|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| This form is to notify OPA of corrections and updates to existing Covered Entity records as found on [HRSA OPA’s public Web site](http://opanet.hrsa.gov/opa/default.aspx). **Fill out all the fields in Section 1 (Required Information)**. **E-mail a completed signed copy 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. Information in this section is required. Complete as it is listed on** [HRSA OPA’s public Web site](http://opanet.hrsa.gov/OPA/Default.aspx). | | | | | | | | | |
| **1a. Covered Entity Name:** | | | | | | | **1b. 340B ID:** | | |
| **1c. Authorizing Official** | | | | | | | | | |
| Name: | | Title: | | | Phone: | | | Email: | |
| **Section 2: Covered entity (complete applicable fields only if reporting a change/update)** | | | | | | | | | |
| **2a. Covered entity name:** | | | | **2b. Covered entity Sub-division:** | | | | | |
| **2c. Grant number (if applicable):** | | | | **2d. Employer Identification Number:** | | | | | |
| **2e. Authorizing Official** (see instructional page for more information) | | | | | | | | | |
| Name: | | Title: | | | Phone: | | | Email: | |
| **☐** Check here if the change in Authorizing Official is applicable to all sites listed under the parent/child tab of the covered entity. | | | | | | | | | |
| **2f. New Authorizing Official Statement** (see instructional page for more information)  **☐** By checking this box I declared that I am now the responsible authority over the covered entity and have the legal authority to bind the covered entity to 340B program requirements and that I am fully aware of my responsibilities to ensure that the covered entity I represent remain complaint with 340B program guidelines. | | | | | | | | | |
| **2g. Section 2 Remarks:** | | | | | | | | | |
| **Section 3: Entity Termination (complete only if requesting entity termination)** | | | | | | | | | |
| **3a. Request covered entity termination - see instructional page for more information about entity terminations**  **☐** Check here if you wish to terminate this entityfrom the 340B program. Use the remarks section to include additional entities by providing each 340B ID,­ or state that the termination request should apply to all related child sites.  The information you provide below may be made available to manufacturers and the public. If 340B drugs were purchased after losing eligibility, HRSA urges working with affected manufacturers regarding possible repayment. | | | | | | | | | |
| a. What is the reason for this termination?  Click here to select a termination reason | | | | | | | | | |
| b. What is the date the entity became ineligible?  Click here to enter a date. | | | | | | | | | |
| c. What is the last date that 340B drugs were or will be purchased under this 340B ID?  Click here to enter a date. | | | | | | | | | |
| d. Please provide a brief description of the facts surrounding the reason for termination and how the effective date was determined: | | | | | | | | | |
| **3b. Section 3 Remarks:** | | | | | | | | | |
| **Section 4: Contract Pharmacy Information (complete only if reporting a change/update)** | | | | | | | | | |
| **4a. Contract Pharmacy Address update (*Address updates to pharmacies that have a DEA register number will occur automatically so long the DEA number for that pharmacy has not changed. Please wait at least 7 days if a change was reported to DEA before submitting a change request to update a pharmacy address.)*** | | | | | | | | | |
| **Name of pharmacy:** | | | **Change to** | | |  | | | |
| **Address line 1** | | |  | | | |
| **Address line 2:** | | |  | | | |
| **City, State, Zip Code:** | | |  | | | |
| **4b. Contract Pharmacy Termination request**  **☐** I wish to terminate this contract pharmacy relationship.  This termination is effective: Click here to enter a date.  Please select a reason for this termination from the drop down box:Click here to select a termination reason | | | | | | | | | |
| **4c. New Contract Pharmacy Representative** | | | | | | | | | |
| Name: | Title: | | | Phone: | | | | | Email: |
| **4d. Section 4 Remarks:** | | | | | | | | | |
| **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.**  ***Print name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***  ***Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*** | | | | | | | | | |

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

Use this form to report changes in **Authorizing Official information, request entity terminations, contract pharmacy arrangements**. For all other changes, please submit your request [online](http://opanet.hrsa.gov/OPA/CRPublicSearch.aspx).

**Section 1**

**1a-1c:** All information in this section is required. If information is missing or incomplete, the form will be rejected. List the covered entity name, 340B ID and Authorizing Official information in the appropriate fields as it appears on the [340B public database](http://opanet.hrsa.gov/OPA/Default.aspx).

**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**](http://opanet.hrsa.gov/OPA/Default.aspx)during an open registration period. For more information on how to register new 340B participants please visit our [main website](http://www.hrsa.gov/opa/index.html).

**2a, 2b:** **Covered entity name and Sub-division update** – Changes in covered entity name and sub-division may require additional documentation.

**2c: Grant number –** If the entity receives Federal funding, please provide the grant number that qualifies this entity for 340B participation. It is the responsibility of the covered to ensure that 340B use is consistent with the scope of the grant.

**2d: Employer Identification Number – Covered entity EIN/TIN as issued by the Internal Revenue Service.**

**2e, 2f: Authorizing Official** – New Authorizing Officials must acknowledge the “**New Authorizing Official Statement”** by clicking the respective check box. 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).

**Section 3**

**3a: Entity Termination -** It is the responsibility of the covered entity to provide accurate information and immediately inform OPA of any material changes in eligibility. All questions in this section must be answered or the termination request will not be processed.

**Section 4**

This section is to notify OPA of corrections/updates to existing Contract Pharmacy information and is not to be utilized to add new arrangements. New Contract Pharmacy Arrangements must be registered [electronically](http://opanet.hrsa.gov/OPA/Default.aspx). For more information on Contract Pharmacy Services visit the [340B implementation section](http://www.hrsa.gov/opa/implementation/index.html) of our main website.

**4a**: **Contract Pharmacy Address update** - 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. Be advised, it is expected that the proposed changes are consistent with the actual written contract the covered entity possesses with the contract pharmacies. OPA may require entities to submit a copy of the pharmacy state and/or DEA license to validate changes. **A change in pharmacy ownership requires a new contract pharmacy registration.**

**4b: Contract Pharmacy Termination request** - It is the responsibility of the covered entity to provide accurate information and immediately inform OPA of any material changes to its contract pharmacy arrangements. It is expected that 340B activity has ceased or will cease on the termination date requested. The covered entity may be asked to provide more specific information about the circumstances surrounding the termination request.

**4c: Contract Pharmacy Representative -** An appropriate contract pharmacy representative should be determined by the contract pharmacy administration. OPA recommends these individuals be knowledgeable in the 340B Program.

**Section 5**

**Authorizing Official Signature –** Change requests must be signed by the Authorizing Official of the covered entity. Change requests submitted without the proper signature will be rejected upon receipt.

**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.**