



Office of Pharmacy Affairs

340B Drug Pricing Program Data Guide for Manufacturers

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Section 1: 340B Drug Pricing Program Guidance

The Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA) administers the 340B Drug Pricing Program (340B Program), which requires that manufacturers participating in the Medicaid Drug Rebate Program enter into agreements with the Secretary of Health and Human Services under which prices charged to participating eligible organizations (“covered entities”) for covered outpatient drugs shall not exceed the amounts determined under a pricing formula defined in the statute (340B ceiling price). The 340B Program enables covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.

The Affordable Care Act (ACA) mandated improvements in 340B program integrity, which included the creation of a system to allow authorized users from the covered entities access to view verified 340B ceiling prices for covered outpatient drugs.

In response to the ACA, HRSA has developed the 340B Office of Pharmacy Affairs Information System (OPAIS) Pricing Application (“OPAIS Pricing Application”) to calculate and verify 340B ceiling prices. This secure, web-based application allows manufacturers participating in the 340B Program the ability to easily upload and submit their quarterly pricing data for their portfolio of covered outpatient drugs to HRSA and validate their prices with the HRSA-calculated 340B ceiling price. Manufacturers are notified of any potential discrepancies in pricing data and are given an opportunity to reconcile the pricing data before HRSA verifies the final 340B ceiling price. Authorized users from covered entities will have view-only access to verified 340B ceiling prices for covered outpatient drugs.

1.1: 340B Laws, Regulations, and Program Guidance

Information on the laws, regulations, and program guidance required for manufacturer participation in the 340B Drug Pricing Program can be found on the HRSA Office of Pharmacy website at <http://www.hrsa.gov/opa/index.html>.

1.2: 340B Listserv

To receive 340B Drug Pricing Program e-mail updates for manufacturers, please subscribe to the [HRSA listserv](#).

Section 2: 340B OPAIS Pricing Application Overview

The OPAIS Pricing Application works by allowing manufacturers the ability to upload quarterly 340B pricing data and submit the data to HRSA for comparison. HRSA calculates the 340B ceiling price by utilizing quarterly pricing data from the Centers for Medicare & Medicaid Services (CMS) Medicaid Drug Rebate Program (MDRP) and a commercial data broker. This 340B ceiling price is compared with the manufacturer's 340B price. If a discrepancy exists between the manufacturer's data and HRSA's data, the manufacturer's dashboard page on the OPAIS Pricing Application will be updated with a list of reconciliation tasks, and the manufacturer will have an opportunity to review and reconcile the price discrepancies before the 340B ceiling price is posted in the pricing system for the applicable quarter. Once the 340B ceiling price is published in the secure OPAIS Pricing Application, authorized users from covered entities will be able to log into the system and have view-only access to the 340B ceiling price.

The OPAIS Pricing Application increases the efficiency of data submissions, improves data integrity, and is user-friendly. The system allows for secure manufacturer submissions through data encryption and storage in a secure manner with defined access controls and data security classifications. The OPAIS Pricing Application meets Federal Information Security Management Act (FISMA) moderate requirements. Access to the OPAIS Pricing Application is restricted to authenticated and authorized users based on account roles and permissions to limit the unauthorized re-disclosure of privileged pricing data. In order to access the system, a manufacturer's Authoring Official (AO) will be required to agree to the OPAIS Rules of Behavior and sign an Attestation Form. This process allows HRSA to validate the applicant's status as a participating drug manufacturer in the 340B Program before issuing a user ID and setting a password. Manufacturers will only have access to pricing data for their designated labeler codes. Authorized users from covered entities can access the application and view the HRSA-verified 340B ceiling prices. Users from covered entities are also required to obtain a user ID and password by agreeing to the Rules of Behavior and signing an Attestation Form in the same manner as the drug manufacturers who use the system. A two-step authentication process is required for all users logging into the OPAIS Pricing Application.

Section 3: 340B Ceiling Price Calculation

$$340B \text{ Ceiling Price} = (\text{AMP} - \text{URA}) * \text{PS} * \text{CSP}$$

Under section 340B(a) of the Public Health Service Act (PHSA), the 340B ceiling price is calculated by subtracting the unit rebate amount (URA) from the average manufacturer price (AMP) for the smallest unit of measure of each covered outpatient drug (as identified by the product's 11-digit National Drug Code (NDC)). To ensure that the final price is operational in the marketplace, HRSA then multiplies this amount by drug's package size (PS), defined as the number of billing units in the labeled quantity from which the pharmacist dispenses, and the case pack size (CSP), defined as the number of salable units in the shipping container). For example, a 2,000 mL bottle of saline is a 340B covered outpatient drug. The package size is 2,000 because that is the number of billing units in the dispensable package. The case pack size is one because that is the number of units at which the product is sold.

Drug manufacturers participating in the Medicaid Drug Rebate Program report the AMP for each of their products to CMS each quarter, and CMS then calculates the corresponding URA for each of those products.

Section 1927(c)(2)(A) of the Social Security Act provides that if a given AMP increases at a rate faster than inflation (the Consumer Price Index for All Urban Consumers, or CPI-U), the manufacturer of that product pays an additional Medicaid rebate amount (reflected in an increased URA). Adjustments under Section 1927(c)(2)(A) could historically result in URAs greater than their associated AMPs, with negative 340B prices as the ultimate result, but the Affordable Care Act added section 1927(c)(2)(D) of the Social Security Act to limit the unit rebate amount to 100% of the AMP effective January 1, 2010. Consequently, an increase in the basic rebate and inflation factor would not result in a negative 340B price, but could result in a zero 340B price (see Section 5.1 for more information).

3.1: AMP, URA, and 340B Price Rounding Issues

Both the AMP and URA values shall have six digits trailing the decimal point, but the rounding rules are different. The AMP value shall be rounded to six decimal places. The URA value shall be rounded to four decimal places, and positions five and six are padded with zeros (see Appendix A for more information).

Incorrect URA formats:

- 00100.992315 (incorrect as positions 5 and 6 are not padded with zeros)
- 00090.198395 (incorrect as positions 5 and 6 are not padded with zeros)

Correct URA formats:

- 00100.992300
- 00090.198400

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The final 340B price shall be rounded to two decimal places using normal mathematical rounding. If the digit in the thousandths is 5, 6, 7, 8, or 9, add one to the hundredths digit and drop all digits to the right of it. If the digit in the thousandths is 0, 1, 2, 3, or 4, do not change the hundredths digit; drop all digits to the right of it.

Table 1: Examples of conversion from calculated 340B price to final rounded 340B price

Calculated 340B price	Final rounded 340B price
00020.951461	00020.95
00320.050812	00320.05
00100.769406	00100.77
02015.055921	02015.06

Section 4: 340B Price Reporting Requirements

Manufacturers are required to report 340B pricing data to HRSA for all covered outpatient drugs. HRSA requests that the data is submitted within a two-week submission period beginning 45 days after the end of the previous quarter. Manufacturers may log into the OPAIS Pricing Application and upload a formatted text file containing their quarterly data (see Appendix A). The application then scans the files for data integrity and potential security threats, and advises the user if any errors have been identified. Manufacturers whose files are initially rejected by the system can correct the underlying issues and upload a new file for processing.

Files that pass initial security and integrity checks are analyzed and the data fields are compared with the AMP, URA, PS, and CSP data points that HRSA has on file. HRSA obtains the AMP and URA data points from CMS on a quarterly basis. PS and CSP data points are obtained from an external data broker (currently First DataBank (FDB)).

If the application detects a discrepancy between the manufacturer's data points and HRSA's data points, the manufacturer is assigned a task to reconcile the pricing data points for a specific NDC. The reconciliation tasks are displayed on the manufacturer's dashboard page within the OPAIS Pricing Application. The manufacturer then reviews the task and reconciles the data points. If an error was made to the data points in the uploaded file, it can be corrected during this reconciliation phase. If a manufacturer believes that their submitted data points are correct and the HRSA data is incorrect, they can inform HRSA of the correct interpretation in the notes section on the product reconciliation page. Figure 1 provides an illustrative diagram of the data flow listed above.

4.1: Database Business Rules

As the final authority of the 340B ceiling price, HRSA has developed extensive business rules to guide the adjudication of the HRSA-verified 340B ceiling price.

Note: The PS and CSP are submitted in separate data fields on the text file. The OPAIS Pricing Application multiplies the PS by the CSP ($PS * CSP$) and examines the product as a single value during the comparison. For example, a manufacturer submits a PS of 5 and a CSP of 3. HRSA has a PS of 3 and a CSP of 5 for the same product. In both instances, the product of the calculation is 15; thus the system will detect a match, and a task to reconcile the PS and CSP will not be assigned.

The business rules are summarized as follows:

- If the AMP, URA, PS, and CSP are present and identical from both sources (either as initially submitted by the manufacturer or after manufacturer reconciliation), processing is complete and the authoritative ceiling price for that product will be made available to covered entities at the beginning of the next quarter.
- If the OPAIS Pricing Application receives a quarterly file from a manufacturer, but HRSA has not received the AMP and URA data points from CMS, and the manufacturer's PS and CSP values match or can be reconciled by the manufacturer to match HRSA's values, then HRSA will treat the product as a voluntary offering in the 340B Program and will make the resulting price available to covered entities at the beginning of the next quarter.

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- If the OPAIS Pricing Application does not receive a quarterly file from a manufacturer within the two-week submission period, the ceiling price will be calculated using the AMP, URA, PS, and CSP data points that HRSA has on file, and the manufacturer will be obligated to honor the resulting 340B ceiling price. If HRSA or the manufacturer subsequently determines that the actual price would have been lower if manufacturer data had been reported, the manufacturer will be obligated to identify the affected covered entities and issue refunds for any overcharges.
- If there is a discrepancy between the manufacturers' AMP, URA, PS, or CSP data points and the data points that HRSA has on file for a specific product, the manufacturer will be assigned a reconciliation task on their dashboard in the OPAIS Pricing Application. Manufacturers shall reconcile any products where the AMP, URA, PS, or CSP data points do not correspond with HRSA's data points.
- In order to further protect the commercially sensitive data from unauthorized re-disclosure, during reconciliation, a manufacturer will not be able to view the AMP and URA data points that HRSA has on file. Manufacturers can access the CMS Drug Data Reporting (DDR) System to research the AMP and URA data points.
- If a manufacturer is unable to reconcile a price discrepancy to match HRSA's values, HRSA will defer to CMS for the AMP and URA data points and the commercial data broker for the PS and CSP data points. If HRSA's values are missing or have a value of zero, then the manufacturer's data will be used.
- HRSA may override the above rules if manufacturers are able to conclusively show inaccuracies or similar shortcomings of CMS-provided AMP and URA or HRSA's commercially procured PS and CSP data.

If the pricing data in the manufacturer's uploaded file matches with HRSA's external data sources, or any discrepancies have been resolved by the manufacturer during reconciliation or by applying the OPAIS Pricing Application's business rules, then the manufacturer's reporting obligations for that quarter will be complete. The resulting ceiling prices will be made accessible to covered entities for the next quarter.

4.2: Covered Entity Alerts

If warranted for a given price, one of two messages will be shown to covered entities when viewing the published 340B ceiling price:

- I. *(*) The 340B ceiling price for this product was calculated by HRSA solely based on CMS data. The Manufacturer did not submit 340B pricing data to HRSA for ceiling price comparison.*

HRSA will publish a 340B ceiling price without comparing it to the manufacturer's data in situations where a manufacturer has not uploaded their quarterly pricing data to the OPAIS Pricing Application or missed the two-week submission period.

- II. *(**) The 340B ceiling price for this product was calculated by HRSA solely based on using only data submitted by the manufacturer. No CMS pricing data was available for ceiling price comparison.*

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HRSA will publish a 340B ceiling price without comparing it with the AMP and URA data points received from CMS in situations where the manufacturer does not participate in the Medicaid Drug Rebate Program and CMS does not have quarterly pricing data to report for the specified product(s).

4.3: Quarterly Submission Timeframes

The OPAIS Pricing Application’s quarterly submission periods are designed to accommodate the quarterly changes in the 340B ceiling price. For example, sales of covered outpatient drugs occurring in Q1 (January 1 – March 30) must be reported to HRSA during the two-week open submission period in Q2 (May 15 – May 31). The system validates the data, calculates a 340B ceiling price, and the manufacturer reconciliation period and HRSA adjudication processes are initiated to ensure that the manufacturer’s pricing data matches HRSA’s pricing data. Once all of the reconciliation and adjudication processes are completed during Q2, the HRSA-verified 340B ceiling price is published at the beginning of Q3 and becomes effective for the entire quarter (July 1 – August 31).

