INSTRUCTIONS FOR COMPLETING "CONTRACTED PHARMACY SERVICES SELF-CERTIFICATION FORM FOR THE 340B PROGRAM"

The "Contract Pharmacy Services Self-Certification Form for the 340B Program" must be completed by a covered entity that will utilize a contract pharmacy arrangement to dispense drugs purchased under the 340B Program, in advance of that arrangement taking effect. In order to ensure that drug manufacturers and drug wholesalers recognize contract pharmacy arrangements, covered entities that elect to utilize a contract pharmacy are required to submit to the Office of Pharmacy Affairs (OPA) a self-certification that they have signed an agreement with the contract pharmacy.

Prior to completing this form, a covered entity must have their own legal counsel review all contracts or other legal documents to ensure that all Federal, State and local requirements have been met. The OPA will not review your contract. The OPA has developed contract pharmacy services guidelines. These guidelines are designed to facilitate program implementation in covered entities that wish to utilize contract pharmacy services to dispense 340B outpatient drugs but do not have access to an "in-house" pharmacy. The agreement between the covered entity and the pharmacy should include those elements outlined in the sample Contract and the Self-Certification Form.

To ensure the legibility of the information submitted on the Self-Certification Form, it has been designed using Adobe Acrobat (for a free download link here). This software allows you to fill in the information on your personal computer. After completing the form, you will then need to print it out, sign it, and then submit it.

The Self-Certification process is not complete unless the form has been completed in its entirety (all requested information is filled in on the form) and the original, signed copy is received by OPA. You will be notified via e-mail when the arrangement has been added to the 340B web-based database. Older versions of this form may not be accepted.

NOTE ON EFFECTIVE DATE – the OPA will NOT post a back-dated effective date. To expedite the process, you may FAX the form to OPA at 301-594-4982, after the document is signed by both the covered entity and the pharmacy, but an original MUST be submitted. Every effort will be made to post the arrangement within one business day. Do not begin the Contract Pharmacy arrangement prior to its posting and effective date shown on the OPA web-based database (link). Please be aware that if your organization is being added as a covered entity in the next quarterly update, the effective date of your Self-Certification may not precede the effective date of your participation as a 340B covered entity. For example, an organization added as a covered entity for the January 1, 2007 quarter may not have a Contract Pharmacy effective date prior to January 1, 2007.

NOTE ON SIGNATURES – the Self-Certification must be signed by a responsible representative of each organization. For the covered entity, the responsible representative may be the President, Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, or Program Director. For the pharmacy, the responsible representative may be the owner, the President, Chief Executive Officer, Chief Operating Officer, or Chief Financial Officer. If you are in doubt regarding the acceptability of a signature, please contact OPA prior to submitting the form.

NOTE ON CONTACT INFORMATION – please list the appropriate individuals in each organization who should be contacted if there is a question from wholesalers or manufacturers regarding the contract pharmacy arrangement.

You may FAX a copy to 301-594-4982, however, you must also submit a signed, original form to:
Office of Pharmacy Affairs, 5600 Fishers Lane, Mail Stop 10C-03, Rockville, MD 20857
For assistance, call 1-800-628-6297

Contracted Pharmacy Services Self-Certification Form for the 340B Program

This is to certify that effective _____ a Contracted Pharmacy Services arrangement is in effect between:

340B ID Number: _____
Covered Entity Name: _____
Street Address**:** _____
_____
City, State, ZIP: _____

and

Pharmacy Name _____
Street Address**:** _____
_____
City, State, ZIP _____

The undersigned represent and confirm that he/she is fully authorized to bind the Covered Entity or the Pharmacy listed, and certifies that the contents of any statement made or reflected in this document are truthful and accurate. The Covered Entity and the Pharmacy will comply with all of the requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines, including, but not limited to, the prohibitions on duplicate discounts/rebates, and drug diversion. The Covered Entity and the Pharmacy agree to be in compliance with the provisions of the Contracted Pharmacy Services Guidelines as set forth in the *Federal Register*, Vol. 61, No. 165, August 23, 1996, which may be found at link. The Covered Entity and Pharmacy agree to notify the Office of Pharmacy Affairs, in writing, if this arrangement is terminated, or if any information on this form changes.

_____ _____
Signature of Responsible Representative of Covered Entity **Date**

_____
(Type or Print Name and Title)

_____ _____
Signature of Responsible Representative of Pharmacy **Date**

_____
(Type or Print Name and Title)

Contact Information for:
Covered Entity

_____
Name
_____
Title
_____
Telephone Number
_____
FAX Number
_____
E-mail address

Contact Information for:
Pharmacy

_____
Name
_____
Title
_____
Telephone Number
_____
FAX Number
_____
E-mail address

Addendum

You may FAX a copy to 301-594-4982, however, you must also submit a signed, original form to:
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For assistance, call 1-800-628-6297

340B ID Number: _____
Covered Entity Name: _____
Street Address**:** _____
_____
City, State, ZIP: _____

In addition to the Covered Entity listed in the self-certification form, the following entities are sites that will need to add the same contract pharmacy arrangement information to the pharmacy listed in the self-certification form.

#	340B ID	Sub-Division Name	Address	City	State	Zip Code
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