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Krista Pedley, PharmD, MS
Captain, United States Public Health Service
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Mail Stop 08W05A
Rockville, MD 20857

Dear Captain Pedley:

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

The Association of American Medical Colleges (AAMC) is pleased to comment on the Health Resources and Services Administration (HRSA)'s proposed guidance entitled, *340B Drug Pricing Program Omnibus Guidance*, 80 Fed. Reg. 52300 (Aug. 28, 2015). The AAMC is a not-for-profit association representing all 145 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and over 90 academic and professional societies. Through these institutions and organizations, the AAMC represents 148,000 faculty members, 83,000 medical students, and 115,000 resident physicians.

The AAMC appreciates HRSA's longstanding recognition that the original and continuing intent of the 340B Drug Pricing Program is to permit safety net hospitals and other covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] AAMC-member teaching hospitals and their clinical faculty, residents, and students are committed to this safety net mission in expanding access to care for underserved and vulnerable patients. While they represent only five percent of all hospitals, major teaching hospitals account for 25 percent of all Medicaid discharges, 18 percent of all Medicare discharges, and 37 percent of the country's charity care. Compared with physician offices and other hospitals, major teaching hospitals provide care to a higher proportion of low-income, dual eligible, disabled, and minority patients. As major referral centers with highly specialized expertise, these academic medical centers (AMCs) serve a sicker, more complex, and more vulnerable patient population – patients who often are unable to seek the necessary care elsewhere.

[1] H.R. Rept. No. 102-384(II), at 12 (1992)

Under the 340B program, certain drug manufacturers offer lower prices on covered outpatient drugs to eligible hospitals and other settings, enabling these eligible entities to reinvest the difference into health care services for underserved and uninsured patients. Through the savings generated from the 340B drug discounts, qualifying AAMC member hospitals have been able to fund a wide range of programs to expand the provision of health care in their communities. For example, hospitals operate a variety of programs and services that otherwise would not be financially viable:

- Programs to provide free or substantially discounted prescriptions to uninsured or low-income patients;
- Dialysis centers in low-income, underserved areas;
- Smoking cessation programs to help uninsured and underinsured patients gain access to cessation drugs;
- Clinics that provide health care to underserved populations;
- Mobile units for patients who are unable to visit a clinic; and
- Multidisciplinary clinics for patients discharged with mental health issues.

Other than modest appropriations to administer the program, the 340B program is self-sustaining in that the financial support hospitals receive is derived from drug manufacturer discounts, rather than through additional federal investments. Restricting the scope of the program would not yield substantial additional funds for the federal government, but could potentially leave patients who rely on these essential programs without the services they have looked to hospitals to provide. Other unintended consequences could result as well. For example, the future health care workforce needs to be prepared to care for populations with differing needs. Such clinics and programs offer valuable opportunities for medical students, resident physicians, and other health professions trainees at teaching hospitals to be exposed to a diverse array of patients, conditions, and care settings throughout the community; if the clinics are forced to close, opportunities for trainees to learn in these settings could be limited. These consequences would undermine the core intent of the 340B program to strengthen care broadly for vulnerable populations.

The AAMC welcomes the opportunity provided by HRSA's proposed omnibus guidance to achieve better clarity regarding how the 340B program is administered. However, many institutions report that should the proposed changes be adopted without significant revisions, continued participation in the 340B program may no longer be viable. We are concerned that a number of the proposed provisions would pose substantial financial and operational challenges to hospitals currently participating in the program, restricting the scope in a manner that is inconsistent with longstanding HRSA policy and the underlying goals of the statute. A narrower 340B program would likely reduce access to patient care services currently supported as a result of the program, thus weakening its impact. Therefore, the comments in this letter are focused on the clarifications needed in the proposed guidance to preserve the ability of major teaching hospitals and other covered entities to continue fulfilling the program's intent.

Below is a summary of our major concerns and comments, which are described in detail in the following section of the letter.