Table 2: Summarizes the general timeframes for each quarter's activities

Calendar Quarter (Rebate Period)	Q1 Jan 1 – March 31	Q2 April 1 – June 30	Q3 July 1 – Sept 30	Q4 Oct 1 – Dec 31
Manufacturer Submission Period	May 15 – May 31	Aug 15 – Aug 31	Nov 15 – Nov 30	Feb 15 – Feb 28
Manufacturer Reconciliation Period	June 1 – June 15	Sept 1– Sept15	Dec 1 – Dec 15	Mar 1 – Mar 15
HRSA Adjudication Period	June 16 – June 30	Sept 16 – Sept 30	Dec 16 – Dec 31	Mar 16 – Mar 31
Ceiling Prices Posted for view-only access by Covered Entities	July 1 (Q3)	October 1 (Q4)	January 1 (Q1)	April 1 (Q2)

Note: The manufacturer’s reconciliation period and HRSA adjudication period may occur earlier than the identified periods as long as the previous step has been completed. For example, if a manufacturer uploads a pricing file on May 15th and HRSA has already received data to conduct a comparison of the ceiling price, then the manufacturer’s reconciliation period could begin prior to June 1.

4.4: Preparing the 340B Ceiling Price for Publication

The process for preparing the 340B ceiling price for publication has two starting points, either starting with data from a commercial data broker or starting with data submitted by a manufacturer. The process flow is detailed below.

Starting Point 1: Data from Commercial Data Broker

1. HRSA obtains AMP and URA data from CMS. PS and CSP data are obtained from a commercial data broker. The system calculates the 340B ceiling price.
2. Skip to Common Process.

Starting Point 2

1. The manufacturer submits data into the OPAIS Pricing Application beginning 45 days after the end of the previous quarter.
2. The system reviews the file to ensure data format is correct and complete.
3. Is the file format correct and all data is complete?
 - If “No,” file is rejected and manufacturer must resubmit a new file. *Return to Starting Point 2.*
 - If “Yes,” skip to *Common Process.*

Common Process

1. Does the manufacturer’s 340B data match HRSA’s 340B data?
 - If “Yes,” the 340B ceiling price is ready to be published the OPAIS Pricing Application for the next quarter. *End of process.*
 - If “No,” the manufacturer receives a notification on the dashboard page that they have been assigned a reconciliation task in the OPAIS Pricing Application.
2. Manufacturer logs into the pricing system and reconciles the price discrepancies.
3. Does the manufacturer’s 340B data match HRSA’s 340B data?
 - If “Yes,” the 340B ceiling price is ready to be published the OPAIS Pricing Application for the next quarter. *End of process.*
 - If “No,” the OPAIS Pricing Application applies its business rules, OPA adjudicates the data, and the 340B ceiling price is ready to be published the OPAIS Pricing Application for the next quarter. *End of process.*

This process is depicted in Figure 1 below.

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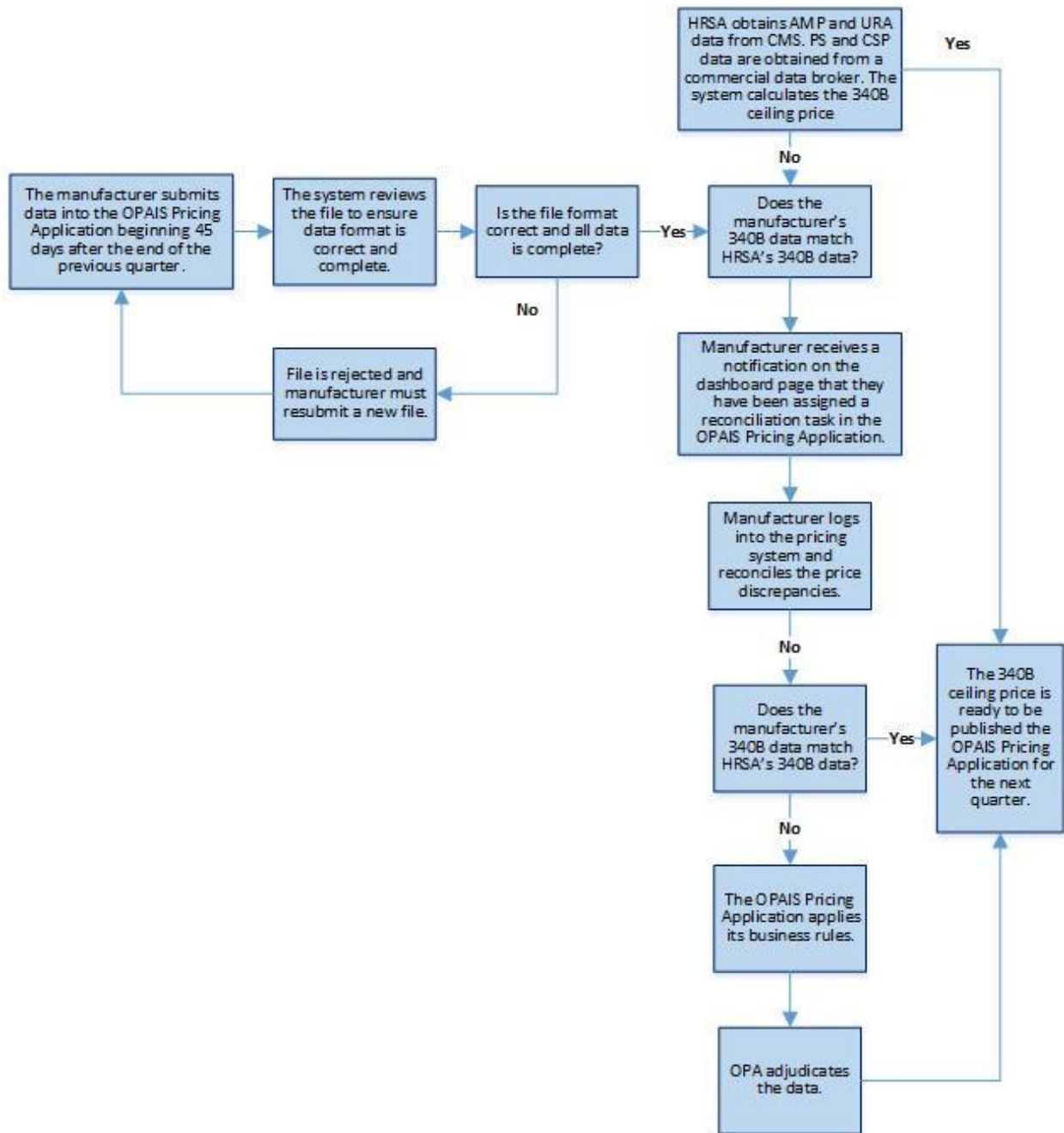


Figure 1: Process overview for preparing the 340B ceiling price for publication

Section 5: Special Pricing Situations

5.1: Penny Pricing

HRSA recognizes that when the URA equals the AMP it is not reasonable for a manufacturer to set a 340B price of zero per unit of measure. In these cases, HRSA's Clarification of Penny Pricing Policy Release dated November 21, 2011 (see Release No. 2011-2) states that the manufacturer charges \$0.01 per unit of measure for a drug with a ceiling price below \$0.01 (multiplying that price by PS and CSP to achieve a final 340B ceiling price).

Example:

- AMP = 00000.000122
- URA = 00000.000100
- PS = 0000050.000
- CSP = 0000001.000

340B Ceiling Price = (AMP – URA) * PS * CSP

- AMP – URA = 00000.000122 – 00000.000100 = 00000.000022
- Round to 00000.01
- (AMP – URA) * PS * CSP = 00000.01 * 50 * 1 = 00000.50
- 340B Ceiling Price = 000000000.50

340B ceiling prices must be based on the immediately preceding calendar quarter pricing data, therefore, manufacturers may not substitute AMP or URA values from prior quarters, wholesale acquisition cost (WAC), or any other non-340B contract price in situations where penny pricing applies. Using the prior quarter pricing or some other price in place of penny pricing would nullify the pricing penalty (AMP increasing faster than inflation) when the 340B ceiling price decreases because of changes to the AMP.

5.2: New Drug Price Estimation

Ceiling prices for covered outpatient drugs are calculated each quarter for the following quarter, based on sales in the immediately preceding quarter. Therefore, data to calculate definitive 340B prices for new drugs will be unavailable for two quarters after market introduction.

HRSA's New Drug Pricing guidelines (60 FR 51488 (October 2, 1995)) state that manufacturers shall continue to estimate the 340B ceiling price for the first three quarters that a new covered outpatient drug is available for sale. Manufacturers shall begin reporting data to the OPAIS Pricing Application in the third quarter that the product is available. Manufacturers must ultimately calculate the actual 340B ceiling price for the first three quarters the drug was available for sale and shall refund or credit covered entities that purchased the product at prices exceeding the reconciled 340B ceiling price no later than the end of the fourth quarter after the drug is available for sale.

Section 6: User Roles

The OPAIS Pricing Application is a role-based system that links certain functions within the application to specific user role profiles. The Authorizing Official (AO) and the Primary Contact (PC) user roles are assigned to manufacturers participating in the 340B Drug Pricing Program. Users for each role are identified by importing the manufacturer's AO and PC from the HRSA Office of Pharmacy Affairs 340B Database at <https://opanet.hrsa.gov/340B/>.

Regardless of the specific role assigned to a user, all users must agree to the Rules of Behavior (Appendix B) and attest to their identity in order to receive access to the system.

6.1: Authorizing Official (AO)

The manufacturer's Authorizing Official (AO) is the individual who signs the Pharmaceutical Pricing Agreement (PPA) or is listed on an approved 340B Manufacturer Change Form. The AO must be a corporate officer or someone who is otherwise authorized to legally bind the company to the terms of the PPA (e.g., Chief Executive Officer, Chief Financial Officer, Chief Operating Officer, etc.). AOs maintain overall responsibility for compliance with 340B Program requirements for their labeler code(s).

The AO has permissions to:

- Assign or change Primary Contact
- Submit quarterly data
- Reconcile pricing data when discrepancies exist

6.2: Contact (PC)

The manufacturer's Primary Contact (PC) is the individual listed in the PPA as the contact person, or someone the AO has listed on an approved 340B Manufacturer Change Form. Every drug manufacturer that submits data through the pricing system must assign a PC for each labeler code in the pricing system. The PC is responsible for submitting the required drug data for the manufacturer's labeler code(s) to HRSA via the OPAIS Pricing Application on a quarterly basis. PCs are also responsible for reconciling the system-identified price discrepancies between the manufacturer's pricing data and HRSA's pricing data.

The PC has permissions to:

- Submit quarterly data
- Reconcile pricing data when discrepancies exist

Section 7: Applying for Access – Authorizing Officials

Within a manufacturer, the AO and PC are the only individuals who are authorized to access the OPAIS Pricing Application to upload and reconcile quarterly pricing data. Only AOs can request account access for a PC. While multiple individuals within an organization may fit the definition of AO (as defined in section 6.1), only the AO currently listed in HRSA’s 340B Registration Database (e.g. the original signee of the PPA or as listed on the 340B Manufacturer Change Request Form approved by HRSA) may request an OPAIS Pricing Application user account for a PC.

7.1: Initial Login

HRSA will initiate the creation of user accounts by sending an e-mail with the subject, “ACTION REQUESTED: HRSA 340B OPAIS Pricing Application New Account Activation” to the manufacturer’s AO e-mail address listed in the 340B Registration Database. This e-mail will contain instructions on how to create an account.

