NAUH
NATIONAL ASSOCIATION OF URBAN HOSPITALS

October 26, 2015

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

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

Dear Ms. Pedley:

I am writing on behalf of the National Association of Urban Hospitals (NAUH) to convey our views on the draft "340B Drug Pricing Program Omnibus Guidance" issued by the Health Resources and Services Administration (HRSA) and published in the *Federal Register* on August 28, 2015 (volume 80, number 167).

Specifically, NAUH is concerned about a number of aspects of the proposed guidance:

1. The exclusion of drugs prescribed for hospital patients upon discharge.
2. The exclusion of drugs prescribed by physicians who are not employed by or independent contractors of hospitals.
3. The exclusion of infusion drugs.
4. The qualification of drug purchases for 340B discounts on a prescription-by-prescription rather than a patient-by-patient basis
5. The requirement that eligible entities requalify annually to participate in the program.
6. The revised approach to qualification for the program based on hospital contracts with local government entities to serve low-income patients.
7. Record-keeping and Medicaid managed care .

We address these issues individually below.

The Exclusion of Drugs Prescribed for Hospital Patients Upon Discharge

NAUH objects to the exclusion for 340B eligibility of drugs prescribed for patients upon their discharge from the hospital. The drugs qualified patients are given when they leave the hospital will be used at home as outpatients and not in the hospital and are the same drugs those patients would be prescribed if they went to their doctor the very next day.

More important, these are the very patients who most need to be handed such medicine when they leave the hospital. The low-income patients for whom the 340B program was created, the very patients whom

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private, non-profit urban safety-net hospitals serve in such significant numbers, often lack the means to pay for their prescriptions – and even, in many cases, the ability to get to a drug store to purchase those prescriptions. For financial reasons, moreover, many may have to choose between filling prescriptions and buying food or paying their rent. The best way to ensure that these patients get the medicine they need to recover from their illnesses or injuries is to put the medicine in their hands when they walk out the hospital door.

In addition, at a time when hospitals are being held accountable, to an unprecedented degree, for their ability to prevent the avoidable readmission of recently discharged patients, this guidance would take away from them one of the most important tools they have in their fight to prevent such readmissions: the ability to ensure that these patients – among the most challenging they serve – have the medicine they need to facilitate their return to good health. The 340B program was created to help hospitals serve their patients more effectively, government is demanding that hospitals keep their recently discharged patients out of the hospital and penalizing them when they fail, and NAUH believes that making the prescription drugs hospitals dispense to their patients upon discharge ineligible for 340B benefits would be counterproductive and even damaging. Hospitals are paying for these drugs and they are dispensing them to patients who meet the 340B criteria, so we believe hospitals therefore should be eligible for 340B discounts for the purchase of drugs for these patients except in cases in which those drugs are part of an all-encompassing rate for a bundle of condition-specific services. We urge HRSA to reconsider this interpretation of the 340B enabling legislation.

The Exclusion of Drugs Prescribed by Physicians Who are Not Employed By or Independent Contractors of Hospitals

NAUH objects to the exclusion from eligibility for 340B discounts for drugs prescribed by physicians who are neither employed by nor independent contractors of hospitals. While hospitals throughout the country are employing physicians and purchasing physician practices in growing numbers, much of the care provided in hospitals and hospital-affiliated facilities eligible for the 340B program is now, and will continue to be, provided by physicians in private practice.

Hospital rely heavily on community physicians – and few hospitals rely on them as much as non-profit hospitals in urban areas. Because these hospitals serve so many low-income, Medicaid, and uninsured patients, it is difficult for them to attract and retain physicians for their own staffs and often difficult for physicians to establish practices in such communities. 88 percent of hospitals employ fewer than half of their physicians while a little more than one-third employ fewer than 20 percent of their physicians. Consequently, when independent physicians are willing to establish practices in our communities, we must take advantage of the services they offer – regardless of their employment status. This is particularly true of medical specialists, who are especially hard to find in such communities. Urban safety-net hospitals need the flexibility to refer their patients to the medical specialists those patients need, and when the pool of those specialists is as small as it is in many of the communities we serve, we must refer them to such specialists regardless of their employment status. In addition, there are places like California where it is against the law for private hospitals to employ physicians.

