

## A COVID-19 340B UPDATE: OPA UPDATES ITS GPO PROHIBITION GUIDANCE AND OTHER OUTSTANDING 340B PROGRAM ISSUES

On March 23, 2020, the Health Resources & Services Administration (“HRSA”) launched a new webpage providing COVID-19 information related to the 340B drug discount program (“340B Program”), including responses to frequently asked questions related to COVID-19. HRSA’s COVID-19 Resources webpage is available [here](#).

In response to the COVID-19 pandemic, hospitals and other 340B Program covered entities (“Covered Entities”) are facing an influx of patients, staffing shortages, drug shortages and supply chain disruptions. As a result, many Covered Entities have sought guidance from HRSA and requested broad waivers or exemptions from certain 340B Program requirements, including delaying the proposed Medicare survey of drug acquisition costs, suspending Medicare Part B payment reductions for outpatient drugs, providing additional flexibility to Covered Entities subject to the Group Purchasing Organization (“GPO”) prohibition to purchase drugs through a GPO and opening 340B registration for eligible Covered Entities, child site and contract pharmacies outside of the normal quarterly registration periods.

The guidance included on the HRSA COVID-19 Resources webpage provides for some limited flexibility in recordkeeping and audits, but otherwise does not provide any general or broad waivers of 340B Program requirements. Instead, HRSA encourages Covered Entities to contact the 340B Prime Vendor, Apexus, if there are specific circumstances where a Covered Entity believes their COVID-19 response may affect their compliance or eligibility in the 340B Program. The Apexus website states that Apexus will coordinate with HRSA technical assistance and evaluate each issue on a case-by-case basis.

### SUMMARY OF HRSA’S 340B PROGRAM COVID-19 GUIDANCE AND RESPONSES TO FREQUENTLY ASKED QUESTIONS

- **Patient Eligibility and Record-Keeping.** Citing statutory limitations, HRSA refused to waive or relax the prohibition on transferring or reselling 340B Program drugs to individuals who are not patients of the Covered Entity. The agency did, however, acknowledge that it is appropriate to take into account the realities of the COVID-19 pandemic in determining whether individuals qualify as eligible patients. HRSA stated that an “abbreviated health record” with self-reporting of the patient’s identity, records of the medical evaluation (including history, testing, diagnosis/condition or clinical impressions) and documentation of the treatment provided or prescribed may be adequate. HRSA noted that the record may be a single form or note page, but Covered Entities must continue to maintain auditable records and ensure it has policies and procedures in place to address the proper dispensing of 340B drugs.
- **GPO Prohibition.** HRSA had until very recently refused to provide any clear guidance regarding Covered Entities’ use of GPO-purchased drugs, even in shortage situations. Effective March, 23, however, HRSA stated that:

...if a hospital is unable to purchase a covered outpatient drug at the 340B ceiling price, the covered entity should first try to obtain the drug at wholesale acquisition cost (WAC). If it is also unable to purchase the product at WAC due to shortages, a hospital may use a GPO (or GPO private label products). Hospitals do not need to report this information to HRSA under the COVID-19 public health emergency. The covered entity should address these situations in their policies and procedures and it must continue to keep auditable records.

This is a significant development, though Covered Entities must still continue to follow OPA guidance that they try in good faith to obtain the drug at wholesale acquisition cost (“WAC”). If it is unable to purchase the product at WAC due to shortages, a hospital desiring to purchase GPO (or GPO private label) products may only then rely on HRSA OPA’s guidance. We highlight OPA’s expectation that covered entities maintain auditable records and address this approach in their policies and procedures since we anticipate this to be an area of audit focus once we are past the acute phase of this pandemic response.

- **Prescribing Providers.** If volunteer health professionals provide care, HRSA advised that Covered Entities should generate emergency documentation indicating the Covered Entity’s responsibility for providing care. This documentation should also recognize the emergency nature of the situation, the name and address of the volunteer health professional and the relationship between the provider and the Covered Entity, and it should be kept on file by the Covered Entity.

- **Ongoing Audits.** HRSA stated that it will conduct 340B Program Covered Entity audits remotely (virtually) for the next several months. If a Covered Entity has specific questions regarding an audit once it has been engaged, contact the Bizzell Group at [340baudit@thebizzellgroup.com](mailto:340baudit@thebizzellgroup.com) to coordinate with HRSA.
- **Telemedicine.** HRSA recommends that Covered Entities outline the use of telemedicine modalities in their policies and procedures and maintain auditable records for eligible patients and 340B Program drugs dispensed. From a practical perspective, OPA's guidance may have only a minimal impact of 340B patient eligibility.
- **Quarterly Registration.** Current HRSA guidance limits registration for covered entities, child sites and contract pharmacies to the first two weeks of each calendar quarter. HRSA also does not activate registrations submitted during the registration period until the beginning of the next calendar quarter. Covered Entities have requested that HRSA keep the registration period open for the duration of the COVID-19 emergency and waive the quarterly wait period for active participation to allow newly enrolled locations to immediately purchase covered outpatient drugs at 340B pricing.

HRSA did not provide a general waiver to the quarterly registration requirements, again directing Covered Entities with a specific concern about eligibility of a new site to contact Apexus.

## OTHER 340B DEVELOPMENTS

- **Implementation of Medicare Survey of 340B Program Hospitals.** CMS had intended to release a drug pricing data request for 340B covered entities that would have required a significant amount of work to complete. CMS did not release the survey on March 23, 2020, however. We understand that it may be delayed for a minimum of a few weeks, if not longer as a result of the COVID-19 response. As 340B hospitals build out their future budgets, they will want to pay close attention to the status of this survey as its results will directly or indirectly impact 340B reimbursement.
- **Suspension of 340B Program Part B Payment Reductions.** CMS has not announced a suspension of the Medicare Part B reimbursement reductions currently applicable to 340B Program hospitals. We will monitor future OPPS guidance and issuances, as well as court communications, for any developments on this front.
- **Waiver of DSH Adjustment Percentage Requirements.** CMS did not provide a waiver from the Medicare DSH payment adjustment percentage requirements for 340B Program hospitals to prevent those hospitals from losing 340B Program eligibility due to their treatment of COVID-19 patients.

## PRACTICAL TAKEAWAYS

The guidance on the HRSA's COVID-19 Resources webpage is relatively limited in scope and flexibility; instead, HRSA appears to be taking a more case-by-case approach to determining what flexibilities may be appropriate.

If a Covered Entity or other 340B stakeholder has specific circumstances where "they believe their COVID-19 response may affect their compliance or eligibility in the 340B Program," they should consider in conjunction with their legal counsel whether or not to reach out to Apexus, HRSA OPA or another state or federal agency since communications with third parties, including Apexus.

The situation is fluid, and we will continue to remain vigilant with respect to developments in the pharmacy and 340B Program space. If you have any questions or would like additional information about this topic, please contact:

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For more information on Hall Render's Pharmacy services, click [here](#).