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340B PROGRAM OMNIBUS GUIDANCE: A DEEPER DIVE

EXECUTIVE SUMMARY

On August 28, 2015, the Health Resources and Services Administration ("HRSA") released its long-awaited proposed 340B Drug Pricing Program Omnibus Guidance. The notice (a copy of which can be found here) proposes to establish guidance addressing a variety of longstanding open questions for covered entities enrolled in, and drug manufacturers participating in, the 340B Program. Once finalized after public comments are submitted and reviewed, the Omnibus Guidance will heavily inform 340B Program compliance obligations for both participating covered entities and manufacturers alike.

Even prior to being finalized, though, the guidance offers insight into current HRSA Office of Pharmacy Affairs ("OPA") interpretations of 340B Program standards. Beyond certain key Omnibus Guidance elements appearing to have been communicated by HRSA OPA auditors during participating 340B "Covered Entity" audits, the guidance itself states that "[t]his notice clarifies many current 340B Program guidances." As such, both 340B Covered Entities and participating manufacturers will need to assess whether and to what extent their 340B Program compliance programs should be informed by the content of this proposed notice prior to finalization.

At a high level, and as discussed in greater detail below, some aspects of the Omnibus Guidance are welcome clarifications. Other elements will clearly limit the access to 340B Program savings by Covered Entities if not revised upon final publication. Still, other components of the guidance could be interpreted to limit 340B savings opportunities for Covered Entities if they are not further clarified by HRSA OPA.

Most notably, these changes include potential updates to standards governing which patients are eligible to receive 340B-priced drugs ("340B Drugs"). For example, the Omnibus Guidance contemplates exclusion of referral prescriptions, updates to outpatient status determinations that could result in the loss of both pre-admit and discharge prescription eligibility and significant limitations on 340B Drugs in the infusion setting. Also of note are potentially unreasonable self-disclosure obligations in the event of potential 340B Drug diversion. Taken together, Covered Entities that rely heavily on 340B Drug discounts to support their community missions could see their savings diminish without potentially significant restructuring of their relationships with prescribing practitioners.

The Omnibus Guidance is not entirely worrisome for Covered Entities, however. The proposed guidance also serves to: i) confirm and/or reiterate prior 340B Program guidance issuances (e.g., multiple contract pharmacy locations are permitted without regard to distance or location); and ii) clarify the definition of Covered Outpatient Drugs in a manner that is perhaps more broad than many Covered Entities had previously considered.

Comments are due to HRSA OPA on or before October 27, 2015. Although interested affinity organizations (e.g., 340B Health, Pharmaceutical Research and Manufacturers of America, American Hospital Association, National Association of Community Health Centers) are certain to submit comments by that date, we encourage interested parties to consider also submitting comments to ensure that HRSA OPA understands the true potential impact of their proposed guidance.

DETAILED DISCUSSION

In light of the sixty-day comment window closing on October 27, we discuss below the key components of the Omnibus Guidance that will most clearly impact 340B Program stakeholders.

- *Eligible Patients - More Restrictive Standards; Telemedicine Allowed*.

  The list of requirements that must be met in order for a patient to be deemed eligible to receive 340B Drugs ("Eligible Patient") could be expanded in a number of notable ways.

  First, HRSA OPA states clearly that an individual who receives follow-up care at a private practice (non-Covered Entity) location is not eligible to receive 340B Drugs. This point is a potentially significant limitation on 340B Program eligibility and is a distinct departure from current 340B Program guidance.

  Second, HRSA OPA now states that an individual must receive health care services from a provider who is either employed by or is "an

independent contractor of the covered entity such that the covered entity may bill for services on behalf of the provider." Previously, HRSA OPA required that the provider be employed by, contracted with or have "other arrangements (e.g., referral for consultation)" with the Covered Entity such that responsibility for the care provided remained with the Covered Entity.

The implications of the change requiring an independent contractor relationship are unclear since the independent contractor relationship is a determination that is based on state law considerations. More significantly, it is unclear if HRSA OPA intends to require that a Covered Entity merely have the option of billing were the provider and Covered Entity to agree on assignment of billing rights or if reassignment is in fact required. If assignment of billing rights is required, the implications would be significant for most Covered Entities and could require a material restructuring of relationships with independent providers or even with contracted providers who retain their own billing rights, whether or not they are employed by a wholly owned physician service organization.

