

US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

03/12/2015

OPDIV:

HRSA

Name:

OPAIS/340B Pricing System

PIA Unique Identifier:

P-1069115-017793

The subject of this PIA is which of the following?

Major Application

Identify the Enterprise Performance Lifecycle Phase of the system.

Operations and Maintenance

Is this a FISMA-Reportable system?

Yes

Does the system include a Website or online application available to and for the use of the general public?

No

Identify the operator.

HRSA

Is this a new or existing system?

Existing

Does the system have Security Authorization (SA)?

Yes

Indicate the following reason(s) for updating this PIA.

PIA Validation

Describe in further detail any changes to the system that have occurred since the last PIA.

none

Describe the purpose of the system.

The Office of Pharmacy Affairs (OPA) is responsible for the administration of the 340B Program. The OPA has established the OPAIS (Office of Pharmacy Affairs Information System) in order to respond to the needs created by the 340B Drug Pricing Program. OPAIS is a system containing a public access web site to identify and verify covered entities, and a confidential stand alone pricing module to compute discounted drug prices. The public access web site is the only source for pharmaceutical manufacturers, wholesalers, and pharmacies to verify that an organization claiming to be a covered entity is a participant in the 340B program and therefore eligible for discounted drug prices. The OPAIS pricing module is the sole official federal source for determining the pricing of discount drugs. The OPAIS public web site contains databases for 340B covered entities, manufacturers, and contract pharmacies.

Describe the type of information the system will collect, maintain (store), or share.

System contains pharmacuetical pricing data. Output of data is local only and copies are either destroyed or maintained under lock and key. No dissimination of data outside of OPA and is not subject to PII.

Provide an overview of the system and describe the information it will collect, maintain (store), or share,

The OPAIS Pricing system is used to calculate and store the 340B ceiling price. The pricing system uses a statutory formula to calculate 340B ceiling prices. All the data in the system are maintained permanently and referenced for their historical value.

Does the system collect, maintain, use or share PII?

No