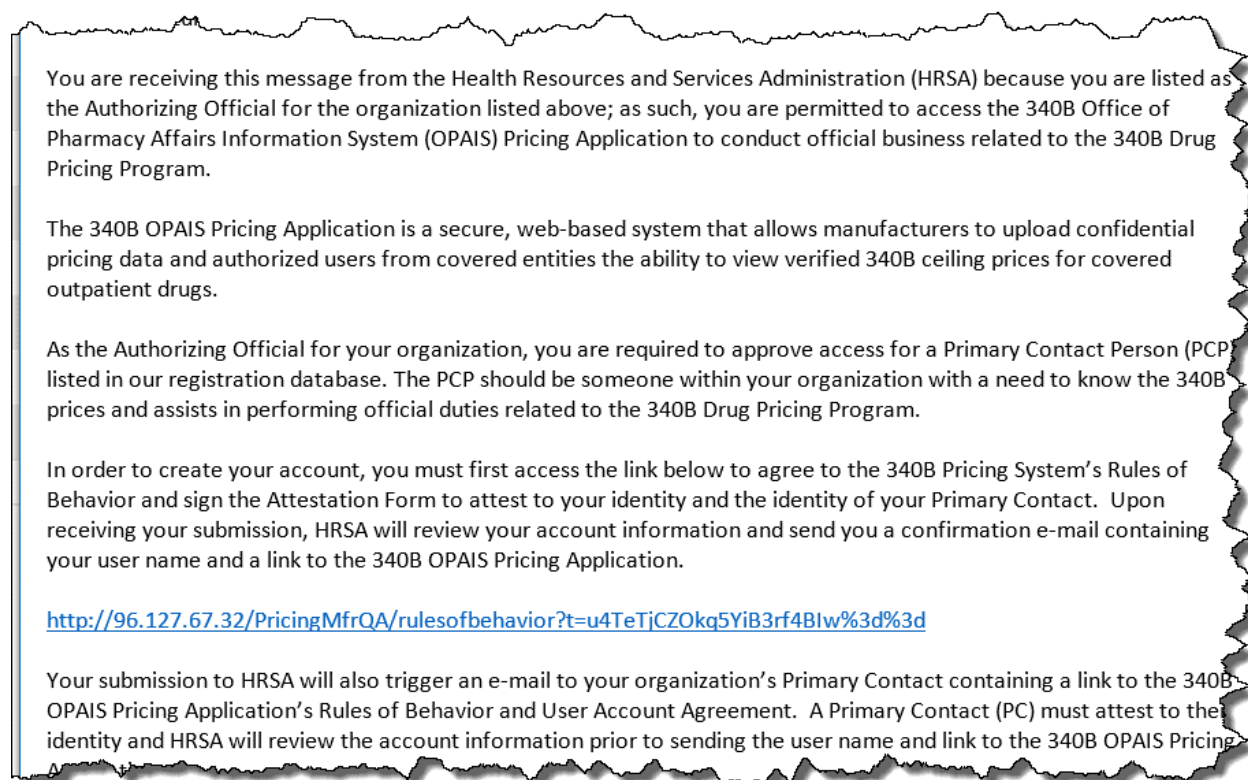


Figure 2: Email Content from HRSA when HRSA initiates creation of user account

7.2: Rules of Behavior

Clicking on the link in the e-mail will direct the AO to the OPAIS Pricing Application's Rules of Behavior, which outline the rules that govern the appropriate use of the pricing application.

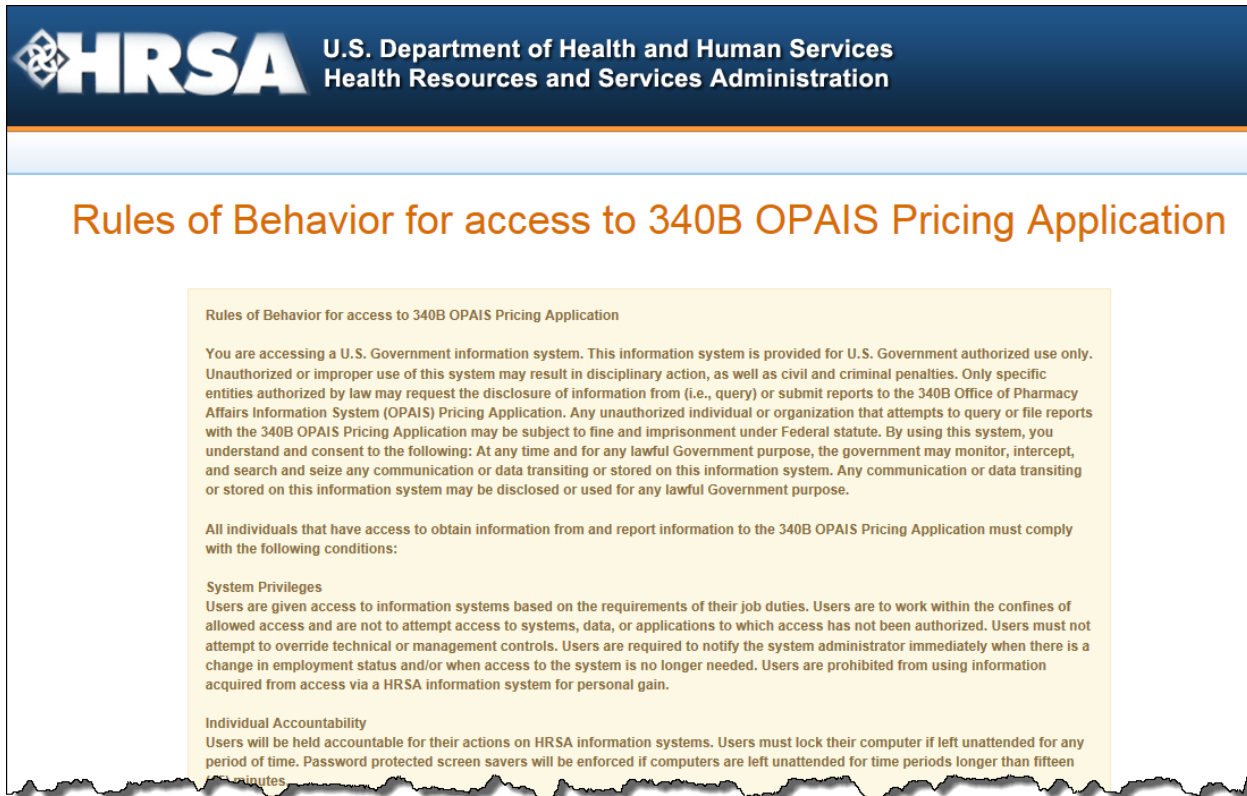


Figure 3: Snippet of top part of Rules of Behavior for access to 340B OPAIS Pricing Application

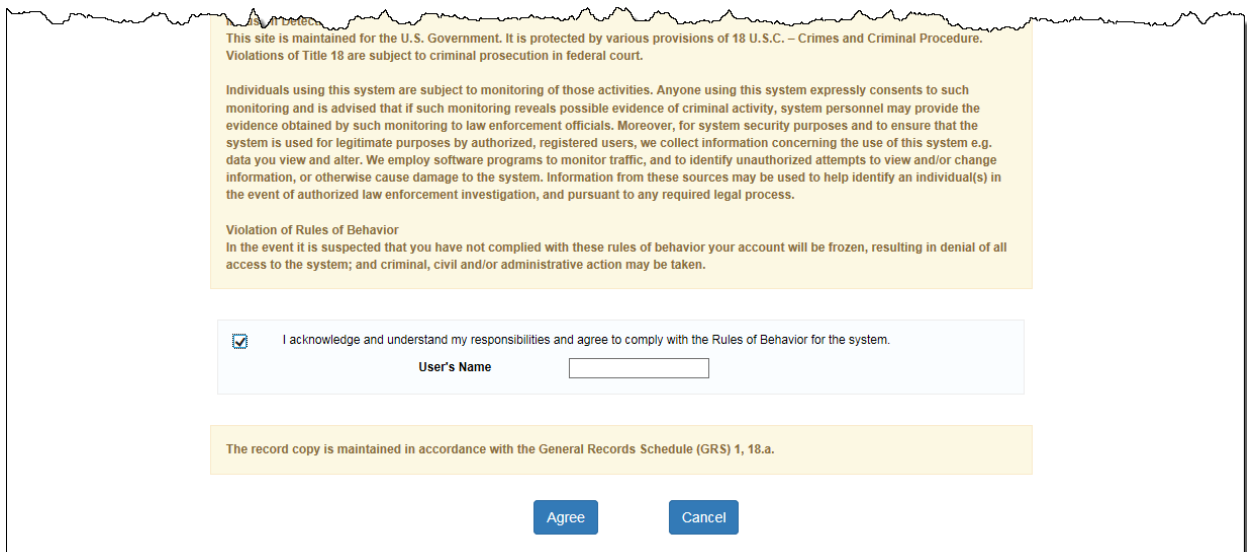


Figure 4: Snippet bottom part of the Rules of Behavior for access to 340B OPAIS Pricing Application

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The purpose of each of the form elements in the Rules of Behavior are elaborated below:

1. **Checkbox** – *“I Acknowledge and understand my responsibilities and agree to comply with the Rules of Behavior for the system.”* – Acknowledge that you have read the HRSA Rules of Behavior by checking the box.
2. **User’s Name** text box – Enter your first and last name.
3. **Agree** button – Click the button to indicate that you agree to the Rules of Behavior.

7.3: Attestation Form

After the AO reads and agrees to the Rules of Behavior, the Manufacturer AO Attestation Form is displayed.

The Manufacturer AO Attestation Form requires the AO to verify his or her identity, their role as an AO for their organization, and attest that their identity has been proofed by their employer at a level HRSA deems to be acceptable. HRSA accepts that a criminal background check and verification of photo ID (government passport or state-issued driver’s license) represent an acceptable level of identity proofing. Furthermore, HRSA accepts that virtually all organizations require at least minimal background checks (credit check, employment history verification, etc.) for potential employees.

The Manufacturer AO Attestation Form also contains a statement that requires the AO to attest that their organization’s identity proofing requirements for their assigned PC meets HRSA’s standards. A list of PCs and associated labeler codes for the manufacturer are displayed from the 340B Registration Database. The AO must review the list to confirm that the individual is authorized to be a PC for the corresponding labeler code. Do not submit the Attestation Form if any of the assigned PCs are incorrect. AOs should instead review the list of PCs in the 340B Registration Database and submit a 340B Manufacturer Change Form to HRSA if the information is incorrect.

HRSA U.S. Department of Health and Human Services
Health Resources and Services Administration

Manufacturer Authorizing Official Attestation Form

Name:
 Title:
 Phone #:
 Email Address:

Authorizing Official

Associated Labeler Code	Labeler Code Name
00044	KNOLL LABORATORIES

Primary Contacts

Associated Labeler Codes	Labeler Code Name	Primary Contact	Title	Phone Number	Email Address
00044	KNOLL LABORATORIES	Joe Smith	PRESIDENT & CEO	123456789	mfrcp8@futrend.com
00044	KNOLL LABORATORIES	Joe Smith	PRESIDENT & CEO	123456789	mfrcp8o@futrend.com

By selecting this checkbox I confirm that I am the Authorizing Official and I have permission to access the 340B OPAIS Pricing Application. I also confirm that the above list of Primary Contacts associated with the Labeler Codes is correct and the Primary Contacts have permission to access the 340B OPAIS Pricing Application.

Note: If any of the information listed on this form is incorrect, please [Click Here](#) to fill out a copy of the 340B Manufacturer Change Form.

Figure 5: Manufacturer Authorizing Official Attestation Form showing acknowledgement checkbox

The Manufacturer Authorizing Official Attestation Form displays the contact information for the Authorizing Official and provides data fields to edit it, as well as associated labeler codes and primary contacts. There is an attestation message, a “Click Here” link to enter changes via the 340B Manufacturer Change form, and “Submit” and “Cancel” buttons.

1. After reviewing the Attestation Form, acknowledge the terms by clicking the checkbox.

The attestation text reads as follows:

“By selecting this checkbox, I confirm that I am the Authorizing Official and I have permission to access the 340B OPAIS Pricing Application. I also confirm that the above list of Primary Contacts associated with the Labeler Codes is correct and the Primary Contacts have permission to access the 340B OPAIS Pricing Application.”

2. Click one of the following buttons:
 - **Submit:** Click this button to submit the Attestation Form.
 - **Cancel:** Click this button to close the Attestation Form and cancel creation of your user account. The User Verification Cancelled page is displayed.

7.4: Setting a Password

The AO’s submission of the Manufacturer AO Attestation Form will direct the AO to the Set Password page. When the user submits the Attestation Form to HRSA, they will be prompted to set a password. All passwords must conform to the password requirements outlined in the OPAIS Pricing Application Rules of Behavior. Submitting the Attestation Form will also initiate a confirmation e-mail to each user that contains their assigned user ID to be used for subsequent logins.

