October 9, 2015

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

Re: RIN 0906-AB08
340B Drug Pricing Program Omnibus Guidance

Dear Director Pedley:

NAVEOS® is a national leader in healthcare data analytics. With respect to the 340B Drug Pricing Program, NAVEOS® assists healthcare providers to understand the 340B Program's eligibility requirements, meet those requirements, and maintain compliance.

NAVEOS® appreciates the opportunity to comment on the Health Resources and Services Administration's (HRSA) 340B Drug Pricing Program Omnibus Guidance published by HRSA on August 28, 2015 (80 Fed. Reg. 52300). The comments focus on the provisions of the proposed guidance that affect hospitals and other covered entities. The purpose of the 340B Program is to enable covered entities "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." (H.R. Rep. No. 102-384(II), at 12 (1992). It is important that any guidance issued, and any enforcement action taken in connection with such guidance, be consistent with this purpose.

COMMENTS

I. HRSA's Authority to Promulgate "Omnibus Guidance"

Although styled as "Omnibus Guidance," the August 28, 2015 notice reads in parts more like legislative rulemaking. As recently reinforced by the United States District Court for the District of Columbia in Pharmaceutical Research and Manufacturers of America v. U.S. Dept. of Health and Human Services in its decision dated May 23, 2014, Congress has limited the authority of the Department of Health and Human Services to promulgate rules to three specific areas:

1. the establishment of an administrative dispute resolution process for claims by manufacturers and covered entities;
2. the "regulatory issuance" of precisely defined standards of methodology for calculation of ceiling prices;
3. the institution of standards for the imposition of monetary civil sanctions applicable to participating manufacturers.

In the final guidance, the agency should clarify that it recognizes the limitations of its authority with respect to the 340B statute and the limitations of its authority to enforce guidance. Also, HRSA should make clear that any guidance will only be applied prospectively to conduct after the effective date of the final guidance.

II. Concerns Regarding the Use of the Medicare Cost Report as the Exclusive Determinant of a Hospital's Eligibility to Participate in the 340B Program

The proposed guidance makes clear that HRSA is relying on a hospital's most recently filed Medicare cost report to determine if a hospital meets the required disproportionate share hospital percentage threshold. While we believe that the most recently filed cost report can be an important resource in determining 340B eligibility, it also has limitations that HRSA should recognize and address.

There has been sustained litigation for the last several decades over inaccuracies in CMS's interpretation and application of the statutory Medicare DSH calculation. These challenges often take many years to resolve. Courts have often sided with hospitals. Once the errors are corrected, many hospitals that were deemed ineligible for the 340B Program (based on the initial Medicare DSH calculations) would in fact have been eligible for the Program for the years that were appealed. While these decisions have resulted in appropriate retroactive changes to many hospitals' Medicare DSH reimbursement, there has been no mechanism for hospitals to retroactively receive the 340B savings to which the hospitals were lawfully entitled. HRSA should correct this situation in its final guidance.

As an example, in the case of Allina Health Services, et al., v. Sebelius, 746 F.3d 1102 (2014), the United States Court of Appeals, District of Columbia Circuit, issued an important decision invalidating the Secretary's position on the proper allocation of Medicare Part C days in the hospitals' Medicare DSH calculation. Although the precise scope of the decision is still in dispute, the case has enormous potential to retrospectively increase many hospitals' DSH percentage. For some hospitals, this increase will push their DSH percentage over the 340B eligibility threshold for those prior years. The case could implicate as many as 9 years of potentially understated DSH calculations. Without HRSA providing an appropriate solution to such situations, these hospitals were denied 340B savings to which they would have been entitled by statute, but were denied because of the government's incorrect statutory interpretations.

In addition, there is a systemic, historical delay of over two years in the publication of the SSI metric that is a key determinant in the hospitals' prospective ability to qualify for the 340B Program. As an example, the 2013 Federal fiscal year SSI metric was published in May of 2015 which was significantly earlier than expected. That improved the situation and allowed calendar year end hospitals to utilize this value in their "as-filed" Medicare cost report (presuming they had not already filed). However this still represents a lag of 15 months between the hospital's actual experience and the published measurement. While this is significantly better than the historical delay of 27 months, the lag results in the use of an untimely and inaccurate metric in determining a hospitals' DSH percentage and by extension their eligibility for the 340B Program.

Although the early publication of the 2013 SSI metric assisted hospitals in submitting a more accurate and timely value, there is no guarantee that CMS will continue this publication schedule moving forward.

There are a number of ways to address the problem. One option is for HRSA to allow all hospitals to submit a statement from a qualified independent auditor certifying that the hospital meets the requisite DSH criteria for participation in the 340B Program. This formal opinion must include the detailed basis for that conclusion. This is the process allowed for certain children's hospitals and should be extended to other types of hospitals.

