OFFICE OF PHARMACY AFFAIRS (OPA) 340B PROGRAM REGISTRATION FOR DISPROPORTIONATE SHARE HOSPITALS

To meet the eligibility requirements for a disproportionate share hospital to participate and be listed as an eligible covered entity under Section 340B(a)(4)(L) of the Public Health Service Act, this registration form must be completed and submitted according to the established deadlines that are published on the OPA website (www.hrsa.gov/opa).

A completed registration package must include:

- (1) This Basic registration information and compliance certification;
- (2) A copy of Worksheet E, Part A from the latest filed Medicare cost report (for the DSH adjustment percentage in II, A, below.);
- (3) A copy of Worksheet S-2 to demonstrate ownership type, and depending upon the hospital type the additional documentation described in II, B, below); and
- (4) Certification of non-participation in a Group Purchasing Organization.

a) If Owned or Operated by State or Local Government, check here \Box

All documentation described in 1-4 above is required to constitute a complete registration package. The entire package must be submitted on the same day to be considered complete. Incomplete packages will not be processed.

I. Hospital Information: Hospital Name:			_
Medicare Provider Number:			
Employer Identification Number:			
Hospital Street Address:			
City:			
Hospital Billing Address (if different):			-
City:			
Hospital Shipping Address (if different):			
City:	State:	ZIP:	
II. Eligibility Criteria			
A. Disproportionate Share Adjustment Percentage: Medicare Cost Reporting Period://	% based on		
B. Type of Hospital			

(Submit supporting documentation to verify State/Local Government ownership or operation). Please refer to the

Office of Pharmacy Affairs website for a description and examples of acceptable documentation.

Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau OMB No. 0915-0327; Expiration Date: 10/31/2015

(You m (<u>ftp://ftp</u> of Phari	Private, Non-Profit Hospital with State/Local Government Contract, check here ust complete and attach State/Local Government Certification form higher and attach State/Local Government Certification form is submitted to the Office hrsa.gov/bphc/pdf/opa/DSHGovtCert.pdf) on the same day the registration form is submitted to the Office macy Affairs. Please refer to the Office of Pharmacy Affairs website for a description and examples of able documentation.)			
	Public or Private Non-Profit Hospital Formally Granted Governmental Powers, check here and the following:			
1.	The identity of the government entity granting the governmental power to the hospital;			
2.	A description of the governmental power that has been granted to the hospital and a brief explanation as to why the power is considered to be governmental; and			
3.	A copy of an official document issued by the government to the hospital that reflects the formal granting of governmental power.			
III. Medica	aid Billing Information: You must answer the following question regarding Medicaid billing.			
Will your entity bill Medicaid for drugs purchased through the 340B Drug Pricing Program? Yes □ No □				
	ease provide the Pharmacy/Clinic Medicaid Provider Number(s) and/or National Provider Identifier(s) to bill Medicaid for 340B drugs (please include the number(s) and State):			
Medicaid P	rovider Number(s) and/or			
National Pr	ovider Identifier(s)and/or			
If your entity bills Medicaid for 340B drugs that may be subject to a payment of a Medicaid rebate to a state, you must submit to OPA the pharmacy/clinic Medicaid number and/or NPI which is used to bill Medicaid for outpatient drugs. If you are unsure of your Medicaid billing number and/or NPI, please check with your State Medicaid agency. It is important that your Medicaid billing status is accurate in the 340B database Medicaid Exclusion File to prevent Medicaid rebates on drugs that were purchased under the 340B Drug Pricing Program and to ensure that the state Medicaid Agency has accurate information for those drugs not purchased under the 340B Program. You must notify OPA prior to any change in your Medicaid billing status.				
For more information, go to: http://www.hrsa.gov/opa/medicaidexclusion.htm				
IV. Desigr	nated 340B Contact and Authorizing Official Information:			
340B Conta Name:	act			
Title:				
Phone:	Ext Fax:			
Email Addr	ess:			
Covered Entity Authorizing Official (Must be authorized to legally bind covered entity (e.g., CEO, CFO, COO)				
Name:				
Title:				

Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau OMB No. 0915-0327; Expiration Date: 10/31/2015 Ext. _____ Fax: ____ Phone: Email Address: V. Signed Agreement: The undersigned represents and confirms that he/she is fully authorized to legally bind the covered entity and certifies that the contents of any statement made or reflected in this document are truthful and accurate. The undersigned further acknowledges the 340B covered entity's responsibility to abide by the following: As an Authorized Official, I certify on behalf of the covered entity that: (1) all information listed on the 340B Program database for the covered entity will be complete, accurate, and

- (2) the covered entity will meet all 340B Program eligibility requirements, including section 340B(a)(4)(L)(iii) and the Statutory Prohibition on Group Purchasing Organization Participation Policy Release 2013-1 which ensures that the covered entity hospital does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement;
- (3) the covered entity will comply with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity;
- (4) the covered entity will maintain auditable records demonstrating compliance with the requirements described above:
- (5) the covered entity has systems/mechanisms in place to ensure ongoing compliance with the requirements described above:
- (6) if the covered entity uses contract pharmacy services, that the contract pharmacy arrangement will be performed in accordance with OPA requirements and guidelines including, but not limited to, that the covered entity obtains sufficient information from the contractor to ensure compliance with applicable policy and legal requirements, and the hospital has utilized an appropriate methodology to ensure compliance (e.g., through an independent audit or other mechanism);
- (7) the covered entity acknowledges its responsibility to contact OPA as soon as reasonably possible if there is any material change in 340B eligibility and/or material breach by the covered entity of any of the foregoing; and (8) the covered entity acknowledges that if there is a breach of the requirements described above that the covered entity may be liable to the manufacturer of the covered outpatient drug that is the subject of the violation, and, depending upon the circumstances, may be subject to the payment of interest and/or removal from the list of eligible 340B entities.

Signature of Authorizing Official:	Date:

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 2.0 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.