



SNHPA

Safety Net Hospitals for Pharmaceutical Access

March 13, 2007

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

Re: Comment on Proposed Guidelines on 340B Drug Pricing Program-
Contract Pharmacy Services (Published in 72 Fed. Reg 1540-1543
(January 12, 2007))

Dear Mr. Lang:

Safety Net Hospitals for Pharmaceutical Access (SNHPA), on behalf of its approximately 400 public and private non-profit disproportionate share hospitals (DSH hospitals), appreciates this opportunity to comment on the Health Resources and Services Administration's (HRSA) proposed changes to the contract pharmacy services guidelines of the 340B drug discount program.¹ Our comments reflect SNHPA's strong and sustained support of the proposed guidelines regarding multiple contract pharmacies. Our comments will additionally focus on the following issues:

- clarification of two provisions of the model agreement;
- recommendation that HRSA allow separate covered entity sites to enter into a master agreement between the sites and a contract pharmacy;
- recommendation that HRSA allow a covered entity to enter into a master agreement between itself and a chain pharmacy, binding on different locations of that chain pharmacy; and,
- recommendation that HRSA not require project-specific approval when establishing 340B network model arrangements.

SNHPA and its member hospitals urge HRSA to adopt the proposed multiple contract pharmacy guidelines. By adopting the guidelines, HRSA will expand access to 340B-discounted drugs to greater numbers of our nation's most medically vulnerable and indigent patients.

¹ Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 72 Fed. Reg. 1540-43 (Jan. 12, 2007).

I. BACKGROUND

In 1996, HRSA published guidelines that permit covered entities to use contract pharmacies to dispense 340B-discounted drugs.² Covered entities enter into a “ship to, bill to” relationship with the contract pharmacy, which enables all covered entities, even those lacking in-house pharmacies, to take advantage of the 340B program.

Current guidelines restrict the use of contract pharmacy arrangements by prohibiting covered entities from contracting with more than one pharmacy. Accordingly, each site of a covered entity currently is entitled to distribute 340B discounted drugs either from an in-house pharmacy or contract pharmacy, but not both.

HRSA has limited the number of contract pharmacies to one per entity, largely in response to the pharmaceutical industry’s concerns that such arrangements increase the risk of drug diversion and that manufacturers will be asked to give two discounts on the same drug, often referred to as “duplicate discounts.” Although it is unclear whether the one-pharmacy-per-entity rule actually mitigates the risks that create concern for the drug industry, it is clear that the restrictions have prevented covered entities from achieving the full potential of the contract pharmacy model in expanding access to 340B prescription drugs for covered entity patients. Restrictions on establishing contract pharmacy arrangements have limited patient access to 340B drugs in at least two ways. First, the one-pharmacy-per-entity rule has limited the geographic reach of a covered entity’s 340B program. Second, if a covered entity operates an in-house ambulatory care pharmacy and uses its in-house pharmacy to dispense 340B drugs, the entity is barred from also entering into a contract pharmacy relationship with an outside pharmacy. Both of these limitations have hindered DSH hospitals’ participation in the 340B contract pharmacy program.

In response to the growing frustration in the 340B community with the one-contractor-per-entity rule, HRSA established in 2001 a demonstration program designed to test new uses of the 340B program based on a waiver of existing contract pharmacy restrictions. The long-term goal of testing these new 340B delivery models – called alternative methods demonstration projects (AMDPs) – is to evaluate the possible relaxation and/or repeal of the one-pharmacy-per-entity standard. The AMDP program is also designed to evaluate the effectiveness of the “network model.” The network model allows multiple covered entities to participate in single purchasing and dispensing systems that serve a common patient population. Patients of a covered entity that is networked with other covered entities can fill their 340B prescriptions at any of the pharmacies within that covered entity network. Notably, none of the eighteen HRSA-approved AMDPs has improperly diverted drugs or exposed manufacturers to duplicate discounts.

² Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549-56 (Aug. 23, 1996).