- The definition of "patient" is unnecessarily restrictive such that it would severely limit drugs eligible for 340B pricing and would undermine hospitals' efforts to expand care and services to underserved populations.
    - The proposal to exclude discharge prescriptions effectively would penalize hospitals that are actively seeking to improve care coordination and continuity of necessary care in the outpatient setting.
    - Tying the prescription to a billable outpatient event would seemingly exclude from 340B pricing drugs administered to an outpatient if the individual is later admitted.
    - We have concerns that proposed requirements with respect to the provider's relationship to the covered entity could inadvertently exclude providers at major teaching hospitals given the complex provider and billing relationships at these institutions.
    - The proposal would exclude patients receiving "only" infusion services from qualifying for 340B.
- Greater flexibility for demonstrating eligibility of off-site outpatient facilities could help expedite the enrollment process for new child sites.
- It is unclear how HRSA plans to apply its proposal to exclude from 340B pricing, drugs that are reimbursed as part of a bundled Medicaid payment, which would result in programmatic and operational challenges for covered entities.

Given the wide-ranging nature of the proposed guidance and the interrelatedness of its many provisions, the AAMC encourages HRSA to work with providers to understand the operational barriers to implementing some of the provisions and to publish a revised proposal, again subject to public comment, before finalizing the guidance. AAMC member hospitals share HRSA's commitment to program integrity and recognize the need for explicit and well-understood guidelines. At the same time, such requirements should not be so burdensome that complying with them is impractical or impossible. **Revising and reposting the proposed guidance for additional comment will help ensure that the final guidance strikes the appropriate balance between feasible, clear requirements to demonstrate compliance and sufficient flexibility for providers such that the patients ultimately served by the program continue to benefit from it.**

Additionally, when HRSA finalizes guidance, it will be essential to provide an effective date and a sufficient transition period to allow providers to come into compliance. Many of the proposals represent a dramatic and sweeping change from current, longstanding practice, and would require hospitals to modify existing processes, renegotiate terms with various parties, retrain staff under the new guidance, implement updated or new systems, and test the functionality of the new practices. In many cases, products with the necessary capabilities may not yet be available on the market. Navigating these changes in what is already an administratively complex and nuanced program will require time, substantial resources, and assurances that the new provisions are applied only prospectively. **To enable hospitals to put in place the appropriate procedures and safeguards against inadvertent violations, and to allow vendors the opportunity to develop products that meet the new needs of covered entities, the AAMC recommends a transition period of one year, at minimum, before the compliance date.**

Discussion of Major Concerns

Patient Definition

While we appreciate HRSA's inclusion in the preamble of telehealth, telemedicine, and other remote arrangements as acceptable uses of 340B pricing,[2] the AAMC is concerned that other aspects of the proposed new patient definition would exclude a substantial number of eligible patients in a manner that is both inconsistent with the authorizing statute and difficult to operationalize. Taken individually, elements of the new definition would impose counterintuitive and onerous restrictions. Combined, the various elements contained in the new definition may make participation in the program untenable for some entities. As described below, the effects of these changes would run counter to the purpose of the program to strengthen safety net facilities' ability to expand access to care for underserved and vulnerable populations.

- *Discharge Prescriptions and Outpatient Status (5).* The AAMC is concerned that the new patient definition would exclude from 340B pricing, both discharge prescriptions; and drugs administered to patients in outpatient observation or ED settings if the treatment leads to an inpatient admission.

  The proposed guidance would seem to prohibit hospitals from using 340B pricing for outpatient drugs prescribed to or ordered for patients that are being discharged from an inpatient stay. By requiring that the patient be "classified as an outpatient when the drug is ordered or prescribed,"[3] the proposed new definition represents, without strong rationale for this requirement, a major reversal of existing HRSA policy of explicit support for the use of 340B for discharge prescriptions. Currently, HRSA's website indicates that "340B drugs can be used for discharge prescriptions to the extent that the drugs are for outpatient use," with the expectation that the covered entity has "auditable records that demonstrate compliance with this requirement."[4] The proposed guidance does not provide any reason of the need for this change.

  As the preamble to the guidance correctly points out, the authorizing statute "establishes the 340B Program as a drug discount program for covered entities furnishing covered outpatient drugs."[5] Given this universally agreed objective of the program, the test for meeting this standard should hinge on whether the drug is for outpatient use, not the classification of the patient at the time of the prescription. Yet, under the new patient definition, it seems that even a drug billed as an outpatient drug and prescribed for outpatient use inexplicably would not qualify for 340B pricing if the drug is prescribed in connection with an inpatient service.

