The Consolidated Appropriations Act, 2022 Hospital Attestation for Reinstatement into the 340B Drug Pricing Program

Background

Section 121 of the Consolidated Appropriations Act, 2022 (CAA 2022) creates an eligibility exception that would permit certain hospitals to be reinstated into the 340B Drug Pricing Program (340B Program). The hospitals eligible for reinstatement are disproportionate share hospitals (DSH), sole community hospitals (SCH), rural referral centers (RRC), children's hospitals (PEDS), and free standing cancer hospital (CAN) that were terminated from the 340B Program due to an inability to meet the statutorily-required disproportionate share adjustment percentage (DSH percentage) of greater that 11.75% for DSH, PEDS and CAN entities and equal to or greater than 8% for SCH and RRC entities during cost reporting periods that begin October 1, 2019 and end no later than December 31, 2022 as a result of any actions taken by or other impact on the hospital in response to or as a result of the COVID-19 Public Health Emergency (PHE).

Attestation

By April 14, 2022 (within 30 days of enactment of the CAA 2022), or within 30 days of failing to meet the DSH percentage, hospitals must submit this attestation to the Health Resources and Services Administration (HRSA) via 340Bcompliance@hrsa.gov to be considered for reinstatement into the 340B Program.

•	I, [insert Authorizing Official name]am
	the Authorizing Official for [insert hospital name],
	340B ID [insert 340B ID]
•	I attest that [insert hospital name]
	340B ID [insert 340B ID] was a covered entity described in subparagraph (L),
	(M), or (O) of subsection (a)(4) of section 340B of the Public Health Service Act on January 26, 2020 (i.e., the day before the first day of the COVID-19 PHE).
•	I attest that due to actions taken by or other impact on the hospital in response to or as a resu of the COVID-19 PHE, for cost reporting periods of October 1, 2019 through December 31, 202
	[insert hospital name],
	340B ID [insert 340B ID] meets either of these criteria:
	(1) The hospital was terminated from the 340B Program for failing to meet the applicable DSH percentage requirement; or
	(2) The hospital has failed to meet the DSH percentage requirement and has not been terminated from the 340B Program.
•	I attest that [insert hospital name]
	340B ID [insert the 340B ID], the applicable cost reporting period is [insert cost report period] and that the
	applicable DSH percent is
•	I attest that [insert hospital name]
	[insert hospital 340B ID] is in compliance with all other applicable 340B
	Program requirements.

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Justification

In this section, please provide information on any actions taken by or other impact on the hospital in response to or as a result of the COVID-19 PHE that may have impacted the hospital's ability to meet the applicable required DSH percentage for participation in the 340B Program. If you need more space, please attach additional pages.

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Important information

If approved, this reinstatement applies only to the parent, associated child sites, and contract pharmacies listed as active in the 340B OPAIS at the time of termination.

Please submit this attestation to 340Bcompliance@hrsa.gov. HRSA will review the attestation and notify the hospital of the reinstatement decision as soon as possible. After the hospital is notified about reinstatement, visit the hospital's record in the OFFICE OPAIS and confirm the record is correct. If not, send a message to 340Bcompliance@hrsa.gov immediately. A hospital that has been reinstated will be considered active in the 340B Program based on the "participation start date" reflected in the hospital's parent OPAIS record. The hospital must comply with all 340B Program requirements as of the "participation start date" and should ensure that all policies and procedures are up to date and auditable records are maintained. HRSA encourages hospitals to:

- Update contract pharmacy agreements to reflect reinstatement into the 340B Program,
- Update 340B Program policies and procedures, and
- Maintain auditable records to reflect reinstated participation in the 340B Program.

The hospital should not register additional child sites or contract pharmacies through this process. If the hospital would like to register additional child sites or contract pharmacies please follow <u>standard</u> <u>registration procedures and periods.</u> Please contact the 340B Prime Vendor at 1-888-340-2787 or <u>apexusanswers@340bpvp.com</u> if you have any questions.

Acknowledgement		
Authorizing Official Signature	Date	