Another option is for HRSA to allow hospitals that are successful in an appeal of their DSH percentage to retroactively receive the appropriate 340B drug price savings for the time-period that was under appeal. Under this option, hospitals would have to put appropriate controls and measures in place to ensure compliance with the 340B Program, in case the hospital is ultimately successful in its DSH related appeal. While this places a significant burden on hospitals that might not win their DSH related appeal, it is certainly better than the current situation where many hospitals are being improperly excluded from the 340B Program for years in which they actually qualify under the DSH eligibility standard and have no ability to recover those savings

CMS could allow the States to release the key values from the monthly "SDX" (State Data Exchange)" data file it receives from the Social Security Administration on a monthly basis. This "SDX file, or a file containing the appropriate information regarding their State's members that have current eligibility for Title XVI or SSI (Supplemental Security Income), are eligible for Federal SSI benefits and their status as to whether said patient is considered to be "institutionalized" could allow hospitals to compile real-time metrics for the SSI fraction as it does the Medicaid fraction today. The SDX or similar data file release would only be made in compliance with HIPAA and as a result of a hospital's successful query of that State's Medicaid Member Information System using the existing protocol for submitting the eligibility queries.

Hospitals could be allowed to keep internal logs that track outstanding SSI applications with statistically valid extrapolation algorithms for identifying and including in their SSI ratio such patient types as compassionate care and presumptively eligible SSI patients; those SSI patients

that have consented to the hospital obtaining real-time eligibility and payment data from the SSI; or any other internal or SSI provided records that can provide a compelling case by a qualified independent auditor certifying that the hospital meets the requisite DSH criteria for participation in the 340B Program. As stated earlier, the certification report must include the basis for that conclusion.

Regardless of how HRSA corrects this persistent problem, it is critical that HRSA act now to ensure that DSH hospitals are no longer improperly denied the benefits of the 340B Program for years in which they are ultimately able to prove that they did, in fact, qualify under the 340B DSH requirements.

III. Concerns Regarding HRSA's Proposed New Six Part Criteria for a Person to Qualify as an "Eligible Patient" for 340B Purposes

The proposed guidance significantly changes and limits who would be considered an "eligible patient" of a covered entity for 340B purposes. We have several concerns regarding the proposed new standards.

The proposed guidance states that to be considered a patient for 340B purposes, the individual must receive healthcare service from a provider who is either employed by, or an independent contractor for, the covered entity such that the covered entity may bill for services on behalf of the provider. The guidance notes that faculty practice arrangements and established residency, internship, locum tenens, and volunteer healthcare provider programs are examples of relationships that would meet this standard. In a change from prior guidance, however, the standard does not include providers who have referral or other arrangements with the covered entity. It also explicitly excludes providers who only have privileges or credentials at the covered entity. This change ignores the realities of modern hospital operations and would unduly harm smaller hospitals with smaller staffs. We ask that the agency reconsider the tight restrictions imposed by this requirement.

Nationally and in many if not most cases, there are far fewer physicians who are either employed by a hospital or in an independent contractor relationship with a hospital than physicians who have credentials and staff privileges at the hospital. This latter group directs the care and writes the prescriptions for many outpatients as well as for inpatients of the hospital.

The proposed guidance would also require that the individual receive a drug ordered or prescribed as a result of the service described in the preceding paragraph. This appears to restrict 340B pricing only to those drugs that are actually prescribed within the walls (including registered offsite clinics) of the covered entity by a covered entity provider. HRSA specifies that the dispensing or infusion of drugs by the covered entity alone would not suffice to establish a patient relationship. This limitation also appears to exclude, for example, drugs prescribed by a covered entity provider during the course of a follow-up visit conducted at a freestanding (non-provider-based) clinic or office setting. We urge HRSA to recognize the efforts of providers to continue to provide care in the most appropriate setting and not to

penalize covered entities that provide such care by restricting patients' access to 340B drugs when the care is provided in such a setting.

Under the proposed guidance, a patient's classification as an outpatient appears to be determined by how the services are billed to the insurer (e.g. Medicare, Medicaid, private insurance). This would seem to prohibit prescriptions written at the time of inpatient discharge from being filled with a 340B drug. It also has implications for pre-admission outpatient services, including drugs dispensed in the emergency room setting to patients subsequently admitted as inpatients. The guidance in this area mistakenly focuses on billing rather than the nature of the medical service provided. The fact that some payers (including Medicare through the 72 Hour Rule) bundle outpatient services into payment for inpatient services does not change the fundamental nature of a medical service; and it is that fundamental premise that provides the clearest definition of the service provision as the dispositive criteria for outpatient status.

We strongly recommend that HRSA revise the guidance to reflect that a service provided to a hospital outpatient is an outpatient service, regardless of whether a payer decides to pay for that service in connection with a subsequent inpatient admission.

IV. Offsite Locations

The proposed guidance improperly narrows the 340B eligibility of offsite clinics. Under the proposed guidance, an offsite facility or clinic would have to:

1. Be listed on the hospital's most recently filed Medicare cost report on a reimbursable line; and,
2. Provide services that have associated Medicare costs and charges.

