General Instructions for Completing the 340B Drug Pricing Program Pharmaceutical Pricing Agreement - Addendum

Section 340B(a)(1) of the Public Health Service Act (PHS Act) provides that the Secretary of Health and Human Services (the Secretary) will enter into a pharmaceutical pricing agreement (the Agreement) with each manufacturer of covered outpatient drugs in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed the average manufacturer price decreased by a rebate percentage. Section 7102(b) of the Affordable Care Act amended section 340B(a)(1) of the PHS Act to add two new requirements for inclusion in the Agreement with the manufacturer:

1. The Agreement "shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug"; and
2. The Agreement "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."

Section 7102 of the Affordable Care Act also amended section 340B(d)(1)(B)(i)(II) of the PHS Act, which requires HRSA to develop a system to verify the accuracy of manufacturer-submitted quarterly pricing data with ceiling price data calculated by the Secretary.

Section 340B(d)(1)(B)(i) of the PHS Act, as amended by section 7102 of the Affordable Care Act, requires HRSA to develop a 340B ceiling price validation system to calculate and verify 340B ceiling prices for covered outpatient drugs as compared to the manufacturers' 340B prices offered to a covered entity. This system will enable HRSA to receive pricing information directly from manufacturers, which will allow HRSA to more efficiently identify discrepancies among the ceiling price variables and resolve them with minimal burden on the industry. As part of HRSA's oversight of the 340B Program, this Addendum to the Agreement will help to ensure that the requirements of the statute are met, including that manufacturers provide HRSA with their calculated prices for the pricing validation system, and the provision to offer covered entities drugs for purchase at or below the applicable ceiling price if such drugs are made available to any other purchaser at any price.

Please print the attached Addendum and have it signed by a corporate officer, such as the Chief Executive Officer. The form utilizes Adobe Acrobat Reader in an interactive format allowing you to input all applicable information on the computer. However, the form cannot be saved with your information for future use. You must print the form to submit it to the Office of Pharmacy Affairs (OPA).

If your organization would like to receive a signed original, please ensure that you submit TWO signed originals to the OPA. Otherwise, the OPA will send you a copy of the signed document.