each ro information necessary to perform their jobs. |
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| PIA - 20: | Identify training and awareness provided to personnel (system owners, managers, operators, contractors and/or program managers) using the system to make them aware of their responsibilities for protecting the information being collected and maintained | Everyone accessing the system is required to take the "HRSA annual IT security and privacy awareness training". |
| PIA - 21: | Describe training system users receive (above and beyond general security and privacy awareness training). | None |
| PIA - 23: | Describe the process and guidelines in place with regard to the retention and destruction of PII. Cite specific NARA records retention schedule(s) and include the retention period(s) | The PII is only retained as long as it is in use. Following the General Records Schedule 1.2, the records in the 340B OPAIS which are terminated for more than 10 years will be deleted permanently from the system. |

For Compliance, the system does not accept PII contained within audit materials. If, in the course of an audit, the CE or Manufacturer sends the PII, OPA rejects the submission and asks for redacted materials without PII. OPA immediately destroys (deletes) any submitted materials containing PII.

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| **PIA - 24:** | Describe how the PII will be secured in the system using administrative, technical, and physical controls. Please address each element in your response | Administrative control: <br> 340B OPAIS uses Role Based Access Control (RBAC): <br> Non-organizational users get their roles based on the currently reviewed and approved registration Authorizing Official (AO) if their account is the current authorizing official on an active and approved Primary Contacts (PC). <br> Organizational users who access to the system must be approved by the system owner, business Security Officer (ISSO). <br><br> Technical control: <br> 340B OPAIS is multi-tier architecture where the presentation layer is separated from the business the database is encrypted. In addition, the database is encrypted to protect data at rest. <br><br> Physical control: <br> Servers containing the data are in the Sterling, VA Data center, part of the HRSA GSS, and they in protection of the data (guarded, ID badges, key cards, etc.) |
| **PIA - 25:** | Describe the purpose of the web site, who has access to it, and how users access the web site (via public URL, log in, etc.). Please address each element in your response | https://340bopais.hrsa.gov - Public and No Login is required <br> https://340bregistration.hrsa.gov - Need Credentials (Username, password, and authentication code) <br> https://340bpricing.hrsa.gov - Need Credentials (Username, password, and authentication code) <br> https://340bpricingsubmissions.hrsa.gov - Need Credentials (Username, password, and authentication code) |
| **PIA - 26:** | Does the website have a posted privacy notice? | No |
| **PIA - 27:** | Does the website use web measurement and customization technology? | Yes |
| **PIA - 27A:** | Select the type of website measurement and customization technologies is in use and if it is used to collect PII | Session Cookies - Does Not Collect PII |
| **PIA - 28:** | Does the website have any information or pages directed at children under the age of thirteen? | No |
| **PIA - 29:** | Does the website contain links to non-federal government websites external to HHS? | Yes |
| **PIA - 29A:** | Is a disclaimer notice provided to users that follow external links to websites not owned or operated by HHS? | No |
| **PIA - 29B:** | Is a TPWA needed for this system? | No |