Requiring that a clinic be listed on a hospital's most recently filed Medicare cost report could improperly delay a clinic's participation in the 340B Program. HRSA should accept an alternative to the cost report for newly enrolling offsite clinics. An offsite clinic should be considered part of the covered entity as soon as it is considered provider-based under Medicare (as evidenced by an attestation or other verification) or submits the Medicare enrollment application for an outpatient facility. Even though Medicare allows a hospital to bill as soon as a clinic meets one of these criteria, HRSA does not recognize a similar eligibility process for 340B purposes. The timing prescribed under the current proposal costs eligible clinics substantial amounts of money in lost 340B drug discount savings to which they are rightfully entitled. HRSA should modify its guidance to allow alternate ways of demonstrating 340B eligibility other than the Medicare cost report.

In addition, the requirement that a clinic must provide services with associated Medicare costs and charges might improperly exclude from the 340B Program certain clinics that are entitled to participate in the Program under the statute. Certain hospital clinics might have no Medicare patients and thus no associated Medicare costs or charges. Examples include clinics that serve exclusively indigent, uninsured, or Medicaid populations; pediatric and obstetric clinics; and

hospital-based clinics serving prisoners. These clinics, if otherwise eligible, are entitled under the statute to participate in the 340B Program. HRSA should clarify how such clinics can participate in the 340B Program.

V. Group Purchasing Organization Prohibition

The guidance reinforces that GPOs may be used when purchasing drugs in an offsite outpatient facility not enrolled in the 340B Program. Prior guidance required the offsite facility to ensure that the drugs were not "utilized or otherwise transferred to the parent hospital" or other 340B sites. The preamble to the newly proposed guidance indicates that an offsite facility must ensure that "GPO purchased drugs are never provided to outpatients of the hospital or other child sites." It is not unusual for a person to be a patient of both a non-340B offsite facility and a participating 340B hospital. The wording of the preamble could create confusion. We request that HRSA clarify that just because an offsite outpatient facility serves a person who is a patient at a 340B participating hospital, the offsite outpatient facility which is not enrolled in the 340B Program is not prohibited from providing drugs purchased through a GPO for such a person. The guidance also provides that when a covered entity cannot access a drug at the 340B price or at wholesale acquisition cost and the drug is needed to prevent disruptions in patient care, a covered entity may purchase the drug through a GPO. We agree that such an exception is appropriate.

HRSA appears to establish an expectation that identification and correction of GPO purchasing errors within 30 days of purchase will not result in a finding that the GPO prohibition has been violated. It is unclear whether a process that takes longer would require a hospital to report the error to HRSA. From the proposed guidance it appears that isolated violations of the GPO prohibition would not require expulsion from the 340B Program, although "isolated violation" is not defined. It has been our observation that covered entities diligently attempt to comply with the GPO prohibition. Despite this diligence, perfection remains an ideal that cannot always be achieved in the real world. HRSA should expand the timeframe for identification and correction of GPO purchasing errors to at least 60 days and make clearer that covered entities falling short of perfection would be subject to expulsion from the 340B Program or receive an alternate form of sanction.

VI. Record Retention

HRSA proposes that all 340B Program records must be retained for at least five years by covered entities, including records from all child sites and contract pharmacies. HRSA should clarify that this requirement is being phased-in to reflect the fact that in the absence of a prior explicit standard, covered entities had different record retention policies. For example, if a covered entity had a record retention policy of three years prior to the finalization of HRSA's guidance, the covered entity cannot be instantly in compliance with a five year requirement.

VII. Contract Pharmacies

We thank HRSA for continuing to recognize the right and importance of a covered entity being able to contract with as many contract pharmacies as the covered entity deems appropriate. Contract pharmacies play an important role in enabling covered entities to receive the full benefit of participation in the 340B Program and in providing patients with greater access to 340B drugs. While we understand the concern with contract pharmacy compliance, we believe that requiring quarterly reviews of each contract pharmacy is unduly burdensome for covered entities. We believe that an annual audit is sufficient to ensure appropriate compliance and oversight of contract pharmacies and that the requirement for quarterly reviews should be eliminated.

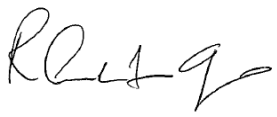
VIII. Manufacturer Audits

We appreciate the agency reinforcing that manufacturer audits of covered entities must be based on "reasonable cause." The requirement that the manufacturer would need to justify that "a reasonable person could conclude, based on reliable evidence, that a covered entity, its child sites, or contract pharmacies may have violated either" the prohibition on diversion or duplicate discounts helps provide an important safeguard against manufacturers' overly aggressive use of audits that would unnecessarily increase the cost and burden to covered entities participating in the 340B Program.

We thank the agency for its recognition of the vital role the 340B Program plays in the health of the patients served by 340B participating hospitals, and for recognizing the importance of 340B savings to participating hospitals.

We thank the agency for its consideration of our comments on this important matter. If you have any questions or require additional information in connection with these comments, please contact me.

Sincerely,



Robert F. Gricius, CPA
Chief Executive Officer