



### 340B PARTICIPANT CHANGE FORM



This form is to notify OPA of corrections and updates to **existing** Covered Entity records as found on [HRSA OPA's public Web site](#). **Fill out all the fields in Section 1 (Required Information). The change form will be rejected if not signed by the Authorizing Official and if any information is missing from Section 1.** E-mail the completed form to the Office of Pharmacy Affairs at [opastaff@hrsa.gov](mailto:opastaff@hrsa.gov); you will be notified when the change has been made or if additional information is required. Additional instructions are on Page 3. For further assistance contact the 340B Prime Vendor at [ApexusAnswers@340bpvp.com](mailto:ApexusAnswers@340bpvp.com) or call 1-888-340-2787.

**Section 1** **Required Information**

<b>340B Covered Entity Name:</b> As listed on <a href="#">HRSA OPA's public Web site</a>	
<b>340B ID:</b> As listed on <a href="#">HRSA OPA's public Web site</a>	
<p style="text-align: center;">***** <b>IMPORTANT</b> *****</p> <p>Change requests should be e-mailed directly to OPA by an organization's Authorizing Official, as listed in the 340B program database. Forms submitted by anyone else may be subject to significant delays, potentially preventing the purchase of 340B drugs. (If the Authorizing Official currently listed in the database is no longer available, the new Authorizing Official should e-mail <a href="mailto:opastaff@hrsa.gov">opastaff@hrsa.gov</a> with the submission of the form.)</p>	<b>Existing Covered Entity Authorizing Official:</b> As listed on <a href="#">HRSA OPA's public Web site</a>  Name: _____ Title: _____ Phone: _____ Email: _____

**Section 2** **New Values Only (do not enter information that is to remain the same)**

New Physical Address		New Bill to Address	
<i>Address line 1</i>		<i>Organization</i>	
<i>Address line 2</i>		<i>Address line 1</i>	
<i>City, State, Zip code</i>		<i>Address line 2</i>	
		<i>City, State, Zip code</i>	

New Shipping Address <i>(for adding a covered entity-owned, in-house pharmacy shipping location)</i>		Medicaid # or NPI #: <i>(To be used only if billing Medicaid for 340B drugs)</i> <i>Indicate Remove/Add</i>
<i>Organization</i>		
<i>Address line 1</i>		
<i>Address line 2</i>		
<i>City, State, Zip code</i>		

**Orphan Drug Exclusion:** Once a hospital subject to the orphan drug exclusion (i.e., critical access hospitals, free-standing cancer hospitals, sole community hospitals and rural referral centers) is enrolled in the 340B Program, it may change its decision regarding whether or not to purchase all orphan drugs outside of the 340B Program on a quarterly basis by notifying HRSA. This information will be verified during the annual recertification process. Please choose one of the following:

- The hospital will purchase orphan drugs under the 340B Program and maintain auditable records to demonstrate compliance with the orphan drug exclusion.
- The hospital cannot or does not wish to maintain auditable records regarding compliance with the orphan drugs exclusion and will purchase all orphan drugs outside of the 340B Program regardless of the indication for which the drug is used and will not use a Group Purchasing Organization (GPO) to purchase those drugs if the hospital is a free-standing cancer hospital.



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New Authorizing official <i>(See instructions)</i>		New Primary Contact Person <i>(See instructions)</i>	
Name:		Name:	
Title:		Title:	
Phone:		Phone:	
Email:		Email:	

#### Section 3

#### Contract Pharmacy Information

The section is to notify OPA of corrections and updates to existing Contract Pharmacy Contact Information. All new Contract Pharmacy Arrangements must be registered electronically at <http://opanet.hrsa.gov/OPA/Default.aspx>. For more information on Contract Pharmacy Services visit <http://www.hrsa.gov/opa/implementation/index.html>.