  Many hospitals employ discharge prescription programs to maximize the likelihood that patients comply with medication therapy regimens when they are no longer under the

[2] 80 Fed. Reg. 52307
[3] 80 Fed. Reg. 52319
[4] http://www.hrsa.gov/opa/eligibilityandregistration/
[5] 80 Fed. Reg. 52307

hospital's care. By ensuring that patients have necessary medications in hand when leaving the hospital, these programs reduce the hurdles that patients – especially low-income and high-risk patients – face in the transition from hospital to home recovery. In addition to improving convenience, the practice seeks to improve patient education on adherence to the prescribed therapy and avoid deterioration of the patient's condition to the point of needing to be readmitted to the hospital.

The proposed change in patient definition to exclude discharge prescriptions from 340B pricing effectively would penalize hospitals that are actively seeking to improve care coordination and continuity of necessary care in the outpatient setting. Excluding these prescriptions and orders from the program is likely to have a significant financial impact on many institutions, substantially reducing the savings available to them to reinvest in expanding patient access and services. The prohibition also would impose substantial operational challenges, since current systems do not allow retail and contract pharmacies to distinguish between prescriptions resulting from inpatient versus outpatient encounters. Hospitals would be forced to incur substantial costs and administrative burdens in modifying their systems to accommodate the new requirement.

An additional concern with the proposed definition is the new requirement that a "patient's classification status is determined by how the services for the patient are billed to the insurer."[6] As a result, outpatient drugs administered to a patient before being admitted to the hospital – which currently appropriately qualify for 340B pricing – would seemingly no longer be eligible for the discounted price if the patient's status later changes to inpatient (as required, for example, under Medicare's 72-hour rule, which does not permit separate billing for outpatient services clinically related to and for three days prior to an inpatient admission). **In other words, it again appears that a covered outpatient drug administered to an outpatient would not qualify under HRSA's new test for patient eligibility.** Here too, limitations of current inventory management systems could force hospitals to forego 340B pricing for covered outpatient drugs that legitimately adhere to the statutory requirements and objectives of the program.

Neither current practice nor the authorizing statute support these changes, and their implementation would undermine the ability of covered entities to fulfill the program's intent.

- *Relationship of the Provider to the Covered Entity (2).* The proposed guidance modifies the current patient definition such that only prescriptions for patients receiving health care services from a provider "employed by the covered entity or who is an independent contractor of the covered entity" would qualify for 340B pricing, discontinuing current allowances for "other arrangements," such as referrals.

  The AAMC appreciates the text in the preamble stating,

[6] 80 Fed. Reg. 52319

> Faculty practice arrangements and established residency, internship, locum tenens, and volunteer health care provider programs are examples of covered entity-provider relationships that would meet this standard.[7]

However, we have concerns that as currently drafted, the proposed guidance could inadvertently exclude a number of providers at major teaching hospitals. The relationships at academic medical centers are varied, complex, and often are established to ensure that patient care, teaching, and research are supported. Though the preamble recognizes faculty practice arrangements as eligible providers, the specific faculty practice arrangements at a given teaching hospital may not meet the new standard of either being employed or an "independent contractor" of the covered entity, as the guidance proposes. In some cases, physicians who practice only at the academic medical center may be employed by the university or the medical school rather than the covered entity hospital. Additionally, the preamble indicates that having privileges or credentials at a hospital would not suffice to meet the new qualifications.

Consider the following example demonstrating the unintended consequences of these changes. An AAMC member institution operates in underserved areas dialysis centers that are currently registered as 340B child sites and serve nearly 900 patients from predominantly low-income backgrounds. Though the centers are owned by the health system and appear on its cost report, they are run by medical directors who are not employed or contracted by the system. Rather, the AMC has a memorandum of understanding with its faculty practice plan for medical director services at the centers, and the AMC's faculty practice plan has an agreement with the medical directors for their services. The physicians under contract with the faculty practice plan are credentialed by the AMC and can order treatment. Patients who seek dialysis at the centers often have multiple comorbidities and are able to receive intravenous infusions and other medications, with greater convenience and at a lower cost. The institution relies on the savings generated through 340B discounts to continue operating the centers, as losing this support could make the centers financially unviable. The centers exemplify the 340B program's intent of enabling covered entities to extend care to vulnerable populations. Yet, under the proposed patient definition, they may no longer qualify for 340B pricing.