II. THE PROPOSED RULE WOULD EXPAND ACCESS TO 340B DRUGS TO VULNERABLE PATIENTS

SNHPA strongly supports the proposed expansion of the multiple contract pharmacy program to all 340B covered entities. By expanding the program, access to pharmacy services for vulnerable populations will be significantly augmented. For this reason, SNHPA and other 340B provider organizations have advocated changes to the one-contractor-per-entity rule for many years. As evidenced by the success of the AMDPs in expanding access to pharmacy services and in establishing a record of compliance with 340B requirements, HRSA's proposed changes to its contract pharmacy guidelines, which permit a covered entity to contract with multiple pharmacies and to enter into one or more contract pharmacy relationships while maintaining an in-house outpatient pharmacy, will broaden access to drugs by our nation's most needy patients.

Allowing each covered entity to enter into multiple contract pharmacy agreements or to supplement its in-house pharmacy with a contract pharmacy's services will support our member hospitals' mission to treat medically indigent patients. Patients of many covered entities would benefit greatly from expanded access to 340B-discounted drugs through chain drug stores, independent pharmacies and other pharmacy establishments that are located closer to where they reside. DSH hospitals, in particular, would gain from adoption of the multiple contract pharmacy provisions. Disproportionate share hospitals tend to have large service areas. DSH hospitals' patients, therefore, would gain access to 340B-discounted drugs from pharmacies in addition to the hospital's in-house ambulatory care pharmacy, if the DSH runs such a pharmacy. The contract pharmacies that supplement hospitals' in-house pharmacy services could be more conveniently located to serve the hospital's patients, especially those who reside a great distance from the hospital. The hospital's patients would no longer be required to visit the DSH's on-campus pharmacy to fill or refill their prescriptions.

Additionally, these guidelines would allow DSH facilities to use mail-order pharmacies to help expand access to the hospital's 340B pharmacy programs. Mail-order pharmacy services would enhance patient convenience and compliance by bringing maintenance medications directly to the patients' homes. Current guidelines preclude 340B hospitals from providing mail-order services because contracting with a mail-order pharmacy would violate the one-contractor-per-entity rule and few hospitals have the resources to build a mail-order pharmacy in-house. Implementation of the proposed guidelines would mean that, for the first time, DSH hospitals could begin serving their patients through an affordable 340B-based mail-order program.

Because the growth of the 340B program supports the mission of our member hospitals to expand access to affordable prescription drugs by our nation's indigent and medically underserved population, SNHPA strongly supports the proposed guidelines for multiple contract pharmacies. Nonetheless, SNHPA has a few comments and concerns that it would like to share with HRSA. These comments are set forth below.

III. THE “ALL COVERED ENTITIES PARTICIPATING” REQUIREMENT IS UNCLEAR

In order to use contract pharmacies to dispense its 340B drugs, a covered entity must certify to the Office of Pharmacy Affairs (OPA) in HRSA that it has a binding and valid agreement with a contract pharmacy to provide 340B outpatient pharmaceutical services. HRSA has proposed that this certification must include the names and identification numbers of “all covered entities participating” in the multiple pharmacy program.³ SNHPA finds the “all covered entities participating” language to be confusing. This requirement could mean that in cases where a covered entity has multiple sites, the covered entity must name each site in its agreement. Alternatively, this requirement could reference the “network model” AMDP, in which multiple covered entities can participate in a unified purchasing and dispensing system. Finally, it could mean that a DSH hospital must name each covered entity that has a participation agreement with a pharmacy under contract with the hospital, including covered entities that are not associated with the DSH hospital. This third interpretation, if followed, would seem pointless and would create an undue burden on the DSH hospital by forcing it to investigate and identify other covered entities that have contracted with a pharmacy participating in the hospital’s pharmacy network. Moreover, such a requirement would not mitigate any risk of duplicative discounts or drug diversion that this requirement was likely added to address.

SNHPA requests, therefore, that HRSA clarify its requirement that a covered entity include the names and identification numbers of “all covered entities participating” in the covered entity’s certification form. SNHPA furthermore discourages HRSA from requiring covered entities to research and identify which other covered entities, if any, have participation agreements with a particular pharmacy, due to the burden that requirement would put on covered entities.

