



October 27, 2015

Krista Pedley, Pharm.D., M.S.
CDR, USPHS
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

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

Submitted electronically via www.regulations.gov

Dear Commander Pedley:

ASHP is pleased to submit comments to the Health Resources and Services Administration's (HRSA) *340B Drug Pricing Program Omnibus Guidance* (draft guidance) published in the Federal Register on August 28, 2015.¹ ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's more than 40,000 members include pharmacists, student pharmacists and pharmacy technicians. For over 70 years, ASHP has been on the forefront of efforts to improve medication use and enhance patient safety.

ASHP has a longstanding history of support for the 340B drug discount program, as many of our members practice in hospitals and health-systems that are 340B eligible and have seen firsthand, the benefits of the program to the patients they serve.. At a time when federal budgets are stretched thin, the 340B program helps maximize federal resources while providing access to life saving medications. Further, the program helps safety net hospitals maintain financial viability which is especially critical for those facilities in rural and underserved areas.

The handling and administration of drugs has changed significantly over the past two decades, and HRSA has issued a number of program guidances and regulations to assist covered entities (CE) and manufacturers in staying current with compliance under the 340B statute. ASHP appreciates the efforts of the agency to issue a single omnibus guidance that is intended to provide additional clarity to participants in the program. However, we are concerned that certain aspects of the draft guidance will reduce access to patient care services currently supported as a result of the program, thereby undermining the purpose of the law which was to "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."²

DEFINITION OF PATIENT

ASHP is concerned that the draft guidance could significantly reduce who qualifies as an eligible patient. Under the draft guidance, an individual is considered a patient "on a prescription-by-prescription or

¹ Federal Register, Volume 80, No. 167. Pages 523 – 52324

² H.R. Rep. No.102-384(II), at 12 (1992).

order-by-order basis” (with the exception of state-operated or funded ADAPs) when the following conditions are met:

1. The individual receives a health care service at a facility or clinic site which is registered for the 340B Program and listed on the public 340B database.
2. The individual receives a health care service provided by a CE provider who is either employed by the CE or who is an independent contractor for the CE, such that the CE may bill for services on behalf of the provider.
3. An individual receives a drug that is ordered or prescribed by the CE provider as a result of the service described in (2).
4. The individual’s health care is consistent with scope of the federal grant, project, designation, or contract.
5. The individual’s drug is ordered or prescribed pursuant to a health care service that is classified as outpatient.
6. The individual’s patient records are accessible to the CE and demonstrate that the CE is responsible for care.

Discharge Prescriptions.

In the proposed changes to the definition of a patient under 340B Program, HRSA states that drugs must be “ordered or prescribed pursuant to a health care service that is classified as outpatient” in order to be considered eligible outpatient drugs. While ASHP does not disagree that the program has always been limited to “covered outpatient drugs,” this new condition has an unintended consequence that will be detrimental to patients. Historically, both in practice and in previous HRSA guidance, prescriptions provided at discharge from an inpatient stay for a patient to take at home were considered “covered outpatient drugs. This shift in policy would prohibit hospitals from using 340B pricing for drugs that are billed as outpatient drugs if they are written or filled upon discharge from an inpatient stay. Using 340B for discharge prescriptions is a longstanding practice that increases medication adherence, reduces readmissions, and ensures that low-income patients can get the drugs they require.

In fact, CMS and The Joint Commission have long recognized the importance that medication adherence has in promoting optimal patient outcomes and includes it their “Core Measures” for success. Many hospitals have instituted a discharge prescription program to ensure patients leave the hospital with all of their needed medications. The draft guidance would effectively penalize 340B hospitals for developing programs that a significant impact on readmissions to the hospital - a significant cost for healthcare as a whole.

- ❖ ***ASHP strongly urges HRSA to clarify that prescriptions provided upon discharge from a hospital stay are considered outpatient drugs and therefore eligible for purchase at their 340B price.***

Infusion Orders

Another area of concern to ASHP is the effect that the definition of an eligible patient will have on the ability to provide infusion services for vulnerable populations. In the section of the definition that states

that “an individual receives a drug that is ordered or prescribed by the CE provider as a result of the service described in (2),” HRSA specifically address infusion services. The agency states that:

An individual would not be considered a patient of a CE whose only relationship to the individual is the dispensing or infusion of a drug. The dispensing of or infusion of a drug alone, without a provider-to-patient encounter, does not qualify an individual as a patient for purposes of the 340B program.

While ASHP agrees that simply dispensing a drug to an individual does not meet the proposed definition of a patient, we disagree that receiving an infusion is the same as receiving a prescription. The administration of infusion drugs is a highly complex service that requires specialized training and education and direct patient-provider interaction. The failure to administer infusion drugs correctly may result in severe consequences for the patient. These patients are infused the same as if infusion orders were written at the hospital. In rural areas, a 340B hospital or child site may be the only infusion provider within a reasonable service area. Further, some providers may choose to not provide infusions to low-income patients in their offices and refer them to the local hospital with infusion facilities.

- ❖ ***ASHP strongly recommends that HRSA reconsider their definition as it relates to infusion services and clarify that simply dispensing a drug does not qualify an individual as a patient under the 340B program.***

ASHP cannot identify a proposed effective date in the draft guidance. We believe that covered entities will need sufficient time to make both policy level changes and changes to health information technology systems. Therefore, ASHP recommends that HRSA set an effective date of the 340B omnibus guidance at no less than 12 months after the date the final guidance is published in the Federal Register.

ASHP appreciates the opportunity to comment on HRSA’s draft omnibus guidance on the 340B program. Please contact me if you have any questions or wish to discuss our comments further. I can be reached by telephone at 301-664-8806, or by e-mail at ctopoleski@ashp.org.

Sincerely,



Christopher J. Topoleski

Director, Federal Regulatory Affairs.