HSCA
HEALTHCARE SUPPLY CHAIN ASSOCIATION
Innovators In Evidence-Based Sourcing

October 23, 2015

Krista Pedley
Director
Office of Pharmacy Affairs
Health Resources and Services Administration (HRSA)
5600 Fishers Lane
Mail Stop 08W05A
Rockville, Maryland 20857

Re: Comments of the Healthcare Supply Chain Association (HSCA) on HRSA's Draft Guidance "340B Drug Pricing Program Omnibus Guidelines" RIN 0906–AB08

The Healthcare Supply Chain Association (HSCA) appreciates this opportunity to provide comment on the Health Resources and Services Administration (HRSA)'s draft guidance entitled "340B Drug Pricing Program Omnibus Guidelines."

HSCA's member group purchasing organizations (GPO) are crucial cost-savings engines for America's hospitals, clinics, nursing homes, and surgery centers. HSCA and its members are committed to lowering costs and increasing competition and innovation in the healthcare marketplace.

We are grateful for HRSA's dedication to providing access to affordable healthcare services to eligible patients, and for HRSA's formal recognition of exceptions to the GPO Prohibition in the 340B Drug Pricing Program. We support the exceptions that HRSA has identified, which acknowledge challenges created by the GPO Prohibition and demonstrate HRSA's flexibility in interpreting the GPO Prohibition in ways that benefit both patients and providers.

HSCA urges HRSA to amend the 340B Drug Pricing Program Omnibus Guidelines to:

I. Expand Exceptions to the GPO Prohibition
II. Clarify Violations of the GPO Prohibition
III. Clarify Period of Time for which Covered Entity Must Make Repayments to Manufacturers

I. <u>Expand Exceptions to the GPO Prohibition</u>

We applaud the exemption of some off-site outpatient facilities from the GPO Prohibition. Such exemption allows hospitals to reap valuable cost-savings created through GPO contracts, while acknowledging the minimal risk GPOs pose to Program integrity. However, we urge HRSA to amend the following in their final guidance:

A. Off-site outpatient facilities should not be required to use separate purchasing accounts in order to meet GPO exemption.

Requiring that hospitals subject to the GPO Prohibition establish separate purchasing accounts for each off-site outpatient facility would be costly and administratively burdensome. Further, requiring separate purchasing accounts serves no Program integrity interests, as the Proposed Guidance separately imposes auditable records requirements.

B. An entire hospital or system should not be removed from GPO exemption if a GPO Prohibition violation is limited to just one participating child site, unless the child site has separate purchasing accounts.

If non-compliance is otherwise able to be isolated to a single off-site outpatient service, the existence of separate purchasing accounts for the location is irrelevant. Allowing hospitals subject to the GPO Prohibition to purchase drugs for all off-site outpatient facilities (340B-participating or not) using shared purchasing accounts, when determined by the hospital to be appropriate and where auditable records can be maintained, creates efficiency and saves valuable hospital resources, while posing no additional risk to Program integrity.

C. Expand exceptions to the GPO Prohibition to include outpatient services that are "within the four walls" of a hospital-covered entity subject the GPO Prohibition, but that are ineligible to participate in the 340B Program or are voluntarily excluded from the Program by the hospital.

Such circumstances might arise if a hospital opens a new service within its main building during the cost report year. Under current HRSA guidance,[1] these services are prohibited from accessing drugs through a GPO, but are also ineligible to access covered outpatient drugs at the 340B price. As such, a hospital must purchase drugs used for these outpatient services at a much higher, non-340B/non-GPO price (e.g., wholesale acquisition cost), unnecessarily increasing the hospital's total drug purchasing costs. This policy contravenes the stated goal of the 340B Program to enable covered entities to stretch scarce resources and does not appear to serve any Program integrity purpose. To the extent that HRSA takes the position that an outpatient service or location is not part of the covered entity for purposes of participation in the 340B Program, such services and locations are also outside of the scope of the statutory restrictions of the GPO Prohibition. HRSA has recognized this concept as to off-site outpatient facilities and should apply a common approach across all ineligible or non-participating locations of a hospital.

D. GPO-purchased drugs should be permitted to be dispensed to an inpatient who is later deemed an outpatient for payment purposes. This exception should extend to status changes arising from hospitals' internal review processes, as well as from third party reviews.

HSCA agrees with the inclusion of a second exception to the GPO Prohibition, which would allow GPO-purchased drugs to be dispensed to an inpatient who, upon subsequent review, is deemed to be an outpatient for payment purposes. The inclusion of this exception in the proposed guidance acknowledges the challenges to hospitals in classifying certain patients and recognizes the importance of GPO purchasing for inpatient use, and the uncertainty of patient status at the time of dispensing. We

[1] See Health Resources and Services Administration, Office of Pharmacy Affairs, Frequently Asked Questions, http://www.hrsa.gov/opa/faqs/index.html (last accessed 9/28/2015).

encourage HRSA to clarify in final guidance that this exception extends to status changes arising from hospitals' internal review processes, as well as from third party reviews.

E. A GPO exception should be made for instances in which applicable hospitals can only access a specific drug through a GPO contract. Additional clarity is needed to determine the standard against which "access" to a drug is measured for the purposes of this exception.