340B OPAIS Pricing Application
Set Password

Login name:

Password:

Confirm password:

Note: Passwords must consist of at least eight (8) characters that cannot be easily guessed and must adhere to the following guidelines:

- Passwords must contain at least one character from each of the following four categories:
 1. English uppercase characters (A-Z)
 2. English lowercase characters (a-z)
 3. Numerical digits (0-9)
 4. Special characters (e.g. @, !, \$, %)
- Characters may not be repeated more than once within a succession.
- Passwords shall not contain all or part of the user's account name.

Figure 6: 340B OPAIS Pricing Application Set Password page

340B OPAIS Pricing Application Set Password page provides spaces to enter your password and password confirmation, as well as instructions for password creation. (Your login name is automatically populated by the system.) The password instructions read as follows:

***Note:** Passwords must consist of at least eight (8) characters that cannot be easily guessed and must adhere to the following guidelines:*

- Passwords must contain at least one character from each of the following four categories:
 1. English uppercase characters (A-Z)
 2. English lowercase characters (a-z)
 3. Numerical digits (0-9)
 4. Special characters (e.g. @, !, \$, %)
- Characters may not be repeated more than once within a succession.
- Passwords shall not contain all or part of the user's account name.

1. Use the “Password” and “Confirm Password” spaces provided to enter your password and confirm it.
2. Click the “Set Password” button to set your password and create your user account.

Once the AO clicks the submit button on the Manufacturer AO Attestation Form, HRSA will process the submitted account information and send a confirmation e-mail containing the user name and a link to the 340B OPAIS Pricing Application. ***Please bookmark this link for future login attempts.***

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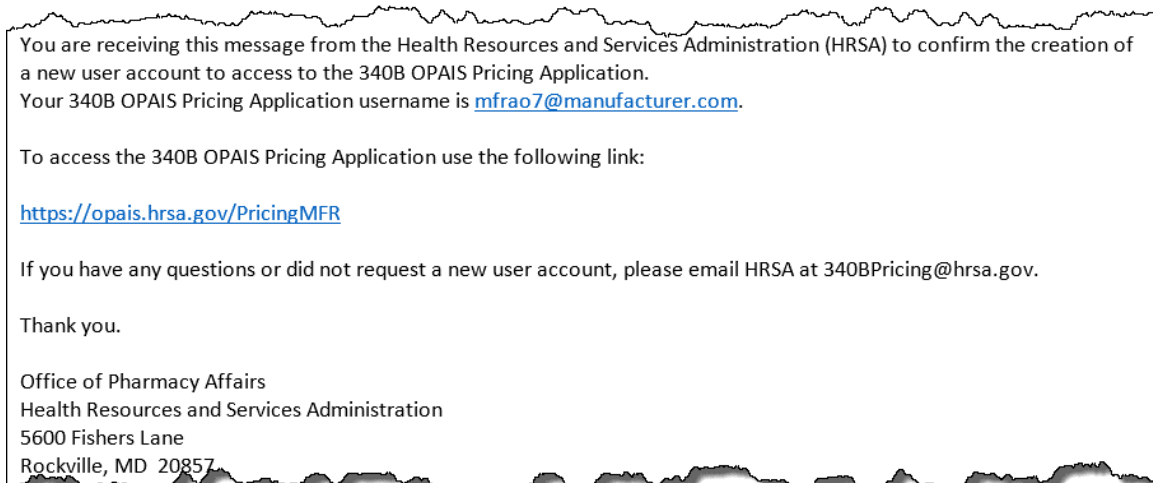


Figure 7: Confirmation e-mail containing user name and link to 340B OPAIS Pricing Application

Clicking the “Set Password” button will establish your password for the 340B OPAIS Pricing Application and you will be directed to the Account Successfully Created page. *Please memorize this password for future login attempts.*

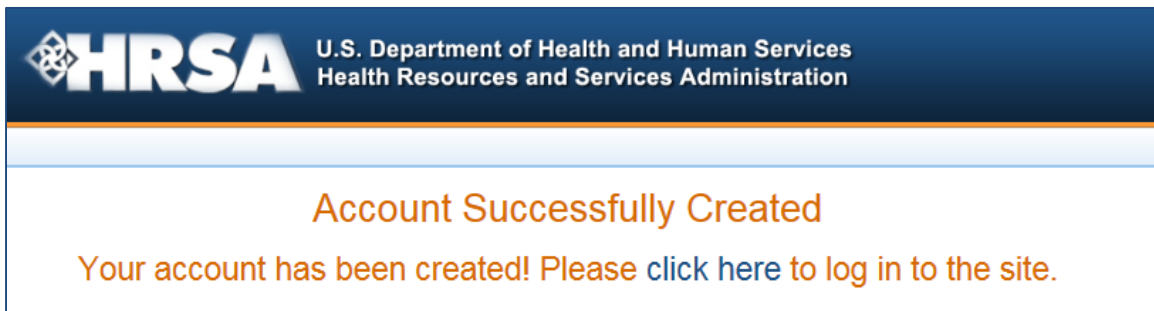


Figure 8: Account Successfully Created page

Section 8: Applying for Access – Primary Contacts

8.1: Initial Login

When the AO clicks the submit button on the Manufacturer AO Attestation Form, a notification e-mail with the subject, “ACTION REQUESTED: HRSA 340B OPAIS Pricing Application New Account Activation,” will be sent to the labeler code’s designated Point of Contact listed in the 340B Registration Database. This e-mail will contain instructions on how to create an account and a link to the account creation page.

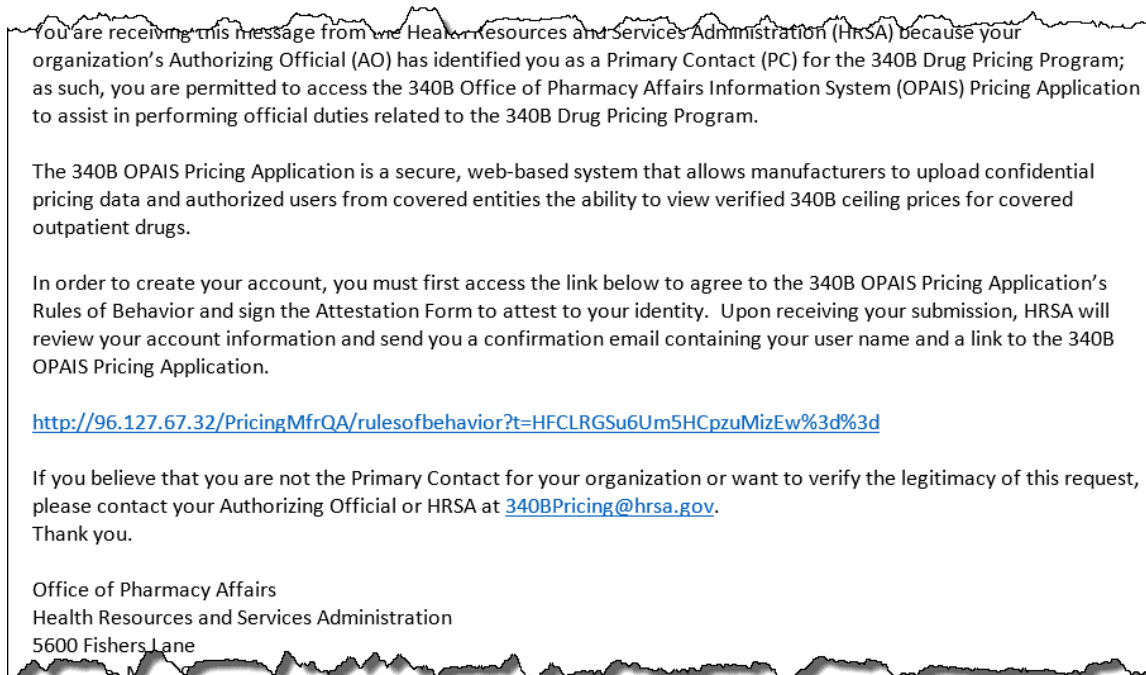


Figure 9: Confirmation e-mail containing user name and link to Rules of Behavior page

8.2: Rules of Behavior

Clicking on the link within the e-mail will direct PCs to the OPAIS Pricing Application’s Rules of Behavior, which outline the rules that govern the appropriate use of the pricing application (see figure in Section 7.2).

8.3: Attestation Form

After the Point of Contact (PC) reads and agrees to the Rules of Behavior, the Manufacturer Point of Contact Attestation Form is displayed, and the PC must attest to their identity and role as a Point of Contact for the assigned labeler code.

The Manufacturer Point of Contact Attestation Form requires the PC to verify his or her identity and role for the organization.

The screenshot shows the 'Manufacturer Primary Contact Attestation Form' from HRSA. The form contains the following fields and data:

Name:	Joe Smith
Title:	PRESIDENT & CEO
Phone #:	123456789 467
Email Address:	mfpc7@futrend.com

Associated Labeler Code	Labeler Code Name
00043	NOVARTIS CONSUMER HEALTH, INC

Below the table is a checkbox with a checkmark, followed by the text: "By selecting this checkbox I confirm that I am the Primary Contact and I have permission to access the 340B OPAIS Pricing Application." At the bottom are two buttons: "Submit" and "Cancel".

Figure 10: Manufacturer Point of Contact Attestation Form showing acknowledgement checkbox

The attestation form shows the name and contact information for the current PC and provides spaces to change it, as well as the associated labeler codes, a checkbox for accepting the attestation text, and “Submit” and “Cancel” buttons.

1. After reviewing the Attestation Form, acknowledge the terms by clicking the checkbox.

The attestation text reads as follows:

“By selecting this checkbox, I confirm that I am the Primary Contacts and I have permission to access the 340B OPAIS Pricing Application.”

2. Click one of the following buttons:

- **Submit:** Click this button to submit the Attestation Form.
- **Cancel:** Click this button to close the Attestation Form and cancel creation of your user account. The User Verification Cancelled page is displayed.

8.4: Setting a Password

Please refer to Section 7.4 for details on setting a password.

Section 9: Returning Users

9.1: 340B Pricing Login

Users can only login after their 340B OPAIS Pricing Application user account is created. To login, access the link contained in your confirmation e-mail. Enter your login name and password on the 340B Pricing Login page.

Figure 11: 340B OPAIS Pricing Application Login page

9.2: Authentication Code

Entering your login name and password will prompt an Authentication Code e-mail to be sent to your e-mail address on file. The Authentication Code e-mail will include an authentication code that must be entered on the Authentication Code page that is displayed after submitting your login credentials.

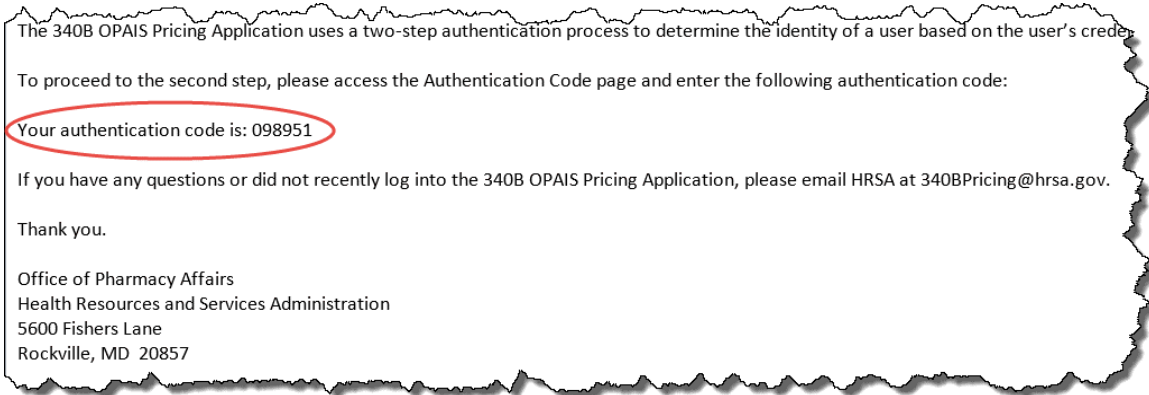


Figure 12: Sample of Authentication Code Email

Note: If you do not see the Authentication Code e-mail in your inbox, please check your junk mail folder. A new authentication code is required for each login attempt.