NAUH believes this exclusion would work to the detriment of low-income patients, the very people these mission-driven providers serve in such great numbers. Qualified hospitals purchase these drugs for these patients – and they are very much the hospitals' patients regardless of the employment status of their doctors – and we urge HRSA to reconsider its proposed guidance that drugs prescribed by physicians who neither work for nor are independent contractors of hospitals be ineligible for 340B status.

The Exclusion of Infusion Drugs

NAUH similarly objects to the exclusion of some drugs, most notably infusion drugs, based on the premise that the program should only serve patients with whom hospitals have a relationship and that if the hospital's only service to such patients is that it provides infusion services, that does not constitute a "relationship."

We disagree: we believe hospitals do, in fact, have relationships with their infusion patients. They are hospitals' patients, and when they are low-income patients who meet the 340B criteria, hospitals are purchasing drugs for those patients and should receive 340B discounts.

The Requirement That Eligible Entities Requalify Annually to Participate in the Program

NAUH believes the proposed requirement that eligible entities requalify annually to participate in the 340B program is similarly burdensome. We believe the current practice, in which hospitals, once certified, remain eligible so long as they continue meet the institutional low-income patient threshold, is sufficient. Requiring annual recertification would be costly and time-consuming and, we believe, would result in the exclusion of very few providers. It would amount to too much time, effort, and cost with far too little benefit, so we urge HRSA to rescind this aspect of the proposed guidance.

The Revised Approach to Qualification for the Program Based on Hospital Contracts With Local Government Entities to Serve Low-Income Patients

Currently, non-profit hospitals may qualify for 340B prescription drug discounts if they have a contract with a state or local government to provide health care services to low-income individuals who are not eligible for Medicare or Medicaid. Providing proof of such contracts has always been sufficient to secure eligibility. The proposed guidance, however, requires two additional steps: that the contract state enforceable expectations of the hospital for the provision of these services and that it be signed by an appropriate state or local official.

If 340B was a new program this might be appropriate but under current circumstances it is not: the program has existed for years and the contracts that obligate qualifying non-profit hospitals to provide such services often have long been in place as well. The change proposed in the published guidance could necessitate the rewriting of thousands of such contracts across the country and result in significant costs and an enormous administrative burden. If HRSA is concerned about individual contracts between specific non-profit hospitals and local or state government it has every right to inquire about those specific contracts and seek clarification or even rewriting, but a blanket requirement for every hospital participating in the program to rewrite every one of its contracts with state and local governments is extreme, burdensome, expensive, and unnecessary. NAUH urges HRSA to reconsider this requirement and, alternatively, perhaps require the terms of all renewal or future contracts to meet more specific and rigorous criteria. Those future criteria, moreover, should clarify that the care hospitals provide under these contracts to qualified patients in non-hospital clinics meets the contractual criteria of direct medical care.

Record-Keeping and Medicaid Managed Care

NAUH supports the proposed guidance's clarification that covered entities may separately decide whether to carve-in or carve-out Medicaid drugs for patients covered by fee-for-service Medicaid and for patients

enrolled in Medicaid managed care plans. We especially support the opportunity to make a separate decision for each managed care organization.

Managed care plans continue to serve a growing portion of Medicaid recipients. As it grows, its adoption has created a host of distinct administrative relationships between providers and payers that vary from state to state and even with individual managed care organizations within states. NAUH believes this clarification will enable covered entities to avoid having to forgo all 340B participation for all Medicaid patients enrolled in managed care plans merely because a relationship with one or more of the those Medicaid managed care plans cannot be structured to sufficiently identify drugs and enable participants to avoid duplicate discounts.

About the National Association of Urban Hospitals

The National Association of Urban Hospitals advocates for adequate recognition and financing of private, non- profit, urban safety-net hospitals that serve America's needy urban communities. These urban safety-net hospitals differ from other hospitals in a number of key ways: they serve communities whose residents are much older and poorer; they are far more reliant on Medicare and Medicaid for revenue; they provide far more uncompensated care; and unlike public safety-net hospitals, they have no statutory entitlement to local or state funds to underwrite their costs. NAUH's role is to ensure that when federal officials make policy decisions, they understand the implications of those decisions for these distinctive urban safety-net hospitals. NAUH pursues its mission through a combination of vigorous, informed advocacy, data-driven positions, and an energetic membership with a clear stake in the outcome of public policy debates.

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NAUH appreciates the opportunity to present these comments about the proposed 340B guidance to HRSA and invites questions about the concerns we have raised.

Sincerely,

Ellen J. Kugler, Esq.