HSCA thanks HRSA for formally recognizing an exception to the GPO Prohibition for instances in which applicable hospitals can only access a specific drug through a GPO contract. Additional clarity is needed, however, to determine the standard against which "access" to a drug is measured for the purposes of this exception. Under the current proposed guidance, the hospital would be required to maintain documentation of its attempts to purchase the drug at the 340B price and at wholesale acquisition cost, and report the circumstances to HRSA. It is not clear whether the hospital's determination that a drug was inaccessible via 340B or wholesale acquisition cost is final, or if HRSA has the authority to disregard the hospital's determination and hold the hospital accountable for a GPO violation arising from such purchase. We encourage HRSA to clarify this provision to provide that a hospital that makes a GPO purchase arising from an inability to access a drug at 340B price or at wholesale acquisition cost, and maintains appropriate documentation, would not be found in violation of the GPO Prohibition for such purchase.

II. Clarify Violations of the GPO Prohibition

HSCA thanks HRSA for its flexibility in interpreting the GPO Prohibition, and for acknowledging differences in the type of incidents of non-compliance with the GPO Prohibition (e.g., "isolated" versus "systemic" non-compliance). We propose that:

A. Clear guidance is necessary as to what would constitute an isolated instance of non-compliance, and what non-compliance would be considered systemic.

As proposed, HRSA intends to impose significant penalties for all GPO non-compliance. For hospitals to understand the expectations and consequences for non-compliance, HRSA must provide hospitals with clear definitions of isolated and systemic non-compliance. Such definitions will assist hospitals in evaluating compliance and further efforts to ensure the integrity of the 340B Program.

B. Penalties for isolated non-compliance should not be overly punitive and/or inconsistent with the public policy rationale underlying the recognition of isolated non-compliance.

Under the proposed guidance, for both isolated and systemic violations of the GPO Prohibition, a covered entity must offer to repay affected manufacturers for any 340B drug purchase made after the date of the first GPO violation. In practice, a hospital for which an isolated incident of GPO non-compliance has been identified would be deemed ineligible for the 340B Program during the period of non-compliance, and as such the Proposed Guidance directs that a hospital would be required to offer a refund to manufacturers of all 340B drugs purchased during the period of non-compliance.

Further, because the proposed guidance does not include a *de minimus* purchase threshold, it appears that an isolated instance of non-compliance could include even a single erroneous GPO purchase. Requiring a refund of 340B purchases occurring during the period of non-compliance for a single isolated GPO purchase is an unreasonable and inequitable penalty. The disparity in cost between a

single GPO purchase and a hospital's entire 340B purchasing during a set time period is immense, and imposing such a disproportionate penalty is unnecessary to further the goals of the 340B Program.

In addition, where the erroneous GPO purchases were of drugs that the hospital would have otherwise been permitted to purchase at the 340B price, the hospital's "non-compliance" actually results in a financial loss to the covered entity and a financial benefit to the manufacturer. Imposing punitive corrective action on such purchases is inconsistent with the intent of the 340B Program and such purchases should be excluded from the determination of whether a violation of the GPO Prohibition has occurred.

C. There should be a *de minimus* purchase threshold, below which GPO purchases would not be deemed non-compliant, to exclude GPO purchases of drugs that would have been eligible for 340B pricing – and to reflect a less severe repayment penalty for isolated incidents of non-compliance.

In lieu of repaying manufacturers the entire cost of the purchased drugs for the period of non-compliance, HSCA recommends that HRSA implement a more reasonable approach to corrective action. For example, HRSA could limit a covered entity's potential repayment obligations arising from an isolated incident of non-compliance, to repayment of an amount equal to the difference between what the hospital paid (the GPO price) and what the hospital should have paid for the drugs based on patient eligibility (e.g., wholesale acquisition cost). We believe this is an equitable corrective action that does not impose unreasonably punitive sanctions on covered entities, or create a windfall for manufacturers. We further believe that limiting the covered entity's repayment obligations only to those manufacturers from which erroneous GPO purchase are made is a proportional penalty, appropriately lessens the administrative and financial burdens on the covered entity, and prevents the unjust enrichment of manufacturers.

We are also concerned that the proposed penalty for systemic non-compliance, removal from the 340B Program, is unduly punitive and disproportional to the nature of the potential non-compliance. Where non-compliance is systemic, but inadvertent, hospitals should not be subject to removal from the 340B Program. As with isolated non-compliance, hospitals should be permitted to correct non-compliance through engaging in repayments to manufacturers from which drugs were erroneously purchased through a GPO account.

III. Clarify Period of Time for which Covered Entity Must Make Repayments to Manufacturers

As currently proposed, draft guidance is unclear regarding the period of time for which a covered entity must offer to make repayments to manufacturers.

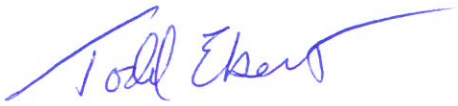
A. The appropriate period for non-compliance should be limited to the actual dates on which erroneous GPO purchases were made.

The proposed guidance states that repayments must be offered "for any 340B drug purchases made after the date of the first GPO violation," but does not set forth an end date for such repayments. In its current form, we believe the proposed guidance would create confusion and potential disputes among covered entities and manufacturers as to the appropriate time period for which the covered entity must make repayments. For example, if a covered entity made an erroneous purchase of a covered outpatient drug on June 1, 2015, but the purchase was not identified until September 1, 2015, the covered entity

should be subject to repayment only as to purchases made on June 1, 2015. In no instance should repayments be required for periods during which the hospital is able to demonstrate that it was in compliance with the GPO Prohibition. We encourage HRSA to set forth such a clear policy in the final guidance.

We look forward to continuing to work with HRSA as you finalize 340B guidance. Please do not hesitate to contact me directly should you have any questions. I can be reached at 202.367.1162 or tebert@supplychainassociation.org.

Sincerely,



Todd Ebert
President and CEO
Healthcare Supply Chain Association