It is not clear in the example above if HRSA would accept under the proposed guidance the memorandum of understanding as a sufficient equivalent to the "independent contractor" requirement. AAMC encourages HRSA to continue recognizing these other arrangements as under current policy. It also is unclear how the provision would apply in states with prohibitions on the so-called "corporate practice of medicine," where employment of physicians is prohibited by law, and the physicians may not be considered "independent contractors" by HRSA.

These concerns are enhanced by the additional language requiring that the "covered entity may bill for services on behalf of the provider."[8] It is not clear whether HRSA intends for the requirement to apply to the facility fee or the billing for the professional

[7] 80 Fed. Reg. 52306
[8] 80 Fed. Reg. 52319

services furnished by the hospital's providers. At academic medical centers, the faculty practice may well be the entity that bills for the physician's professional services. In many circumstances, and for a myriad of reasons, the covered entity may not be billing for those services. These established billing arrangements should not disqualify associated prescriptions from 340B eligibility.

Even without prong (2), many elements of the proposed guidance restrict 340B pricing to services and prescriptions within the covered entity or its eligible off-site facilities and clinics. As currently drafted, the intended goal of this additional layer is unclear. Without clarification, the proposed change risks inadvertently disqualifying prescriptions and services offered by providers within eligible sites and consistent with the program's intent. Moreover, the challenges associated with operationalizing this requirement would be substantial and may force some covered entities to cease their participation in the program.

- *Infusion (3).* The proposed guidance excludes from 340B pricing, infusion orders that are not written as a result of services provided by an eligible provider of the covered entity or one of its registered sites. As with some of the other facets of the definition, this new requirement establishes a counterintuitive characterization of "patient." Infusion services involve administration of medication intravenously under the careful attention of supervising physicians and other skilled health professionals. Hospitals are legally responsible for the clinical care these individuals receive. For all intents and purposes, the individual would be a considered a "patient" of the covered entity. Yet, if the order originated from outside of the covered entity or one of its child sites, it appears the individual would not be considered a "patient" under 340B.

  One example of the paradoxical nature of the new definition is an AMC that operates an off-campus infusion clinic. The clinic is hospital-based and a registered 340B child site of the AMC. However, some of the orders for infusion drugs originate from non-hospital-based clinics located in the same facility that are staffed by the AMC's employed physicians. Thus, even though the physicians are employed by the AMC and practice in the same physical building as the AMC's registered infusion clinic, infusion services ordered by these physicians (and provided at the registered 340B clinic under the supervision of the AMC's physicians) would not qualify for 340B pricing. Further, even if the ordering physician was at a registered site, the guidance is not clear on the frequency with which the "covered entity provider-to-patient encounter"[9] would need to occur to deem the infusion as an eligible service.

  Installing the necessary technology to ensure compliance with this new requirement will also pose challenges for covered entities. Current systems do not distinguish whether an order for an outpatient was written on premises versus outside.

  Infusions are highly complex services that require careful attention and skilled clinical care. **Administration of infusion drugs should not be treated in the same manner as**

[9] 80 Fed. Reg. 52307

dispensing of a drug and should not be excluded from 340B pricing as the guidance proposes.

Eligibility of Off-Site Outpatient Facilities

The proposed guidance would require covered entities to demonstrate that off-site facilities are included on the hospital's Medicare cost report – consistent with current guidance – but also to demonstrate that "services provided at the facility or clinic have associated Medicare costs and charges" before they can be successfully registered as child sites.[10] We note that this additional requirement may inadvertently disqualify certain settings such as free clinics, pediatric clinics, and obstetrics and gynecology clinics.

Additionally, the AAMC appreciates HRSA's attention to identifying alternative mechanisms for demonstrating eligibility of child sites. Currently, covered entities that wish to enroll new clinics into the 340B program endure a substantial time lag before they can do so, waiting as long as 18 months for the site to appear on the covered entity's cost report. One potential way to expedite this process is for HRSA to allow greater flexibility by reaching beyond the cost report as the sole source for demonstrating eligibility of the site. For example, if HRSA does not believe that form CMS 855A, Medicare Enrollment Application for Institutional Providers, is sufficient on its own, perhaps an alternative could be to combine the form with a requirement that the covered entity demonstrate that costs and revenue are attributed to the hospital. As another alternative, in the interim period between the clinic becoming a hospital outpatient clinic and its appearance on a hospital's cost report, the hospital can attest that the clinic is licensed under the hospital's provider number and will appear on the cost report as expeditiously as possible.

