



# SNHPA

## Safety Net Hospitals for Pharmaceutical Access

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March 13, 2007

### VIA E-MAIL AND FIRST CLASS MAIL

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 Patient Definition (Published in 72 Fed. Reg. 1543-1546 (January 12, 2007))

Dear Mr. Lang:

This letter sets forth comments by Safety Net Hospitals for Pharmaceutical Access (SNHPA) on proposed guidelines published in the Federal Register on January 12, 2007 relating to the definition of "patient" as that term is used in section 340B of the Public Health Service Act. Established in 1993 as the Public Hospital Pharmacy Coalition, SNHPA represents approximately 400 public and private non-profit disproportionate share hospitals (DSH hospitals) that participate in the 340B drug discount program. The 340B statute prohibits the resale or transfer of a discounted drug purchased by a covered entity to a person who is not a "patient" of the entity. How the Health Resources and Services Administration (HRSA) chooses to define "patient" will directly affect both the quantity and kinds of pharmaceuticals that DSH hospitals can purchase through the 340B program which, in turn, will impact the benefit that hospitals and their patients will derive from the program. Accordingly, SNHPA appreciates the opportunity to submit comments on this vitally important issue.

SNHPA understands the importance of assuring compliance with the 340B prohibition against reselling or transferring 340B drugs to individuals who are not covered entity patients, a practice often referred to as "diversion." SNHPA therefore fully supports both HRSA and the Office of Pharmacy Affairs (OPA) in their efforts to protect and enhance the integrity of the 340B program. We also appreciate that further

clarification of the anti-diversion requirement so as to more plainly prohibit use of 340B drugs under arrangements and in business relationships that might abuse the program and its underlying purposes, is an appropriate goal in administering the program.

We nevertheless fear that in understandable zeal to establish more clear boundaries to the concept of a “patient” relationship, HRSA has developed and proposed new guidelines that, if strictly enforced and not substantially revised, will have a number of unintended, negative consequences. Specifically, we believe the proposed new policies would drive some 340B hospitals out of the program altogether and, for others, would obstruct the use of 340B drugs in many legitimate scenarios that are fully consistent with Congressional intent in creating the program. Member DSH hospitals have told us, for example, that, assuming a literal interpretation and implementation of the new guidelines as proposed, they will not receive sufficient benefit from 340B discounts in the future to warrant continued participation in the program. We have also heard from our members that savings from 340B purchases realized by individual hospitals on an annual basis could shrink by millions of dollars (in one case, by as much as \$5 million) if the guidelines are implemented in their present form, and that loss of these savings would seriously undermine the capacity of these hospitals to continue adequately to serve their indigent and uninsured patients.

As we discuss more fully below in regard to particular aspects of the proposed patient definition guidelines, some of what we perceive as deficiencies in the guidelines may merely reflect a need for greater clarity in defining terminology or a simple oversight in considering practical aspects of program administration. Some aspects of the proposed guidelines, however, appear to reflect what we regard as serious misconstructions of the governing statute or attempts to “legislate” changes to the 340B program without sufficient statutory basis. We are hopeful that, upon further reflection and consideration of public comment on the proposed guidelines, HRSA and OPA will choose to rethink and revise many of these provisions.

## **I. GENERAL COMMENTS**

Before proceeding to discuss some of the particular provisions of the proposed guidelines that we find problematic, it may be useful first to identify certain overarching concerns and recurring themes in SNHPA’s reasons for urging extensive revision of the newly proposed patient definition guidelines. These general comments fall into three areas relating to (A) HRSA’s authority to establish certain proposed policies, (B) the ability of DSH hospitals to implement such policies, and (C) the need to accommodate 340B hospitals’ legal mandate to provide safety net services. These comments are described in more detail below.

