Maryland
Hospital Association

October 27, 2015

Krista Pedley, PharmD, MS
Captain, USPHS
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, Mail Stop 08W05A
Rockville, MD 20857
Sent Via Email

RE: 340B Drug Pricing Program Omnibus Guidance – HRSA RIN 0906-AB08, (Vol. 80, No. 167, August 28, 2015)

Dear Captain Pedley:

On behalf of the Maryland Hospital Association's (MHA) member hospitals and health systems that are covered entities under the 340B drug pricing program, we appreciate the opportunity to comment on the Health Resources and Services Administration's (HRSA) proposed omnibus guidance. Maryland's hospitals are committed to the mission of the 340B program: providing and improving access to quality care for our state's most vulnerable populations. Our hospitals are especially engaged in this endeavor under the state's new waiver agreement with the Center for Medicare and Medicaid Innovation (CMMI).

While we appreciate HRSA's efforts to clarify aspects of the 340B program, we are concerned that certain provisions of the proposal redefine the program's scope in a manner that essentially narrows the program and the access to care it provides. Further, our hospitals' fixed budgets, set through the CMMI agreement, have not accounted for such a significant change. These provisions, therefore, will significantly burden our hospitals and jeopardize their ability to serve the most disadvantaged patients in our communities.

General Comments

Additional eligibility provisions: The addition of new factors to determine whether an individual is a covered patient removes the focus of the program from the patient, since they require that hospitals review the patient's eligibility based on each drug prescribed. This new eligibility test requires that hospitals develop methods to track this eligibility, and to ensure that the prescription dispensed is credited properly to a 340B patient. Making these provisions operational will require additional time, effort, and resources that are an unplanned burden under the state's fixed global budget system.

New limitations: The proposal also contains new limitations that will severely hinder our hospitals' ability to continue treating our most vulnerable populations.

6820 Deerpath Road, Elkridge, MD 21075 ▪ 410-379-6200 ▪ www.mhaonline.org

First, HRSA proposes under the per-prescription definition that a 340B qualifying prescription must be the result of a billable outpatient event. This new definition seems to exclude those outpatient visits, such as observation or emergency department visits, that lead to an admission. Following this logic, drugs prescribed upon discharge, and therefore utilized in the same settings as other outpatient drugs, will not qualify for 340B pricing. This distinction is arbitrary, yet will significantly impact the patients our hospitals serve. **We believe that all outpatient drugs should be covered under the 340B program, regardless of the method by which the related services are reimbursed.**

Second, the proposal deems ineligible for 340B discounts those patients receiving only infusion services. Since infusion therapies are almost always provided with other services, many of which are mandated by the state or by Medicare, a hospital administering infusion services has significant responsibility for the patient. Singling out those instances where such patients receive only infusion services as ineligible for 340B discounts is haphazard and arbitrary, as these patients are clearly patients of the hospital. **These limitations would have a devastating effect.**

Further, these proposals are a departure from current HRSA guidance, which allows the 340B drug discount to apply to both patients receiving infusion-only services and to inpatient patients for their discharge prescriptions. Our hospitals have operated under this guidance, and the new payment system is built on this premise. **Our hospitals therefore cannot account for this seismic shift in the program.**

We urge that HRSA amend these proposals to ensure that the revisions are truly clarifying in nature, and allow our hospitals to continue providing the care that our patients need.

Conclusion

Thank you again for the opportunity to comment, and for your consideration of the impact the proposed provisions will have on the unique status of Maryland's all-payer rate setting model with a fixed global budget. Unlike other states, Maryland's hospitals do not balance bill commercial carriers to make up for any loss of funds. As a practical matter, then, the impact of narrowing the 340B program will be particularly harmful for our hospitals and the patients they serve.

Sincerely,

Nora E. Hoban
Senior Vice President