In applying these proposed standards, HRSA OPA notes that an individual would not be eligible to receive 340B Drugs if the only relationship to the Covered Entity is the infusion of that drug. For example, a patient on vacation who requires ongoing infusion services would not be eligible to receive 340B Drugs, placing the Covered Entity in the position of either having to refuse the service or purchase the drug at a significantly higher wholesale acquisition cost ("WAC") price. HRSA OPA does not discuss in detail why it thinks an infusion in provider-based space of a Covered Entity is not sufficient to establish responsibility for that patient's care.

Another notable component of the guidance was HRSA OPA's statement that telemedicine visits are sufficient to establish 340B patient eligibility where permitted under state law.

- *Outpatient Status Determinations - Increased Complexity and Discharge Prescriptions*.

  340B pricing is only available for outpatient drugs. One longstanding area of uncertainty surrounding the 340B Program has been how outpatient status is distinguished from inpatient status, with many Covered Entities taking the position that outpatient status should be based on functional status at the time a drug is administered. The Omnibus Guidance, however, states that "an individual is considered a patient if his or her health care service is billed as outpatient to the patient's insurance or third party payor."

  This standard, if implemented, could prove to be difficult to implement given patient preauthorization and status recharacterization issues. Furthermore, it could serve to reduce certainty regarding 340B Drug accumulations, forcing Covered Entities subject to the "GPO Prohibition" to purchase more drugs at higher WAC prices. Finally, if implemented, this standard could be construed to functionally limit the application of 340B Program eligibility to both pre-admit and discharge prescriptions.

- *DSH Percentage Determinations and Child Site Eligibility - Relationship to Current Standard*.

  HRSA OPA appears to reiterate its position that Covered Entity and 340B "Child Site" eligibility are determined based on the most recent as-filed Medicare Cost Report. As such, situations where Child Site enrollment could take close to two years could still occur. Also, HRSA OPA did not restate its prior position that amended and restated Medicare Cost Reports could form the basis for 340B Program reinstatement where a cost reporting error results in inappropriate loss of 340B eligibility.

  We note, however, that HRSA OPA is actively seeking comments on alternatives to demonstrating the eligibility of an off-site outpatient facility or clinic. In discussing this issue, HRSA OPA referenced its prior consideration (and rejection) of CMS Form 855A submissions as a proxy for site eligibility.

- *Contract Pharmacies - Few Changes, One Notable Comment*.

  Though some anticipated that it might, the Omnibus Guidance did not materially limit or alter the 340B Program contract pharmacy model. It may be the case that HRSA OPA intends that the Eligible Patient definition changes noted above would serve to indirectly limit the scope of these arrangements. Interestingly, the guidance did state that contract pharmacy arrangements should be implemented "...in accordance with all... applicable Federal, State, and local laws, including the Federal anti-kickback statute." This presumably is a reference to implementation of compliant pricing models in the contract pharmacy setting.

- *Self-Reporting, Self-Disclosures and Repayment - Proposed New Standards*.

  The Omnibus Guidance proposes to implement some clear standards regarding repayment obligations. In particular, HRSA OPA states that Covered Entities are "expected to work with manufacturers regarding repayment within 90 days of identifying the violation."

Meanwhile, manufacturers are expected to effectuate refunds "within 90 days of the determination by the manufacturer or HHS that an overcharge occurred." For those familiar with False Claims Act repayment obligations, the difference between identifying a violation and determining that an overcharge occurred could be significant. As such, additional clarification is needed on how HRSA OPA intends to interpret these terms.

- *Maintenance of Auditable Records*.

  HRSA OPA is proposing to require that 340B Program stakeholders retain auditable records for a period of at least five years. Previously, no formal record retention standard existed, leading to disparate approaches that varied by Covered Entity and manufacturer alike.

PRACTICAL TAKEAWAYS

While this guidance is not final and is likely subject to change after the comment period, it nonetheless represents a major step toward clarifying longstanding 340B Program questions (while simultaneously creating new ones). While HRSA's goal is surely to make it easier for all 340B Program stakeholders to comply with the 340B Program's mission and purpose, it will be important for stakeholders to submit comments to help ensure that HRSA OPA is considering the impact of its proposals, whether intended or not.

Going forward, 340B Covered Entities and manufacturers alike face the unenviable task of assessing whether to view this guidance as a proposal or as a clarification of existing guidance. These stakeholders will also be faced with significant uncertainty that will only be resolved on publication of the final rule.

Whatever the final state of the Omnibus Guidance, we encourage all 340B Program stakeholders to actively participate in the comment process to ensure that their concerns are considered and that HRSA understands the true scope of impact of their proposed changes. Again, interested 340B Program stakeholders must submit comments on or before October 27, 2015.

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