Enter your authentication code and click the Submit” button.

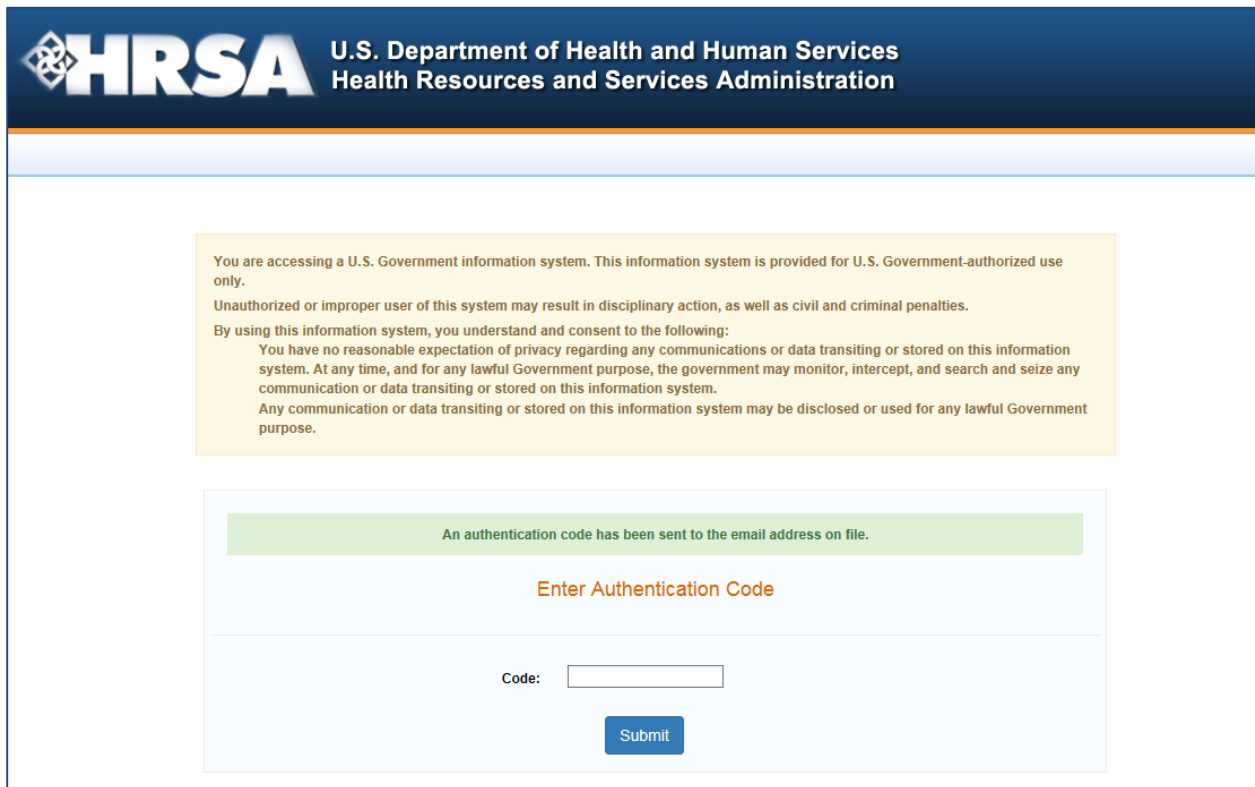
A screenshot of the "Enter Authentication Code" page. At the top is the HRSA logo and "U.S. Department of Health and Human Services Health Resources and Services Administration". Below is a yellow box with a disclaimer: "You are accessing a U.S. Government information system. This information system is provided for U.S. Government-authorized use only. Unauthorized or improper user of this system may result in disciplinary action, as well as civil and criminal penalties. By using this information system, you understand and consent to the following: You have no reasonable expectation of privacy regarding any communications or data transiting or stored on this information system. At any time, and for any lawful Government purpose, the government may monitor, intercept, and search and seize any communication or data transiting or stored on this information system. Any communication or data transiting or stored on this information system may be disclosed or used for any lawful Government purpose." Below the disclaimer is a green box: "An authentication code has been sent to the email address on file." Underneath is the heading "Enter Authentication Code" in orange. At the bottom is a form with "Code:" followed by a text input field and a blue "Submit" button.

Figure 13: Enter Authentication Code page

9.3: Rules of Behavior (Short Form)

After entering the authentication code, you will be directed to a short form of the Rules of Behavior. After reading the Rules of Behavior, acknowledge the terms by clicking the checkbox and entering your full name in the “User’s Name” field. Then click the “Agree” button.

HRSA U.S. Department of Health and Human Services
Health Resources and Services Administration

Dashboard Manufacturer Quarterly Upload Reconciliation Task Listing Log Out

Rules of Behavior for access to 340B OPAIS Pricing Application

Rules of Behavior for access to 340B OPAIS Pricing Application

HRSA system users are required to comply with HRSA information technology (IT) security policies regarding the protection of HRSA information systems from misuse, abuse, loss, or unauthorized access or modification. By logging on to this system you certify that you have read, understood and agree to comply with the Office of Pharmacy Affairs Information System Rules of Behavior

You are accessing a U.S. Government information system, which includes
(1) this computer, (2) this computer network, (3) all computers connected to this network, and (4) all devices and storage media attached to this network or to a computer on this network.

This information system is provided for U.S. Government-authorized use only. Unauthorized or improper use of this system may result in disciplinary action, as well as civil and criminal penalties.

By using this information system, you understand and consent to the following:

- You have no reasonable expectation of privacy regarding any communication or data transiting or stored on this information system. At any time, and for any lawful Government purpose, the government may monitor, intercept, and search and seize any communication or data transiting or stored on this information system.
- Any communication or data transiting or stored on this information system may be disclosed or used for any lawful Government purpose.

I acknowledge and understand my responsibilities and agree to comply with the Rules of Behavior for the system.

User's Name

Agree Cancel

Disclaimer: This application is only supported by Chrome or Internet Explorer version 9, and 11 or later. Please change or update your browser as needed.

Figure 14: Rules of Behavior short form page

9.4: Manufacturer Attestation Page for Authorizing Officials

The Manufacturer Authorizing Official Attestation page is displayed. After reviewing your contact information and associated labeler codes, acknowledge by clicking on the checkbox and then clicking the “Submit” button.

Note: If any of the information listed on this form is incorrect, please click on the ‘Click Here’ link at the bottom of the page, to fill out a copy of the 340B Manufacturer Change Form.

HRSA U.S. Department of Health and Human Services
Health Resources and Services Administration

Dashboard Upload Data File Reconciliation Log Out

Manufacturer Authorizing Official Attestation Form

Name:

Title:

Phone #:

Email Address:

Associated Labeler Code	Labeler Code Name
00001	PRAMOD INC
00002	ELI LILLY AND COMPANY
00002	ELI LILLY AND COMPANY
00002	ELI LILLY AND COMPANY
00002	ELI LILLY AND COMPANY
00002	ELI LILLY AND COMPANY
00003	BRISTOL-MYERS SQUIBB COMPANY
00004	Genentech USA

By selecting this checkbox I confirm that I am the Authorizing Official and I have permission to access the 340B OPAIS Pricing Application.

Note: If any of the information listed on this form is incorrect, please [Click Here](#) to fill out a copy of the 340B Manufacturer Change Form.

Figure 15: Manufacturer Authorizing Official Attestation Form showing acknowledgement checkbox

9.5: Manufacturer Attestation Page for Primary Contacts

The Manufacturer Primary Contact Attestation page is displayed. After reviewing your contact information and associated labeler codes, acknowledge by clicking the checkbox and then clicking the “Submit” button

HRSA U.S. Department of Health and Human Services
Health Resources and Services Administration

Dashboard Upload Data File Reconciliation Log Out

Manufacturer Primary Contact Attestation Form

Name:

Title:

Phone #:

Email Address:

Associated Labeler Code	Labeler Code Name
00043	NOVARTIS CONSUMER HEALTH, INC

By selecting this checkbox I confirm that I am the Primary Contact and I have permission to access the 340B OPAIS Pricing Application.

Figure 16: Manufacturer Point of Contact Attestation Form showing acknowledgement checkbox

Section 10: Change Password/Forgot Password

To change your password, or if you have forgotten your password, click the “Click here to recover your account” link at the bottom of the 340B Pricing Login page.

HRSA U.S. Department of Health and Human Services
Health Resources and Services Administration

340B OPAIS Pricing Application Login

You are accessing a U.S. Government information system. This information system is provided for U.S. Government-authorized use only.
Unauthorized or improper use of this system may result in disciplinary action, as well as civil and criminal penalties.
By using this information system, you understand and consent to the following:
You have no reasonable expectation of privacy regarding any communications or data transiting or stored on this information system. At any time, and for any lawful Government purpose, the government may monitor, intercept, search and seize any communication or data transiting or stored on this information system.
Any communication or data transiting or stored on this information system may be disclosed or used for any lawful Government purpose.

Login name:
Password:

[Sign in](#)

Having trouble logging in?
[Click here to recover your account.](#)

Disclaimer: This application is only supported by Chrome or Internet Explorer version 9, and 11 or later. Please change or update your browser as needed.

Figure 17: 340B OPAIS Pricing Application Login page showing the “recover account” link

The “Forgot your password?” page is displayed. Enter your login name and click the “E-mail Link” button.

HRSA U.S. Department of Health and Human Services
Health Resources and Services Administration

Forgot your password?

Login name

[Email Link](#)

Figure 18: “Forgot your password?” page

An e-mail with a link to the reset password page will be sent your e-mail address on file.

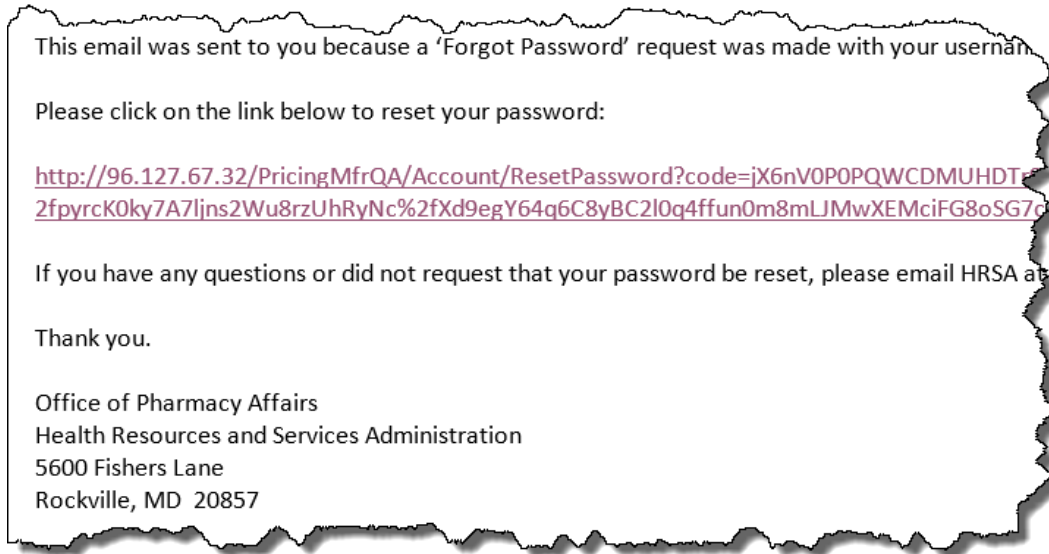


Figure 19: Snipped of “Forgot Password” email with reset password link

Note: If you do not see the e-mail in your inbox, please check your junk mail folder.

Click on the link to reset your password. The “Enter your new password” page is displayed.