### **A. SOME OF HRSA’S PROPOSED CHANGES APPEAR TO GO BEYOND INTERPRETATION OF “PATIENT”**

Rather than focusing on the relationship between a covered entity and the individual receiving a drug or drug treatment – which is the essence of the issue as to an

individual's character as a patient – the proposed drug guidelines focus largely on the relationship between covered entities and their records and the relationship between covered entities and the doctors or other medical professionals who furnish care and prescribe medications. While it may be valid to look to certain aspects of covered entity recordkeeping or utilization of medical staff as among a wide range of indicia of whether a given individual is a facility's "patient," almost exclusive focus on recordkeeping and prescriber/caregiver standards in the guidelines tends to divorce them from the very issue they are ostensibly intended to address.

The result is a collection of rules pertaining to recordkeeping practices, staffing policies, and professional arrangements that threaten, through formalistic application, to exclude use of 340B drugs by individuals who are plainly patients of covered entities under any common sense definition. In pronouncing these rules, moreover, certain provisions of the guidelines go far beyond merely interpreting what the governing statute means by the term "patient," and instead would impose restrictions and requirements in the 340B program that have no apparent basis in the law.

#### **B. SEVERAL ASPECTS OF THE NEW GUIDELINES ARE IMPRACTICAL AND TOO COMPLICATED TO IMPLEMENT**

The guidelines make determination of who is or is not a patient too complicated. The number of criteria to be applied in making such a determination has been increased from three under previous guidelines to eight under the new guidelines. This additional complexity promises to be particularly problematic for pharmacists at the counter of outpatient pharmacies operated by or under contract with 340B covered entities, who will be required to make on-the-spot decisions about whether to dispense 340B drugs to individuals whose status as "patients" hinges on application of multiple criteria and information that may not be readily accessible to the pharmacists. Assuming implementation of the proposed guidelines, a hospital's pharmacist presented with a prescription and faced with making a decision as to whether to fill the prescription with 340B drugs would need to know the prescriber's relationship to the hospital, whether the hospital maintains records that document the services and illness/condition resulting in the prescription, whether the services were rendered at the hospital or at a provider-based site of the hospital, the ownership status of the records, whether a physician employed by or under contract with the hospital executed a proper referral of the patient to a non-hospital prescriber, and whether the patient will return to the hospital within 12 months of when the referral, if there was one, was made.

Moreover, the guidelines do not take sufficient cognizance of practical and logistical realities, not only those relating to the amount and type of information reasonably accessible to those dispensing 340B drugs, but also the realities of modern health care delivery systems and the myriad arrangements under which medical professionals treat patients at safety net health care facilities. There is an extraordinarily wide variety of relationships and arrangements that exist in the real world between health care facilities and the medical professionals who render care and treatment at or on behalf of those facilities. Consequently, it is virtually impossible to formulate a precise, one-

size-fits-all description of the type of legal or business relationship between a treating professional and facility that validly distinguishes a patient from a non-patient. HRSA's present attempt to define "patient" in terms of a narrow zone of professional-facility relationships thus has the effect of excluding individuals who are in fact patients of 340B providers from the benefits of eligibility to receive 340B drugs.

In addition, the guidelines fail adequately to take into account the practical role of safety net health care facilities in serving the local communities of which they are a part. By drastically constricting the use of 340B drugs according to rigid, administrative criteria that are essentially external to the substance of the relationship between a safety-net provider and a needy patient population, the guidelines would obstruct achievement of one of the core purposes of the 340B program – enabling covered entities to provide a "safety net" of care, including pharmaceutical care, to the indigent and otherwise vulnerable populations in areas where the entities are located. We would like to elaborate on this last point below.

**C. HRSA'S DEFINITION SHOULD ACCOMMODATE HOSPITALS' LEGAL MANDATE TO FUNCTION AS SAFETY NET PROVIDERS**

In addressing the question of who qualifies as a patient of a 340B hospital, it is essential to understand that 340B hospitals are different from other hospitals. Hospitals participating in the 340B program operate under a legal mandate to provide services to defined populations. Except in emergency situations, other hospitals usually have no such legal obligation to provide care. Non-340B hospitals may choose to provide services to patients who are unable to pay, but such a decision is typically based on the institution's mission rather than a legal mandate. The legal obligation for 340B hospitals to serve defined populations arises out of (1) state or local law or (2) a contract with state or local government. Public hospitals participating in 340B generally operate under the first kind of legal mandate. Private non-profit hospitals enrolled in 340B typically operate under the second. Indeed, it is because of these legal obligations that 340B hospitals qualify for the program in the first place.

