



October 19, 2015

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

RE: 340B Drug Pricing Program Omnibus Guidance

Dear Director Pedley,

On behalf of the Arizona Hospital and Healthcare Association (AzHHA), thank you for the opportunity to comment on the 340B Drug Pricing Program Omnibus Guidance. AzHHA is a statewide association of 71 hospitals, affiliated healthcare systems, and allied healthcare organizations across Arizona. Our members are committed to working collectively to improve the quality of healthcare and the health of all Arizonans. As of August 2015, 15 of our member hospitals are 340B covered entities. According to the HRSA database, three are registered under the sole community hospital (SCH) criteria, six are registered under the critical access hospital (CAH) criteria, and six are registered under the disproportionate share hospital (DSH) criteria. All but two are located in rural areas of the state.

AzHHA strongly supports the 340B program's current intent and purpose. It has enabled eligible hospitals and other covered entities to stretch scarce federal resources to support, expand and improve access to healthcare services in their communities. AzHHA members have used savings derived from the program to:

- Provide financial assistance to patients unable to afford their prescriptions;
- Fund and expand access to medical services, such as obstetrics, oncology and pediatrics;
- Provide clinical pharmacy services relating to chronic disease and medication management;
- Offer free immunizations; and
- Expand community outreach and education programs.

AzHHA appreciates HRSA's effort to clarify ambiguity surrounding the 340B program. Our members work diligently to meet all program requirements, and we believe several aspects of the guidance will facilitate compliance. However, we have concerns that other proposals appear to be without basis or justification. **We are particularly concerned about the proposed change to patient eligibility, which move away from defining an eligible patient in terms of his or her relationship with the hospital.** For example, HRSA's proposal that a prescription must result from a billable outpatient event in order to qualify for 340B drug discount pricing appears to exclude observation and emergency department visits when they lead to an inpatient admission. Hospitals would also be prohibited from prescribing 340B discounted drugs to inpatients at discharge. In addition, patients receiving only infusion services would not be eligible for 340B drug discounts. These proposals would significantly reduce the volume of drugs eligible for 340B drug discount pricing at Arizona hospitals, jeopardizing our member hospitals ability to serve the most disadvantaged patients in their communities, including low-income patients, uninsured patients, and patients receiving cancer treatments. We offer the following comments on the proposed omnibus guidance.

DEFINITION OF ELIGIBLE PATIENT

Healthcare Professional Eligibility

The guidance would replace the criteria that an "individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity" with the criteria that the "individual receives a health care service provided by a covered entity provider who is either employed by the covered entity or who is an independent contractor of the covered entity, such that the covered entity *may bill for services on behalf of the provider*" (emphasis added). The guidance stipulates that having privileges or credentials at a covered entity is not sufficient to create the required covered entity-patient relationship. Specifically, a covered entity's ability to utilize 340B drugs would be restricted to services provided by employed or contracted physicians for whom the covered entity "may bill."

It is unclear to us what the intent of such a billing requirement is, and whether the covered entity must actually bill as a condition precedent based on HRSA's use of the term "may bill." Arizona hospitals and health systems utilize a variety of physician arrangements for care delivery. While some are moving to an employed physician model and others have a contractual arrangement under which they bill for services on behalf of their practitioners, most do not. In rural Arizona, for example, many critical access hospitals bill for physician services under method II, but this is not a universal practice. Rural sole community hospitals and hospitals operating in metropolitan areas often employ a mixed medical staff model that may include individual community physicians, contracted group practices, and physicians directly employed by the hospital or

employed by a health system that operates the hospital. If HRSA intends to require a covered entity to meet a billing requirement for an eligible prescriber, this could prevent contracted physician groups from being considered eligible, even though they work exclusively in a hospital's outpatient department under contract, if such groups bill and collect their own professional fees. In addition, physicians who are employed by a healthcare system that operates a covered entity may likewise be considered ineligible prescribers because the covered entity is not the employer.

AzHHA recommends that HRSA remove from the proposed patient definition the requirement that a patient receive health care services from a provider who is either an employee or independent contractor of a hospital, such that the hospital *may bill for services on their behalf*. The proposed change is a concerning departure from HRSA's current guidance. Moreover, it does not reflect the many types of relationships hospitals have with their physicians, and it overlooks today's complex health care environment.