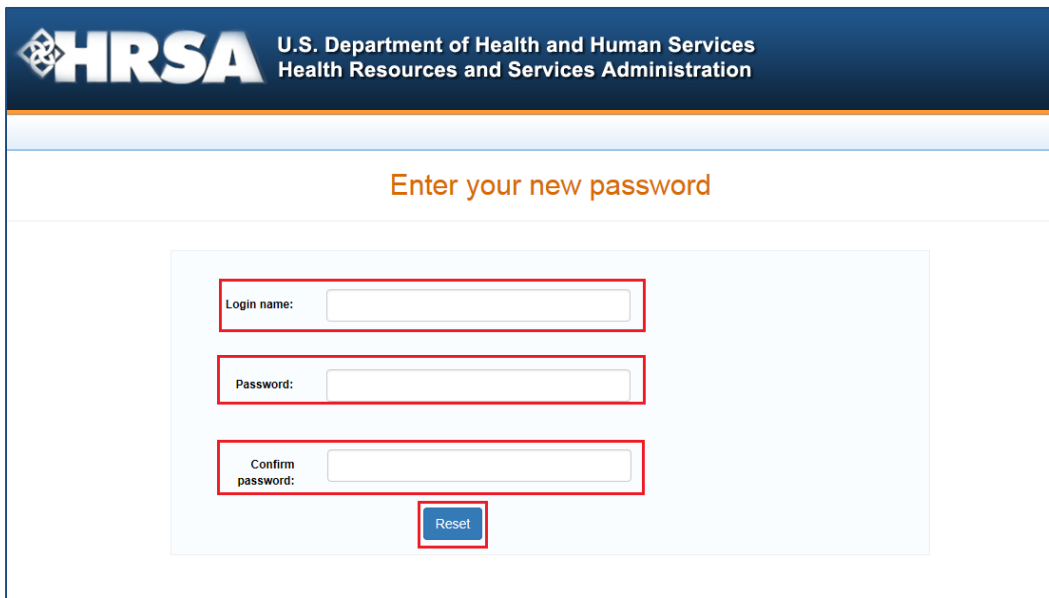


Figure 20: Enter New Password page

1. In the spaces provided, enter your Login Name, enter your new password, and re-enter your new password to confirm it.
2. Click the “Reset button.” Your password is reset and a password reset confirmation is displayed.

Section 11: Manufacturer Dashboard

The Manufacturer Dashboard page is displayed after a successful login.

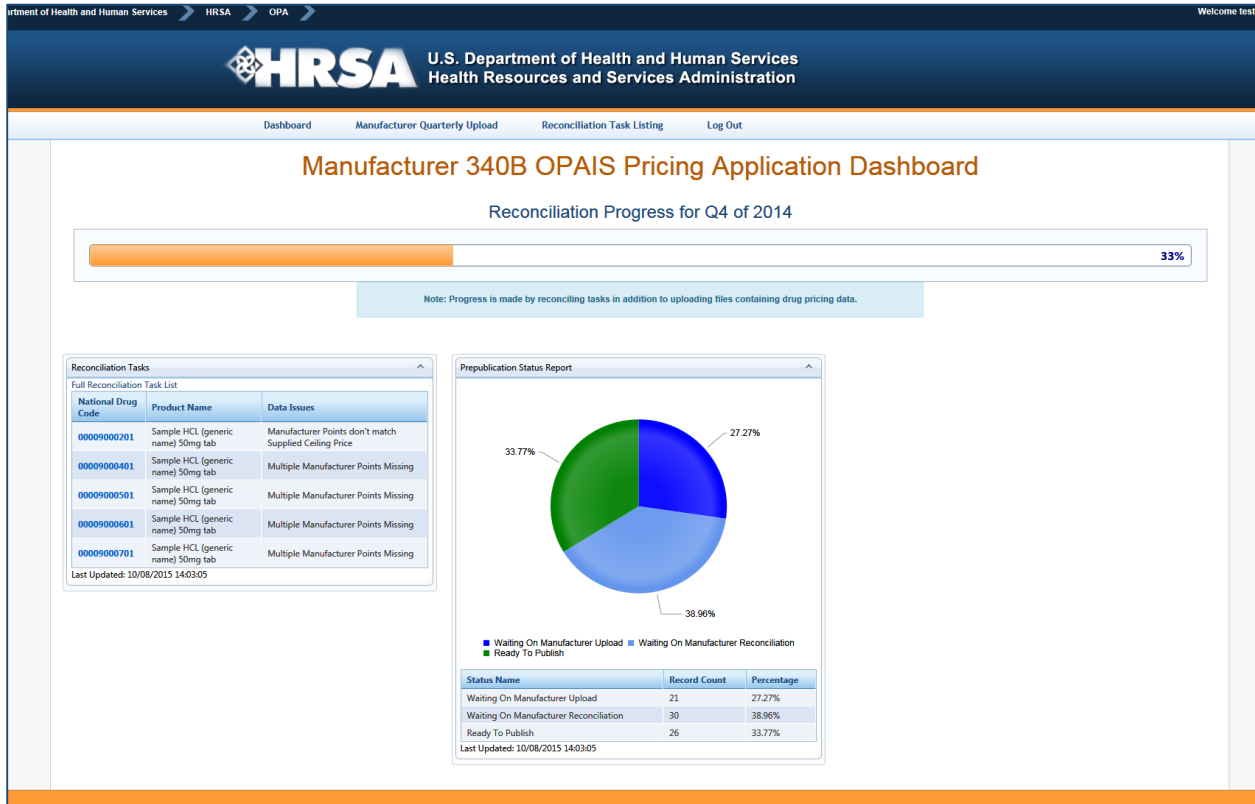


Figure 21: Manufacturer Dashboard page

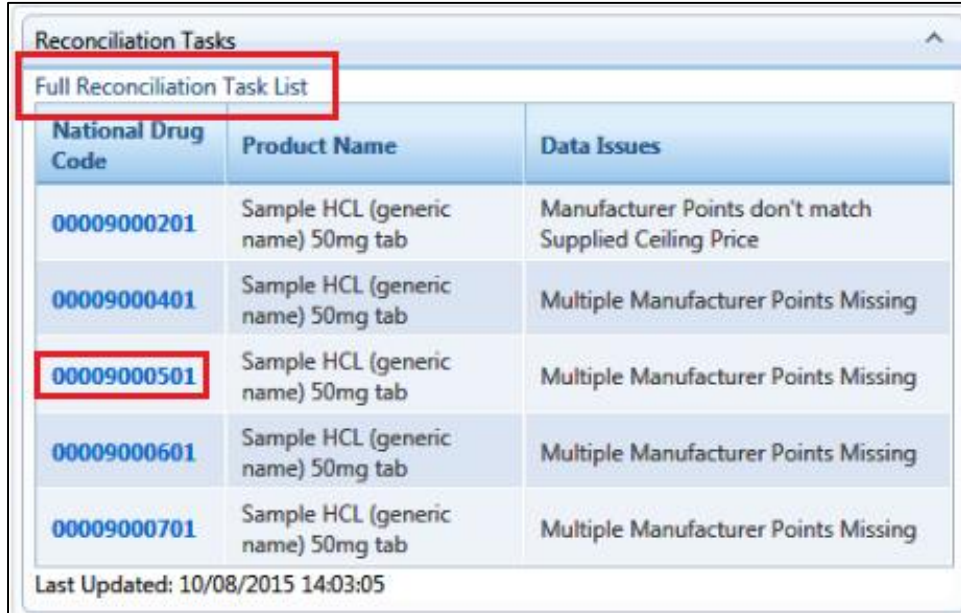
11.1: Top Five Reconciliation Tasks and the Prepublication Status Report

The Manufacturer Dashboard page contains widgets that display your quarterly reconciliation status and assigned reconciliation tasks. The Top Five Reconciliation Tasks widget contains a list of five reconciliation tasks that have been assigned to you for the current quarterly uploading period.

340B Drug Pricing Program Data Guide for Manufacturers

Clicking on the Full Reconciliation Task List will display the full list of reconciliation tasks that have been assigned to you for the current quarterly uploading period.

The National Drug Codes (NDCs) contain hyperlinks that will direct you to the Reconciliation Record Details Pop-up to reconcile the pricing data for a specific NDC.



National Drug Code	Product Name	Data Issues
00009000201	Sample HCL (generic name) 50mg tab	Manufacturer Points don't match Supplied Ceiling Price
00009000401	Sample HCL (generic name) 50mg tab	Multiple Manufacturer Points Missing
00009000501	Sample HCL (generic name) 50mg tab	Multiple Manufacturer Points Missing
00009000601	Sample HCL (generic name) 50mg tab	Multiple Manufacturer Points Missing
00009000701	Sample HCL (generic name) 50mg tab	Multiple Manufacturer Points Missing

Last Updated: 10/08/2015 14:03:05

Figure 22: Full Reconciliation Task List

The Prepublication Status Report widget contains a pie chart that indicates the reconciliation status for the current quarterly uploading period.

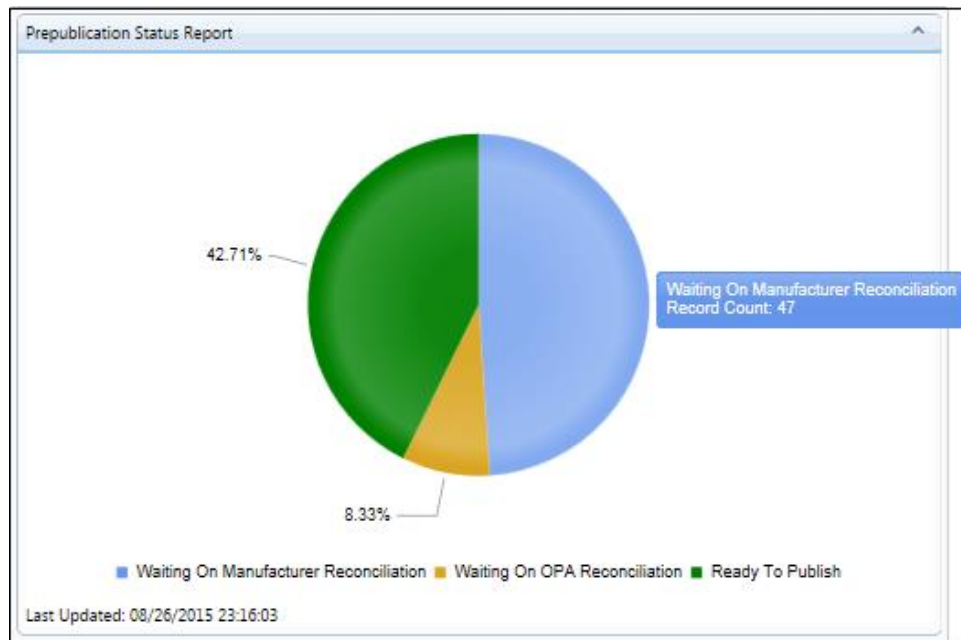


Figure 23: Prepublication Status Report

The statuses can reflect any of the following situations:

- **Waiting on Manufacturer Reconciliation** – One or more of your uploaded data points did not match HRSA’s data’s points, so you will need to manually reconcile the pricing data for that specific NDC.
- **Waiting on OPA Adjudication** – You have manually reconciled the data points for a specific NDC, and HRSA is currently reviewing your changes.
- **Ready to Publish** – The submitted data points for these products match what HRSA has on file. The 340B ceiling price for these product NDCs is ready to be published for the next quarter.

11.2: Menu Bar Navigation

The Manufacturer Menu Bar displays the following Menu options:

- Dashboard
- Manufacturer Quarterly Data Processing
- Reconciliation Task Listing
- Log Out



Figure 24: Manufacturer Menu Bar

- **Dashboard:** Displays the Manufacturer Dashboard page.
- **Manufacturer Quarterly Data Processing:** Selecting the Manufacturer Quarterly Data Processing will display the Upload Manufacturer Instrument File and Manually enter Product Data sub-menu options.
- **Reconciliation Task Listing:** Clicking the Reconciliation menu option will display the Reconciliation Task Listing sub-menu option is displayed. Selecting the Reconciliation Task Listing will direct you to the entire list of reconciliation tasks assigned to you for the quarterly submission period.
- **Log Out:** Clicking the Log Out menu option logs you out of the 340B OPAIS Pricing Application.

Section 12: Manufacturer Quarterly Data Processing

12.1: Manufacturer Quarterly Submission Period Notification E-mail

Up on HRSA quarterly data upload (CMS, FDB and MDRP), manufacturers can upload or manually load their data. At the beginning of each quarterly upload period, manufacturers will receive an e-mail notification informing them that the two-week submission period has begun and they can log into the OPAIS Pricing Application to load their quarterly pricing data.

12.2: Upload Manufacturer Instrument File

To upload your quarterly pricing data during the manufacturer submission period, click on the Upload Data Manufacturer Instrument File menu option to display the Upload Manufacturer Instrument file and Manually Enter Product Data sub-menu options.