Covered Outpatient Drugs

The AAMC supports the ability of covered entities to use 340B for all Medicaid drugs regardless of whether the drugs are bundled into payment made for other services. We oppose the proposal in the guidance to exclude from 340B pricing outpatient drugs that are reimbursed as part of a bundled Medicaid payment. We also note that additional clarity is needed to better understand how HRSA intends to apply the proposed change. For example, one reading of the preamble is that HRSA intends the exclusion to apply solely to bundled Medicaid drugs administered to Medicaid patients for whom the covered entity is actually reimbursed on a bundled basis. This interpretation, though arguably narrower than other alternatives, will pose challenges for covered entities. However, other readings of the proposed guidance would likely yield even more extensive consequences for covered entities. Without clarification, it is difficult for AAMC to comment meaningfully on the proposal. Similarly, it is not clear whether HRSA intends for the drug to be 340B ineligible only when included in a prospectively set packaged price, or if drugs included in retrospective bundled payment arrangements would be subsequently disqualified from 340B pricing. AMCs participating in Medicaid payment reforms often do not know whether a patient has triggered a bundled payment at the time of service, and their affiliated pharmacies rarely know at the time a drug is dispensed, making compliance with this type of retrospective exclusion a challenge.

[10] 80 Fed. Reg. 52317

As mentioned earlier, the AAMC strongly encourages HRSA to revise and repost the guidance for public comment before finalizing the policy, and this provision is a prime example of the need for such an opportunity. Operationalizing this requirement in its narrowest form would require hospitals to implement continuous monitoring systems to determine Medicaid reimbursement policies for each state and limit 340B purchases accordingly. Such 340B tracking technologies may not currently be available. Further, the proposal runs counter to trends in the health care system to increasingly promote new payment and delivery system reforms, including bundled payments.

Additional Concerns

The AAMC shares the views of the broader hospital community with respect to a number of additional record-keeping, manufacturer, program integrity, and other requirements in the proposed guidance. Some of these concerns are described briefly below, and we commend to your attention the comments of the American Hospital Association, where hospitals' views are articulated in greater detail.

- *Medicaid Managed Care* – The AAMC appreciates that the proposed guidance permits covered entities to make individual carve-in/carve-out decisions by site and for Medicaid fee-for-service (FFS) and Medicaid managed care organizations (MCOs). However, the guidance effectively leaves covered entities subject to changes imposed by the states and Medicaid MCOs, while holding covered entities responsible for preventing duplicate discounts. Also, additional guidance would be welcome on HRSA's expectations for the required written agreements with state Medicaid agencies/MCOs and contract pharmacies that will dispense drugs to Medicaid FFS or MCO patients.

- *Contract Pharmacy Arrangements* – The AAMC notes that the provisions requiring covered entities to conduct an annual audit and quarterly reviews of each contract pharmacy *location*, rather than each *arrangement*, will add substantial burden to program participation without adding substantial value, since sites under the same agreement typically employ the same centrally located software and processes.

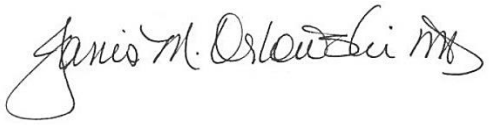
- *Materiality* – The AAMC encourages HRSA to maintain current policy requiring covered entities to report "material" noncompliance to the agency, rather than the guidance's proposal that covered entities report all violations, including the most inconsequential. We note that by expanding self-disclosure requirements to even the most minor breaches, HRSA may be forced to expend limited staff time and resources to a high volume of harmless violations rather than more serious noncompliance.

- *Group Purchasing Organizations and Systemic Errors* – While we appreciate the Group Purchasing Organization (GPO) exceptions outlined in the proposed guidance, the AAMC also seeks clarity on the characteristics of a "systemic violation" of the GPO prohibition.

- *Inventory Management* – The AAMC encourages HRSA to clarify that improper accumulations that are corrected before a replacement order is placed do not constitute diversion. The preamble suggests that an improper accumulation, "even if it is prior to placing an order,"[11] would constitute the sale or transfer of drugs to someone who is not a patient.

Again, the AAMC appreciates the opportunity to provide these comments on HRSA's proposed guidance. We look forward to working with you toward our mutual objective of strengthening the 340B Drug Pricing Program such that its participants can continue advancing the valuable goals of the program.

Sincerely,



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[11] 80 Fed. Reg. 52308