Billable Outpatient Event

The proposed guidance would limit 340B pricing to drugs ordered or prescribed to the patient when the patient has an outpatient billable event. Under this proposal, it appears that inpatients discharged from hospitals with prescriptions would not qualify as 340B eligible patients for purposes of getting their prescriptions filled. This runs counter to current guidance, which allows 340B drug pricing to apply to discharge prescriptions when the drugs are for outpatient use and the hospital maintains appropriate documentation. Many 340B hospitals across Arizona have relied on this guidance to create programs to reduce avoidable readmissions for low-income patients.

In addition, the proposed guidance suggests that patients receiving treatment in outpatient observation or the emergency department that leads to an inpatient admission would no longer qualify as an eligible patient, even if that patient receives drugs while in the outpatient setting. In the case of a Medicare patient, the program's 72-hour billing rule requires that all diagnostic or outpatient services furnished to a Medicare patient in the three days prior to an inpatient admission be bundled in the inpatient bill for reimbursement. In these instances, hospitals routinely document, in the medical record, whether a drug was administered in the outpatient or inpatient setting.

AzHHA strongly opposes tying 340B pricing to an outpatient *billable* event and believes that all outpatient drugs should be considered for purposes of the 340B program, regardless of how these drugs or their associated services are billed or reimbursed. Rather than making these exclusions, we recommend that HRSA utilize current documentation mechanisms to ensure that 340B drug discount pricing applies only to drugs that are for outpatient use.

Infusion Services

The proposed guidance also stipulates that a patient will not be considered eligible for 340B pricing if “the only health care received by the individual from the covered entity is the infusion of a drug...” Infusion services are rarely provided in isolation of other services. A hospital that oversees an infusion clinic assumes legal and clinical responsibility for the patient. Nursing and monitoring services must be provided under state and federal law. We are extremely concerned that this proposal is offered without explanation or justification. When coupled with the proposed physician eligibility requirements it has the potential for shuttering oncology services in some parts of rural Arizona. These services have allowed patients to receive treatment closer to home, eliminating hours of travel time to and from metropolitan areas. Infusion centers in Arizona also provide treatment to many seasonal visitors whose continuity of care could be disrupted by this proposal.

It is clear to us that patients receiving infusion services at a hospital or hospital-based outpatient clinic are patients of the hospital and, therefore, should be defined as eligible 340B patients. **We recommend this proposal be withdrawn so patients receiving infusion services provided at 340B hospitals or their outpatient sites continue to qualify for 340B drug discount pricing.**

HOSPITAL ELIGIBILITY

Under existing guidance private hospitals that qualify for the 340B program under the disproportionate share hospital criteria must have a contract with a state or local government to provide healthcare services to low income individuals not entitled to Medicare or Medicaid. The proposed guidance stipulates that these contracts “should create *enforceable expectations* for the hospital for the provision of health care services, including the provision of direct medical care.” (Emphasis added.) **We seek clarification from HRSA on the criteria the agency would use to determine an “enforceable expectation.”**

OTHER ISSUES

We support many of the other proposals included in the guidance, particularly those related to program integrity for drug manufacturers. Exceptions added to the group purchasing organization prohibition seem reasonable to us. We have queried members about the proposals related to contract pharmacy arrangements. Some report they are no longer utilizing contract pharmacies due to the administrative burden. Others report that the additional burden required by the proposed audits and quarterly reviews will necessitate their reconsideration of these arrangements. **We urge HRSA to**

reconsider the administrative burden associated with the proposed guidance on contract pharmacy arrangements.

Finally, in the proposed guidance, HRSA does not reference an effective date. **We recommend that HRSA establish an effective date for the guidance that is no less than 12 months after the date the final guidance is published in the Federal Register.** This will enable hospitals time to develop new policies and procedures and implement information technology changes that are necessary to comply with the guidance.

Thank you for the opportunity to comment on the proposed guidance. Please feel free to contact me if you have any questions.

Sincerely,

A handwritten signature in blue ink that reads "Debbie Johnston". The signature is written in a cursive, flowing style.

Debbie Johnston
Senior Vice President, Policy Development
Arizona Hospital and Healthcare Association