

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. Failure to recertify may be grounds for removal from the 340B Program.

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 is complete, accurate, and correct;
- (2) the covered entity meets all 340B Program eligibility requirements, including (if applicable) 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, the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity, and the exclusion of orphan drugs for critical access hospitals, free-standing cancer hospitals, sole community hospitals and rural referral centers.
- (4) the covered entity maintains 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 is being 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:

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