Figure 25: Manufacturer Menu Bar showing Manufacturer Quarterly option selected

The Manufacturer File Upload page is displayed.



Figure 26: Manufacturer File Upload page

To upload quarterly data select the sales period and file to be uploaded:

1. **Sales Year and Sales Quarter:** Select the sales year and sales quarter to match the sales year and quarter of your pricing data file.
2. **Manufacturer Data File Location:** Click “Select” to select the manufacturer data file location on your computer. The file starts uploading immediately.

3. **Analyze Data:** When you click the “Analyze Data” button, the Data Upload Analysis page is displayed.

12.3: Data Upload Analysis

When you click the “Analyze Data” button the Data Upload Analysis page is displayed. The page shows the file statistics for the upload, the number of rows inserted into the database, and the number of errors. There are buttons for “Start New Upload” and “Process Files.”

Data Upload Analysis

MANUFACTURER INSTRUMENT

File Statistics	
File size:	8.38 KB
Number of Records:	44
Number of Valid Records:	44
Processing Time:	0:00:00.078

Rows Inserted	
ETL_ManufacturerInstrument	44

Error Information	Actual Data	Fault Field	Row Number
No records to display.			

Figure 27: Data Upload Analysis page

- **Start New Upload:** If there are invalid records, you can fix the records on the Manufacturer Data file and click ‘Start New Upload’ to re-upload the Manufacturer Data file.
- **Process Files:** Click ‘Process Files’ to process and load the records and the Processing Upload page is displayed.

12.4: Processing the Uploaded File

Clicking the “Process Files” button on the Data Upload Analysis page causes the system to process and load the records. Once the process is complete the Processing Upload page is displayed.

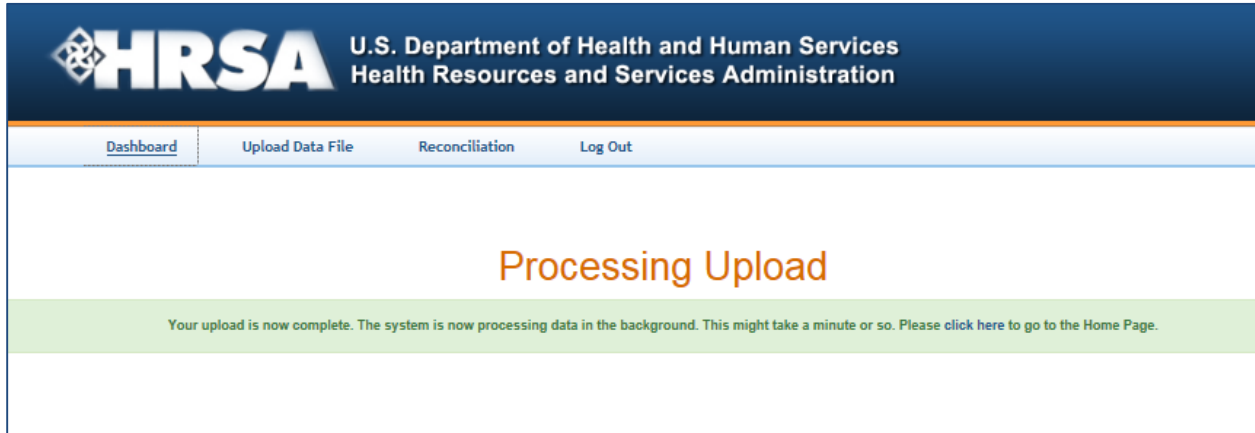


Figure 28: Processing Upload page

To return to the Home page, click on the “click here” link in the message.

12.5: Manually Enter Product Data

To manually enter your quarterly pricing data during the manufacturer submission period, click on the Manually Enter Product Data menu option. The Manual Product Data Entry List is displayed.



Figure 299: Manual Product Data Entry List

- **Column Heading:** When you click on any of the column headings, such as Manufacturer Name, the report is sorted in ascending or descending order.
- **Column Filter:** When you click on any of the column filters the column filter menu is displayed.

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The image shows two UI components. On the left is a column filter menu with a dropdown arrow pointing down. The menu is currently open, showing the following options: NoFilter (highlighted), EqualTo, NotEqualTo, GreaterThan, LessThan, GreaterThanOrEqualTo, and LessThanOrEqualTo. On the right is a page scroll options menu with a dropdown arrow pointing down. The menu is currently open, showing the following options: No Filter, 1, 2, 3, and 4.

- **Column Filter Menu:** The column filter menu options will vary based on the data displayed in the columns.
- **Page Scroll Options:** To scroll through the report, page scroll options are displayed at the bottom of the last row.

The image shows a page scroll and page size control bar. It includes navigation buttons for first, previous, next, and last, along with a page number indicator showing '1' selected from a list of '1 2 3 4 5 6'. To the right is a 'Page size:' dropdown menu currently set to '10'.

12.6: Product Data Entry

When selecting any of the hyperlinked National Drug Codes, the Product Data Entry page is displayed with the following details:

The image shows a screenshot of the 'Product Data Entry' page in the HRSA system. The page header includes the HRSA logo and the text 'U.S. Department of Health and Human Services Health Resources and Services Administration'. The navigation bar contains links for 'Dashboard', 'Manufacturer Quarterly Data Processing', 'Reconciliation Task Listing', and 'Log Out'. The main content area is titled 'Product Data Entry' and contains a form with the following fields and values:

National Drug Code:	48102000902
Product Name:	NAPROXEN TABLETS 375MG
Labeler Code:	48102
Manufacturer Name:	PHARMACEUTICALS USA, INC.
Average Manufacturer Price:	100
Unit Rebate Amount:	50
Package Size:	1
Case Package Size:	1
Ceiling Price:	\$50.00

At the bottom of the form are two buttons: 'Cancel' and 'Accept Data'.

Figure 30: Product Data Entry

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The product data entry page include the following:

- **National Drug Code**
- **Product Name**
- **Labeler Code**
- **Manufacturer Name**
- **Average Manufacturer Price (AMP):** Enter AMP here
- **Unit Rebate Amount (URA):** Enter URA here
- **Package Size (PS):** Enter PS here
- **Case Package Size (CSP):** Enter CSP here
- **Calculated Ceiling Price:** The calculated ceiling price represents the 340B price based off the AMP, URA, PS, and CSP values entered by the user. For example, if you change the AMP value, the calculated ceiling price will immediately change.
- **Accept Data:** You click the “Accept Data” button if you would like to accept the entries made by the user. With “Accept Data” data entry are saved and the record is removed from your Manual Product Data Entry List.
- **Cancel:** You click the “Cancel” button if you would like to continue to keep the record on your Manual Product Data Entry List and you plan to review the record later. With “Cancel” the data entry made are not saved and the record is not removed from your Manual Product Data Entry List.

Section 13: Reconciliation Tasks

A reconciliation task is created when the application detects a discrepancy between the manufacturer’s data points and HRSA’s data points. A reconciliation task requires that the manufacturer reconcile the pricing data points for a specific NDC.

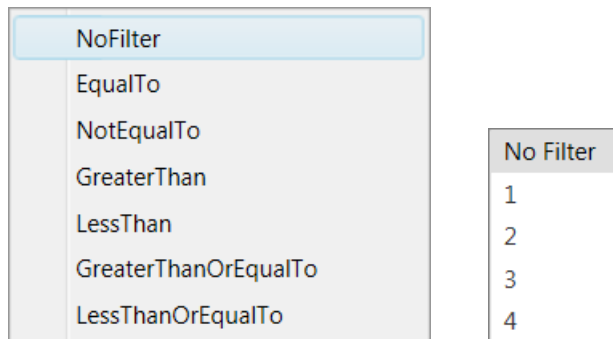
13.1: Accessing your Reconciliation Tasks

Clicking on the “Reconciliation Task Listing” option in the menu bar will display the Reconciliation Task Listing page, showing all reconciliation tasks assigned to a manufacturer.

National Drug Code	Sales Year	Sales Quarter	Product Name	Manufacturer Name	Data Issues
00009000201	2014	4	Sample HCL (generic name) 50mg tab	PFISER	Manufacturer Points don't match Supplied Ceiling Price
00009000401	2014	4	Sample HCL (generic name) 50mg tab	PFISER	Multiple Manufacturer Points Missing
00009000501	2014	4	Sample HCL (generic name) 50mg tab	PFISER	Multiple Manufacturer Points Missing
00009000601	2014	4	Sample HCL (generic name) 50mg tab	PFISER	Multiple Manufacturer Points Missing
00009000701	2014	4	Sample HCL (generic name) 50mg tab	PFISER	Multiple Manufacturer Points Missing
00009001001	2014	4	Sample HCL (generic name) 50mg tab	PFISER	Manufacturer Points don't match HRSA Points
00009001101	2014	4	Sample HCL (generic name) 50mg tab	PFISER	Manufacturer Points don't match HRSA Points
00009002101	2014	4	Sample HCL (generic name) 50mg tab	PFISER	Manufacturer Points don't match Supplied Ceiling Price
00009002201	2014	4	Sample HCL (generic name) 50mg tab	PFISER	Multiple Manufacturer Points Missing
00009002301	2014	4	Sample HCL (generic name) 50mg tab	PFISER	Multiple Manufacturer Points Missing

Figure 31: Reconciliation Task Listing page

- **Column Heading:** When you click on any of the column headings, such as Manufacturer Name, the report is sorted in ascending or descending order.
- **Column Filter:** When you click on any of the column filters the column filter menu is displayed.



- **Column Filter Menu:** The column filter menu options will vary based on the data displayed in the columns.
- **No Filter:** The “No Filter” options are displayed.

- Page Scroll Options:** To scroll through the report, page scroll options are displayed at the bottom of the last row.



13.2: Reconciling a Record

When selecting any of the hyperlinked National Drug Codes, a pop-up with record details is displayed.

National Drug Code:	00009000201	
Product Name:	Sample HCL (generic name) 50mg tab	
Labeler Name:	PFISER	
Average Manufacturer Price: Unit Rebate Amount: Package Size: Case Package Size: Calculated Ceiling Price: Supplied Ceiling Price: Notes:	Manufacturer data points	HRSA data points
	<input style="width: 100%;" type="text"/> <input style="width: 100%;" type="text"/> <input style="width: 100%; text-align: center;" type="text" value="100.000"/> <input style="width: 100%; text-align: center;" type="text" value="1"/> <input style="width: 100%; text-align: center;" type="text" value="5.88"/> <input style="width: 100%; text-align: center;" type="text" value="5.87"/> <input style="width: 100%;" type="text"/>	<input style="width: 100%; text-align: center;" type="text" value="100.000"/> <input style="width: 100%; text-align: center;" type="text" value="1"/> <input style="width: 100%; text-align: center;" type="text" value="Ceiling Price could not be calculated."/>
	<input style="width: 100%; background-color: #4a86e8; color: white;" type="button" value="Accept Changes"/> <input style="width: 100%; background-color: #e91e63; color: white;" type="button" value="No Changes"/> <input style="width: 100%; border: 1px solid #ccc;" type="button" value="Cancel"/>	

Figure 32: Reconciliation Record Details Page

The data points on the page include the following:

- Average Manufacturer Price (AMP):** If you need to change the supplied AMP or if the AMP is missing, enter it here.
- Unit Rebate Amount (URA):** If you need to change the supplied URA or if the URA is missing, enter it here.
- Package Size (PS):** If you need to change the supplied PS or if the PS is missing, enter it here.
- Case Package Size (CSP):** If you need to change the supplied CSP or if the CSP is missing, enter it here.
- Calculated Ceiling Price:** The calculated ceiling price represents the 340B price based off the AMP, URA, PS, and CSP values entered on the pop-up screen. For example, if you change the AMP value on the pop-up screen, the calculated ceiling price will immediately change.
- Supplied Ceiling Price:** The supplied ceiling price represents the 340B price based off the AMP, URA, PS, and CSP values that are listed in the manufacturer's text file that the manufacturer uploads to the 340B OPAIS Pricing Application.

