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March 13, 2007

Mr. Bradford R. Lang  
Public Health Analyst  
Office of Pharmacy Affairs  
Healthcare Systems Bureau  
Health Resources and Services Administration  
5600 Fishers Lane  
Parklawn Building, Room 10C-03  
Rockville, MD 20857

**Re: Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services;  
Notice Regarding Section 602 of the Veterans Health Care Act of 1992  
Definition of “Patient.”**

Dear Mr. Lang:

The American Society of Health-System Pharmacists (ASHP) is pleased to respond to the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) January 12, 2007 Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services and the Notice Regarding Section 602 of the Veterans Health Care Act of 1997 Definition of “Patient.” ASHP is the 30,000-member national professional and scientific association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term-care facilities, and other components of health systems. ASHP members practice in hospitals and integrated health systems where they are involved in many phases of the medication-use process, promoting public health by fostering safe and effective use of medicines in hospitals and health systems.

ASHP is pleased that the Office of Pharmacy Affairs (OPA) has published proposed clarifications and guidelines pertaining to contract pharmacy services and the definition of “patient” for purposes of the 340B program, and supports the expansion of contract pharmacy services to allow covered entities to utilize multiple contract pharmacy service sites. The Society does, however, have some concerns regarding the savings realized from an entity’s participation in the 340B program, and ensuring these savings remain with the entity under the contract pharmacy arrangement, which is consistent with the intent of the program. Furthermore, ASHP agrees with OPA that annual audits should no longer be required to be provided to OPA under the contract pharmacy arrangement, but the Society encourages OPA to maintain an auditing requirement to ensure the integrity of the program and the contract pharmacy arrangement. ASHP also recommends that OPA require that pharmacy records from contract pharmacies be readily available to participating entities, to ensure patient safety and continuity of care.

Additionally, ASHP sees the need for clarifications to the definition of “patient” for whom the covered entity can purchase discounted pharmaceuticals under the 340B Program. However, ASHP has some concerns regarding the extent of the clarifications, and their impact on the hospital pharmacists’ ability to fill prescriptions using 340B-priced drugs. The Society recommends that OPA provide further clarification that would allow a discharge prescription to be filled with a 340B drug. ASHP is also concerned that OPA’s proposed definition of a patient will be difficult, if not impossible, for pharmacists to apply.

### **Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services**

- Savings realized from participation in 340B Drug Pricing Program - ASHP supports OPA’s expansion of contract pharmacy services to allow covered entities to utilize multiple contract pharmacy service sites. However, ASHP is concerned that 340B Program integrity be maintained during the contracting process, and that savings realized from participation in the program stay with the covered entity to help subsidize prescriptions, increase the number of patients whom the entity can subsidize, and expand services and formularies.

In order to maintain the integrity of the 340B program, ASHP recommends that OPA include in its final guidelines, and in its suggested contract provisions, language to reinforce the requirement that all savings from the program should remain with the covered entity. While the Society understands and recognizes the contracting pharmacy performs services for the covered entity, and should be compensated fairly for these services, ASHP is concerned that, without written guidance, all of the savings from the program will not be returned to the covered entity.

- Annual audits no longer required - Since, to date, there has been no evidence of drug diversion or duplicate manufacturer’s discounts on 340B drugs in the Alternative Methods Demonstration projects (AMDPs) program, ASHP agrees with OPA that annual audits should no longer be required to be provided to OPA. ASHP also supports OPA requirements that covered entities maintain fully auditable records. However, ASHP believes the language in the proposed guidelines should be clarified to require covered entities to include appropriate sampling of multiple contract pharmacy arrangements in the course of routine annual audits, applicable and achievable in all settings. ASHP also encourages OPA to provide an example of how a hospital’s existing annual financial audit process could incorporate a sampling of multiple contract pharmacy arrangements. Additionally, in the Appendix containing suggested contract provisions, the Society believes that OPA should provide suggested contract language explicitly stating that the contract pharmacy must provide appropriate sampling to the covered entity to ensure compliance with the audit requirement.
- Continuity of Care - ASHP recognizes that allowing multiple contract pharmacy arrangements provides increased access to 340B-priced drugs to patients. This accessibility benefits both the patient and the covered entity. However, ASHP

recommends that OPA include in its final guidelines a requirement that entities provide for continuity of care by ensuring pharmacy records from each pharmacy that contracts with a covered single entity are readily available to that covered participating entity, thus ensuring patient safety.

### **Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of “Patient”**

- 340B drugs prescribed in conjunction with outpatient services - ASHP supports OPA’s clarification of the definition of patient for 340B program purposes; however ASHP has some concerns regarding discharge prescriptions. According to the guidelines, the third criterion of the patient definition requires that 340B drugs be prescribed only in conjunction with outpatient services. Under this interpretation of the requirement, a patient who is discharged from the hospital with a prescription may not have his prescription filled with a 340B drug unless he obtains separate outpatient services and obtains another, duplicate prescription. Furthermore, as the proposed guidelines are written, even a patient who had a health care relationship with the covered entity on an outpatient basis prior to being admitted to the hospital would be prohibited from filling his discharge prescription with a 340B drug.

ASHP does not believe OPA intended the guidelines to have such an effect. We urge OPA to amend its proposed guidelines, allowing discharge prescriptions to be filled with 340B drugs.

- Undue burden – ASHP is concerned that OPA’s proposed definition of a patient will be difficult for pharmacists to apply, and will constitute an undue burden to hospital pharmacy practice. Under this definition, OPA requires the dispensing pharmacist to know the prescriber’s relationship to the hospital, whether the services arise from the hospital or a provider-based site of the hospital, and the ownership status of the medical records. Additionally, under the proposed guidelines, to demonstrate the necessary retention of ongoing responsibility for the health care, the covered entity is required to provide health care to the individual at the hospital or provider-based facility within 12 months after the time of referral. This requirement is not one that the dispensing pharmacist can meet or enforce.

ASHP urges OPA to recognize that pharmacists do not have the time or the resources to gather the information required under the proposed guidelines relating to patient definition. Furthermore, if the dispensing pharmacist takes the time to determine the required information, the time allocated to ensuring compliance with 340B patient definition requirements will be diverted from patient counseling and other tasks necessary to ensure patient safety and safe medication use.

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ASHP appreciates this opportunity to present its comments on the 340B Drug Pricing Program contract pharmacy services and definition of “patient” guidelines to OPA. ASHP and its members are interested in working with OPA to find resolutions to our concerns, particularly regarding the “undue burden” issue. The Society would also like to extend its continued support of the program and interest in making it successful and enduring. Feel free to contact Justine Coffey, Director of Federal Regulatory Affairs if you have any questions regarding our comments. She can be reached by telephone at 301-664-8702, or by e-mail at [jcoffey@ashp.org](mailto:jcoffey@ashp.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Brian M. Meyer". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Brian M. Meyer  
Director, Government Affairs Division