SNHPA believes strongly that, in establishing the 340B drug discount program, Congress intended for disproportionate share hospitals to use the program to assist the populations which the hospitals are legally obligated to serve. A county hospital that is required under state law or county ordinance to treat all county residents who lack health insurance should therefore be permitted to use the 340B program to assist the hospital in fulfilling this legal obligation. Similarly, a private non-profit hospital under contract to serve a state or local correctional or mental health population should be allowed to use 340B drugs in meeting the pharmacy needs of these patient groups. HRSA's definition of patient should accommodate such uses of the 340B program. A narrower construction of the law would lead to the illogical result that a 340B hospital could not use a federal assistance program to assist it in meeting an obligation that qualifies the hospital to participate in the program in the first place. No other covered entity group faces this risk.

AIDS Drug Assistance Programs (ADAPs), for example, are expressly permitted to use the 340B program for any individual enrolled in and receiving benefits from an ADAP program, regardless of who prescribes the individual's medications and the status of the individual's health care records. Community health centers, hemophilia treatment centers, family planning clinics and other non-DSH covered entity groups are likewise allowed to use 340B drugs freely for any patient to whom the covered entity is obligated under its federal grant to provide services. SNHPA urges HRSA to adopt a similar policy for 340B hospitals in order to promote consistency and fairness within the program.

In particular, SNHPA recommends that, notwithstanding a 340B hospital's ability to meet HRSA's specific and generally applicable patient definition test for a given population, the hospital should be permitted to use 340B drugs for that population if (1) it is legally obligated to care for the group and (2) the hospital's 340B status arises out of that legal obligation. The latter standard would be met if the hospital's legal obligation arises out of the fact that it is owned or operated by state or local government or if the obligation arises out of the hospital's contract with state or local government and such contract is relied on by the hospital to qualify for the program. In most cases, the hospital should be able to meet all of the patient definition requirements because the hospital is the party providing the requisite package of services. In some instances, however, hospitals have to outsource the delivery of care to other parties because they lack the resources in-house. It is in these situations where it is important for HRSA to recognize an exception to its patient definition standards so that the hospitals do not forfeit their capacity to use the 340B program to serve populations for whose benefit the program was established.

On a related note, SNHPA would like to recommend again that HRSA specify language that must be included in all state or local contracts on which non-profit hospitals rely on for their participation in the 340B program. While we are confident that a significant majority of private non-profit hospitals participating in the 340B program are providing substantial levels of indigent care, SNHPA believes the government should establish more specific federal standards to ensure program integrity. We direct you to the attached letter to HRSA dated July 13, 2006 articulating SNHPA's specific recommendations in this area. Should HRSA choose to adopt such recommendations, we only ask that they be applied prospectively so that existing contracts between 340B hospitals and their state or local governments do not need to be renegotiated.

## **II. SPECIFIC CONCERNS AND RECOMMENDATIONS**

Having described SNHPA's general concerns with the proposed changes to the 340B definition of patient, we would like to turn now to our more specific comments and recommendations relevant to HRSA's January 12<sup>th</sup> notice. These specific comments are set forth below. A summary of our recommendations is set forth in section III of this letter.

**A. ONLY LIMITED CHANGES TO THE CURRENT RECORD KEEPING STANDARD ARE NECESSARY TO IMPROVE 340B PROGRAM INTEGRITY**

Current guidelines establish, as one criterion for the status of an individual as a covered entity's "patient," a requirement that the entity maintain records of health care services for the individual. The proposed new guideline would require not only maintenance of such records, but also that the health care records so maintained must be owned, controlled and possessed by the entity. We fail to see how the additional criteria of ownership, control and possession of records enhance the extent to which a facility's maintenance of health care records about an individual indicates a patient relationship.