340B Drug Pricing Program Data Guide for Manufacturers

- **Notes:** You can enter notes to document why changes were made to the data points. Notes will be required if you click “No Changes.” There is a 250 character limit to comments in the Notes section. The following explanations are sufficient to input into the Notes section for common issues:

Table 3: Notes content for Reconciliation Record Details

Input in Notes	Definition
Discontinued	Occurs when a product has been discontinued but it still reportable to CMS
Expired	Occurs when a product is expired but it is still reportable to CMS
Inner label	The NDC is for an inner package, which is reportable to CMS but not for sale under the 340B Drug Pricing Program.

- **Accept Changes:** You click the “Accept Changes” button if you would like to keep the changes you made to data points. With “Accept Changes” changes made to data points are saved and the record is removed from your Reconciliation Task List.
- **No Changes:** You click the “No Changes” button if for example you do not have enough information to reconcile the record. With “No Changes” changes made to data points are not saved and the record is removed from your Reconciliation Task List.
- **Cancel:** You click the “Cancel” button if you would like to continue to keep the record on your Reconciliation Task List and you plan to review the record later. With “Cancel” changes made to data points are not saved and the record is not removed from your Reconciliation Task List.

Section 14: Quarterly Pricing File Layout Specifications and Field Descriptions

The OPAIS Pricing Application accepts pricing data in fixed-width text (.txt) files according to the following layout. All field contents shall be justified and padded to the indicated width per the definitions below.

Table 4: Quarterly Pricing File Layout Specifications and Field Descriptions

Field	Size	Position	Remarks
Labeler Code	5	1-5	NDC1
Product Code	4	6-9	NDC2
Package Size Code	2	10-11	NDC3
Period Covered	5	12-16	QYYYY (Qtr/Yr)
Average Manufacturer Price (AMP)	12	17-28	99999.999999
Unit Rebate Amount (URA)	12	29-40	99999.999999
Package Size	11	41-51	9999999.999
Unit Type	3	52-54	(e.g., CAP, TAB, ML)
Case Pack	11	55-65	9999999.999
340B Price	12	66-77	999999999.99
FDA Product Name	65	78-142	FDA Product Name
Labeler Name	39	143-181	Name of Manufacturer/Labeler
Wholesale Acquisition Cost (WAC)	12	182-193	999999999.99

14.1: Data Field Definitions

- Labeler Code:** First National Drug Code segment, identifying the labeler. Numeric values only, 5-digit field, right-justified and zero-filled for 4-digit labeler codes.
- Product Code:** Second segment of National Drug Code. Alpha-numeric values, 4-digit field, right-justified, zero-filled for 3-digit product codes.
- Package Size Code:** Third segment of National Drug Code. Alpha-numeric values, 2-digit field, right-justified, zero-filled for 1-digit package size codes.
- Period Covered:** Calendar quarter and year covered by data submission. Numeric 5-digit field, QYYYY. The period covered represents the year and quarter in which the sale occurred and should reference the previous quarter (please refer to the Quarterly Submission Timeframes section for additional guidance).
- Average Manufacturer Price:** Average manufacturer price (AMP) per unit per product code only for the period covered, based on sales. If a drug is distributed in multiple package sizes, there will be one “weighted” AMP for the product, which will be the same for all package sizes. Numeric values, 12-digit field; 5 whole numbers, the decimal and 6 decimal places; right-justified; zero-filled. Compute to 7 decimal places and round to 6 decimal places.

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- **Unit Rebate Amount (URA):** The average total rebate required under section 1927(c) of the Social Security Act with respect to the drug (for a unit of the dosage form and strength involved) during the quarterly reporting period. Refer to Centers for Medicare & Medicaid Services (CMS) Medicaid Drug Rebate Program website for URA calculation data. Numeric values, 12-digit field; 5 whole numbers, the decimal and 6 decimal places; right-justified; zero-filled Compute to 6 decimal places and round to 4 decimal places, pad positions 5 and 6 with zeros.
- **Package Size:** The number of billing units in the labeled quantity from which the pharmacist dispenses.
- **Unit Type:** One of the eight unit types by which the drug can be dispensed.
 - AHF = refers only to injectable Anti-Hemophilic Factor units
 - CAP = Capsule
 - SUP = Suppository
 - GM = Gram
 - ML = Milliliter
 - TAB = Tablet
 - TDP = Transdermal patch
 - EA = EACH (Refers to drugs not identifiable by any other unit type)
- **Case Pack:** The number of salable units in the shipping container.
- **340B Price:** $340B\ Price = (AMP - URA) * PS * CSP$ for the quarterly reporting period. Numeric values, 12-digit field; 9 whole numbers, the decimal, and 2 decimal places; right-justified; zero filled. Round to two decimal places.
- **FDA Product Name:** Drug name as approved by the FDA.
- **Labeler Name:** Corporate name of entity identified by the labeler code.
- **Wholesale Acquisition Cost (WAC):** Published catalog or list price for a drug product to wholesalers. The submitted WAC should represent the value from the last day of the period covered. Numeric values, 12-digit field; 9 whole numbers, the decimal, and 2 decimal places; right-justified; zero filled. Round to 2 decimal places.

Section 15: Appendix B: 340B OPAIS Pricing Application Rules of Behavior

Users must adhere to the OPAIS Pricing Application's Rules of Behavior. A full version of the rules will be presented at the user's initial login:

15.1: Initial Login Rules of Behavior Long Form

When users initially create an account, they must accept the full rules of behavior (see Figure 3). Thereafter, they will only need to agree to the Rules of Behavior short form for subsequent logins.

The text of the Login Rules of Behavior long form is as follows:

You are accessing a U.S. Government information system. This information system is provided for U.S. Government authorized use only. Unauthorized or improper use of this system may result in disciplinary action, as well as civil and criminal penalties. Only specific entities authorized by law may request the disclosure of information from (i.e., query) or submit reports to the OPAIS Pricing Application. Any unauthorized individual or organization that attempts to query or file reports with the OPAIS Pricing Application may be subject to fine and imprisonment under Federal statute. By using this system, you understand and consent to the following: At any time and for any lawful Government purpose, the government may monitor, intercept, and search and seize any communication or data transiting or stored on this information system. Any communication or data transiting or stored on this information system may be disclosed or used for any lawful Government purpose.

All individuals that have access to obtain information from and report information to the OPAIS Pricing Application must comply with the following conditions:

System Privileges

Users are given access to information systems based on the requirements of their job duties. Users are to work within the confines of allowed access and are not to attempt access to systems, data, or applications to which access has not been authorized. Users must not attempt to override technical or management controls. Users are required to notify the system administrator immediately when there is a change in employment status and/or when access to the system is no longer needed. Users are prohibited from using information acquired from access via a HRSA information system for personal gain.

Individual Accountability

Users will be held accountable for their actions on HRSA information systems. Users must lock their computer if left unattended for any period of time. Password protected screen savers will be enforced if computers are left unattended for time periods longer than fifteen (15) minutes.

Disciplinary Action

If users violate any of these Rules of Behavior and/or HRSA policies, they may be subject to disciplinary action at the discretion of their management. These actions, depending on the severity of the violation, may include a verbal or written warning, removal of system access, reassignment to other duties, or termination. Illegal activities on the part of HRSA users will be referred to the appropriate law enforcement organization and could lead to prosecution with fines or imprisonment as possible outcomes.

Ownership

This system is the property of the U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA) and is for authorized users only. The system is for official 340B business only. Unauthorized access or use of this system may subject violators to criminal, civil and/or administrative penalties.

Responsibilities

Information and activities associated with the OPAIS Pricing Application shall not be false, inaccurate or misleading; shall not violate any law, statute, ordinance or regulation; and shall not contain any viruses or any malicious code that may damage, detrimentally interfere with, surreptitiously intercept, or expropriate any system, data, or personal information. "Information" is defined as any information you provide to the OPAIS Pricing Application in the course of using this system. "Activities" is defined as any process of interacting with the OPAIS Pricing Application.

Passwords

Individual users are provided with a unique user ID and initial password to access this system. The first time you log in to the system, you will be forced to establish your own password to continue to use the system. You are responsible for maintaining the integrity of, and are held accountable for, everything done using your user ID and password. No other person, including those at the HRSA Office of Pharmacy Affairs, has access to your password. Passwords shall not be shared with others. You agree to change the password immediately, and notify the HRSA Office of Pharmacy Affairs if password security is suspected to be compromised. Do not respond to suspicious e-mail requesting for password change, that is, do not click on the link provided by suspicious e-mail; report immediately and delete the e-mail.

Users must create and use passwords consisting of at least eight (8) characters that cannot be easily guessed and must adhere to the following guidelines:

- Passwords shall not contain all or part of the user's account name.
- Passwords shall not contain slang, jargon or personal information.
- Passwords shall not be the same password as for other non-HRSA accounts (e.g., personal e-mail accounts, trading, etc.).
- Passwords must contain at least one character from each of the following four categories:
 1. English upper-case characters (A-Z)
 2. English lower-case characters (a-z)
 3. Numerical digits (0-9)
 4. Special character (e.g. @, !, \$, %)
- Characters may not be repeated more than once within a succession.

Users are required to change their passwords every 60 days or at the interval prescribed for the system. Users are also prohibited from reusing the previous twenty four (24) passwords. Users must not write down nor share passwords or User-IDs. If a password is suspected of compromise, users must change the compromised password immediately and report the suspected compromise to their supervisor and the Help Desk. Users must not enter passwords in a file or record stored in any information system for the purpose of affecting an "autologin" feature, unless the feature has been approved for use by the HRSA Chief Information Security Officer (CISO). HRSA reserves the right to change passwords or terminate access to an information system at any time.

Confidentiality

The system contains personal information protected under the provisions of the Privacy Act of 1974, 5 USC Section 552a. Violations of the provisions of the Privacy Act may subject the offender to criminal penalties.

Information reported to the OPAIS Pricing Application is confidential and shall not be disclosed except as specified in Section 340B of the Public Health Service Act. The HHS OIG has the authority to impose civil money penalties on those who knowingly and intentionally violate the provisions of Section 340B of the Public Health Service Act. Persons or entities that receive information either directly or indirectly are subject to the confidentiality provisions specified within the Rules of Behavior. When an authorized agent is designated to handle OPAIS Pricing Application queries, both the entity and the agent are required to maintain confidentiality in accordance with the Rules of Behavior.

Intrusion Detection

This site is maintained for the U.S. Government. It is protected by various provisions of 18 U.S.C. – Crimes and Criminal Procedure. Violations of Title 18 are subject to criminal prosecution in federal court.

Individuals using this system are subject to monitoring of those activities. Anyone using this system expressly consents to such monitoring and is advised that if such monitoring reveals possible evidence of criminal activity, system personnel may provide the evidence obtained by such monitoring to law enforcement officials. Moreover, for system security purposes and to ensure that the system is used for legitimate purposes by authorized, registered users, we collect information concerning the use of this system e.g. data you view and alter. We employ software programs to monitor traffic, and to identify unauthorized attempts to view and/or change information, or otherwise cause damage to the system. Information from these sources may be used to help identify an individual(s) in the event of authorized law enforcement investigation, and pursuant to any required legal process.

Violation of Rules of Behavior

In the event it is suspected that you have not complied with these rules of behavior your account will be frozen, resulting in denial of all access to the system; and criminal, civil and/or administrative action may be taken.

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Below the Rules of Behavior text, there is a checkbox entitled “*I acknowledge and understand my responsibilities and agree to comply with the Rules of Behavior for the system.*” as well as a “User’s Name” text box, and “Accept” and “Cancel” buttons (see Figure 4).

To accept the Rules of Behavior, the user must click the checkbox, type their name in the text box and click the “Accept” button.

15.2: Rules of Behavior Short Form

Once the full rules of behavior have been accepted and a user account is created, users will agree to the Rules of Behavior short form for each subsequent login, as follows:

You are accessing a U.S. Government information system. This information system is provided for U.S. Government-authorized use only.

Unauthorized or improper user of this system may result in disciplinary action, as well as civil and criminal penalties.

By using this information system, you understand and consent to the following:

You have no reasonable expectation of privacy regarding any communications or data transiting or stored on this information system. At any time, and for any lawful Government purpose, the government may monitor, intercept, and search and seize any communication or data transiting or stored on this information system.

Any communication or data transiting or stored on this information system may be disclosed or used for any lawful Government purpose.

Below the Rules of Behavior text, there are text boxes for the user’s Login Name and Password and a “Sign In” button (see Figure 11). By logging in the user indicates acceptance of the Rules of Behavior.