IV. HRSA SHOULD NOT REQUIRE APPLICATION OF THE NEW MODEL AGREEMENT TO EXISTING CONTRACT ARRANGEMENTS

HRSA included in the proposed guidelines a model agreement with provisions that remain essentially the same as those set out in the original contract pharmacy guidelines in 1996.⁴ One notable change is the removal from the model agreement of language referring to one contract pharmacy per entity. The model agreement from 1996 includes a clause that the contract pharmacy “will provide *all* pharmacy services....The limitation of one pharmacy contractor per entity does not preclude the selection of a pharmacy contractor with multiple pharmacy sites, as long as only one site is used for the contracted services” (emphasis added). The proposed model arrangement replaces the “all pharmacy services” with “comprehensive pharmacy services,” and deletes the “limitation of one pharmacy” language.⁵

³ Certification, 72 Fed. Reg. at 1542.

⁴ Contract Pharmacy Services Revised Final Mechanism, 61 Fed. Reg. at 43555.

⁵ Contract Pharmacy Services Mechanism, 72 Fed. Reg. at 1541.

This modification of the agreement is necessary and understandable. SNHPA, however, requests that HRSA clarify whether a covered entity that currently has an agreement with only one contract pharmacy must revise and renegotiate its agreement with that pharmacy to match the language in the new guidelines, if adopted, when and if the covered entity subsequently enters into agreements with multiple pharmacies. SNHPA further urges HRSA to waive the certification requirement for a covered entity that has a pre-existing agreement between itself and a single contract pharmacy, and that then enters into additional contract pharmacy relationships. SNHPA also requests that HRSA affirm that neither a contract pharmacy nor a covered entity must renegotiate its existing agreement based on this regulatory change.

V. HRSA SHOULD ALLOW MULTIPLE SITES OF A COVERED ENTITY TO ENTER INTO A MASTER AGREEMENT

Consistent with the current contract pharmacy guidance, the proposed guidelines imply that a covered entity must enter into separate contracts between each of its sites and each pharmacy that participates in the covered entity's 340B program. For example, under the proposed guidelines, if one DSH hospital has three separate sites, and each site uses the same contract pharmacies to dispense its 340B drugs, each site may be required to negotiate and contract separately with those pharmacies.

This requirement would be unduly burdensome on the covered entity, and would produce no added benefit. It would not protect against drug diversion or duplicative discounts any more effectively than if the covered entity were allowed to contract on behalf of all of its sites. This requirement only would add paperwork and associated costs to the covered entity.

SNHPA supports HRSA's proposed model provision that "[i]n cases where a covered entity has more than one site, it may choose between having each site billed individually or designating a single covered entity billing address for all 340B drug purchases."⁶ Insofar as HRSA therefore recognizes the improved efficiency when a covered entity with multiple sites may consolidate its *purchasing and billing* of 340B drugs, SNHPA urges HRSA to explicitly permit centralized *contracting* between a covered entity's multiple sites and a contract pharmacy. This would eliminate the requirement that multiple sites of a single covered entity enter into separate written contracts with each pharmacy that participates in the hospital sites' 340B program, and instead require a single master contract between the covered entity on behalf of all of its sites and its contract pharmacy or pharmacies.

VI. HRSA SHOULD ALLOW MASTER AGREEMENTS COVERING MULTIPLE PHARMACY SITES OF THE SAME PHARMACY CHAIN

HRSA's proposed guidelines imply that a covered entity must enter into separate contracts between the covered entity site and each pharmacy location of a chain pharmacy that may participate in the covered entity's 340B program. The proposed

⁶ Model Agreement Provisions, 72 Fed. Reg. at 1541.

guidelines state, “[t]he use of multiple contract pharmacy service sites refers to any arrangement wherein a covered entity site seeks to provide drugs at 340B discounted prices for its patients at more than one pharmacy *location*”⁷ (emphasis added). This reading of the proposed guidelines defines a single contract pharmacy in terms of its separate geographic location, even though each separate location of a given chain pharmacy does not necessarily have a legally severable or distinct status. The proposed guidelines therefore suggest that if a covered entity seeks to contract with a local or national chain pharmacy that is owned and operated by the same corporate parent, that entity must separately negotiate with each of the chain’s pharmacy locations that would dispense the entity’s 340B discounted drugs, even if the agreements would include similar, if not identical, contractual terms.