New Values (do not enter information that is to remain the same)

New Contract Pharmacy Address and Name change <i>(Note: For an a Contract Pharmacy that has already been registered with OPA)</i>			
Name of Pharmacy:		Change to	
Address line 1:			
Address line 2:			
City, State, Zip:			

New "Contract Pharmacy Signing Official" for the covered entity		New "Contract Pharmacy Signing Official" for the pharmacy	
Name:		Name:	
Title:		Title:	
Phone:		Phone:	
Email:		Email:	
New "Contract Pharmacy Contact Person" for the covered entity		New "Contract Pharmacy Contact Person" for the pharmacy	
Name:		Name:	
Title:		Title:	
Phone:		Phone:	
Email:		Email:	

Use this block for additional comments or changes not accommodated in the form:  
(such as a request to terminate a covered entity or contract pharmacy relationship)

**Authorizing Official Signature (Change request forms MUST be signed by the Authorizing official in all cases)**

By signing, I represent and confirm that I am fully authorized to bind the covered entity and certify that the contents of any statement made of reflected in this document are truthful and accurate. The covered entity will comply with all of the requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulation or guidelines including, but not limited to, the prohibition on duplicate discounts/rebates, and drug diversion.

*Signature:* \_\_\_\_\_

*Date:* \_\_\_\_\_

**Instructions for completion of “340B PARTICIPANT CHANGE FORM”****Section 1**

All information in this section is required. If information is missing or incomplete, the form will be rejected.

List the covered entity name and 340B ID in the appropriate fields as it appears on the [340B public database](#). You may add more than one 340B ID if the change will affect child site relationships. Provide the Authorizing Official information as it exists in the public database. If the Authorizing Official is no longer with the organization, the new Authorizing Official must email [OPASTaff@HRSA.gov](mailto:OPASTaff@HRSA.gov) with a statement that he/she is now the responsible authority for the covered entity along with the change request form.

**Section 2**

This section is to update or add information to an existing 340B covered entity record. Please note, this form is **not** to be utilized to add new 340B entities to an organizing or outpatient facilities/clinics (**outpatient facilities/clinics should be added online at <http://opanel.hrsa.gov/OPA/CERRegister.aspx?mode=opf&isnew=true>**).

**Bill to, Ship to address** - For billing and shipping address changes, the organization name must be included. Indicate if the change is a removal, addition or revision of the address in the comments section. You may also add more than one shipping address utilizing the comments section.

**New Authorizing Official** - An Authorizing Official must be a senior managing official that has the authority to bind the organization with the federal Government (such as the CEO/CFO/COO). Be advised, the new Authorizing Official must email [OPASTaff@HRSA.gov](mailto:OPASTaff@HRSA.gov) with a statement that he/she is now the responsible authority over the covered entity along with the change request form.

**New Primary Contact** - Must be someone under direct employment with the covered entity. OPA recommends this person be knowledgeable about the 340B Program.

**Medicaid # or NPI #** - Adding a Medicaid Provider number or a National Provider Identifier (NPI) will set the Medicaid billing question to “Yes” and the numbers will be added to the Medicaid Exclusion file. If every number is removed from the covered entity billing information section, the Medicaid billing question will default to “No”. Additional Medicaid Exclusion/Duplicate Discount information may be found by visiting the [OPA website](#).

**Section 3**

For contract pharmacy changes (including **pharmacy name, address line, city, state, and zip code**), provide the existing contract pharmacy information in the appropriate field as it appears in the public database. Add the updated information in the corresponding field across from the information to be replaced. Please be advise, changes in contract pharmacy information must be reflected in the actual Pharmacy Services agreements the covered entity possesses with the contract pharmacies. OPA may require entities to submit a copy of the pharmacy DEA license to validate changes.

**Contract Pharmacy Signing Official Blocks** - This changes the “CE signing official” and/or the “CP signing official block in the “Contract Details” of the covered entity record in the public database. Signing Officials must possess the legal authority to bind their respective organizations into contracts and 340B program guidelines.



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**Contract Pharmacy Contact Person Blocks** - This changes the "CE Primary Contact" and/or the "CP Primary contact" block in the "Contract Details" of the covered entities record in the public database. The "Primary Contact" for the covered entity must be under direct employment with the covered entity. An appropriate primary contact for the pharmacy should be determined by the contract pharmacy administration. OPA recommends these individuals be knowledgeable in the 340B Program.

**Public Burden Statement:** An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0327. Public reporting burden for this collection of information is estimated to average 0.5 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 10-29, Rockville, Maryland, 20857.