If a covered entity were required to enter into separate agreements with each location of a chain pharmacy that would dispense its 340B drugs, there would be no added protection against drug diversion or duplicative discounts. This requirement, in fact, could add to the risk that drug diversion or duplicative discounts might occur by requiring covered entities to monitor the contract of more pharmacy sites than the optimal, efficient number. This requirement would produce an extra cost and burden on the covered entity without any perceivable benefit. SNHPA therefore requests that HRSA clarify that a covered entity may enter into a master agreement with a chain pharmacy, and urges HRSA to explicitly state that a covered entity may enter into a master agreement between the covered entity and a pharmacy chain that would be binding on all those chain pharmacy locations that are enumerated in the master agreement.

VII. HRSA SHOULD EXEMPT 340B NETWORK MODEL ARRANGEMENTS FROM AMDP APPROVAL

As mentioned above, HRSA established AMDPs in 2001 to evaluate, in part, the value of the “network model.” The network model allows multiple covered entities and their sites to participate in single purchasing and dispensing systems that serve a common patient population, which accommodates the realities of how health systems work. Patients of a covered entity that is networked with other covered entities can fill their 340B prescriptions at any of the pharmacies within that covered entity network, and the pharmacies share a common inventory for the drugs dispensed to patients of networked covered entities. For example, a federally qualified health center (FQHC) and a DSH hospital can form a network whereby patients from the FQHC can have their prescriptions filled at the hospital’s in-house pharmacy and vice-versa. Because, under current guidelines, covered entities that operate multiple sites may only purchase and use 340B drugs on a site-specific basis, a network model AMDP would also allow multiple-site covered entities to buy and dispense 340B drugs centrally without having to segregate their inventories and use of the discounted drugs by site.

The network model has been successful on two accounts. First, like the multiple contract pharmacy model AMDPs, the network model AMDPs have broadened the

⁷ Contract Pharmacy Services Mechanism, 72 Fed. Reg. at 1541.

geographic reach of each covered entity's 340B program that has networked with another covered entity. Patients are therefore able to access pharmacy services more readily and conveniently. Second, covered entities that are networked have enjoyed economies of scale that a single covered entity could not achieve. In a network model, because the entities' inventories are amalgamated, each covered entity is able to purchase drugs more economically than if it had bought the drugs separately, independent of its network partner. Additionally, the covered entities can eliminate unnecessarily duplicative administrative responsibilities and costs by joining together as a network. For example, combining inventories for each covered entity's patients would save each covered entity in the network the inconvenience and cost of keeping separate inventories. Through the network model, the covered entity saves a significant amount of money, which can then be invested in the direct provision of health care to its patients.

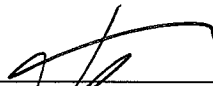
As the success of the AMDPs demonstrates, there is no additional risk of drug diversion or duplicative discounts associated with the network model. As with multiple contract pharmacies, the network model extends access to the 340B program to patients who may live far from a covered entity's in-house or contract pharmacy. Additionally, the model allows covered entities to save money and invest those captured funds in direct care to patients. SNHPA strongly encourages HRSA, therefore, to extend the network model AMDP to all covered entities and allow covered entities to utilize the network model. At a minimum, HRSA should exempt multiple-site covered entities from having to obtain AMDP approval to implement a network model arrangement exclusively involving the covered entity's own multiple sites.

VIII. CONCLUSION

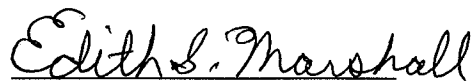
In summary, SNHPA and its member hospitals appreciate the opportunity to voice their strong support for the proposed guidelines that extend the multiple contract pharmacy model previously limited to AMDPs to all covered entities. We further urge HRSA to consider the points above to clarify certain provisions of the new guidelines and to extend the network model AMDP to all covered entities.

If you have any questions about our comments, please contact Edith Marshall or William von Oehsen at 202-872-6753 or 202-872-6765 respectively.

Sincerely,



William H. von Oehsen
President and General Counsel



Edith Marshall
Special Counsel and Director of
Legal Affairs