Although DSH hospitals maintain records for their 340B-eligible patients, they often do not own and/or possess such records. This is especially true when hospitals provide services to patients outside their institutional walls, such as in correctional facilities, nursing homes, schools, or other specialized facilities that may work in partnership with a hospital to serve a local community or a particular vulnerable population. In these circumstances, ownership of records sometimes resides with the hospital's "partner" rather than with the hospital, or records are co-owned by both facilities involved in caring for the target population. In other instances, a hospital may outsource maintenance of its records so that it no longer physically possesses them, even though the records remain hospital property. All of these record keeping arrangements are common in modern-day health care delivery, but would undermine an individual's patient status under HRSA's proposal, even though they have no real bearing upon the nature of the treatment relationship between the facility and the individual recipient of health care. Also, because many 340B hospitals are not separate legal entities (especially if they are state or county owned), it is unclear that they can own anything, including health records, independent of their parent legal entity. Thus some hospitals may be unable to meet the proposed record keeping test with respect to any of their patients.

Another area of risk under the proposed notice relates to the kinds of records being maintained by the covered entity. The current maintenance-of-records test can be satisfied by records other than a traditional medical chart, but it is unclear how the ownership, control, and possession criteria would apply to electronic medical records. Although the notice acknowledges that covered entities may rely on shared electronic patient records that can be accessed, added to and edited by several parties from different locations, the guidelines still require the covered entity to maintain control, ownership, and possession of a patient's health record. But applying these concepts to electronic data and the hardware and software systems that are used to support, store and organize such data is by no means a simple or readily comprehensible task. Indeed these proposed standards could entangle 340B administration and enforcement in a morass of complex intellectual property issues that surround software-based electronic information systems and the records such systems are designed to organize and maintain.

In light of the above-mentioned considerations, we strongly believe the wiser policy would be to retain the current record keeping and record maintenance standards

relative to the 340B patient definition,<sup>1</sup> but to clarify and tighten those provisions in just a few salient respects. First, we suggest that HRSA should clarify that a covered entity cannot be said to “maintain” a health care record unless it incurs costs in performing such maintenance and the costs appear on a reimbursable line of the Medicare cost report. This limitation would prevent a covered entity from claiming that it maintains patient records that are simply copies of records generated by outside parties and supplied to the entity for the sole purpose of satisfying the maintenance-of-record test. Second, we would urge HRSA to clarify that whatever record is relied upon to satisfy the 340B maintenance-of-records test, it must reflect the services giving rise to the order or prescription that the covered entity wants to fill with 340B drugs. Besides providing evidence that an individual is a *bona fide* patient of the covered entity, the maintenance-of-records requirement should serve a secondary purpose, namely, to provide an audit trail reflecting how a particular 340B-discounted drug is used by the provider. With respect to prescriptions written by outside physicians, the records should reflect that a referral to the prescribing physician was made or that the outside physician and covered entity are working together in caring for the patient. Third, we believe HRSA policy guidelines should provide that pharmacy records alone cannot satisfy the maintenance-of-record test. The current guidelines specify that the dispensing of drugs to an individual is insufficient by itself to establish a patient relationship that would allow the covered entity to use 340B-priced drugs for that individual.<sup>2</sup> Consistent with this exclusion is the suggestion that a covered entity must maintain more than a pharmacy record to meet 340B standards. With these discrete and narrowly targeted modifications, we believe the present record-maintenance test is clearer, more easily administered, and more likely to effectively and efficiently promote both the goals and the integrity of the 340B program than the much more unwieldy and complex standard that has recently been proposed.

**B. HOSPITAL MEDICAL STAFF SHOULD BE AUTHORIZED TO WRITE 340B PRESCRIPTIONS EVEN IF THEY ARE NOT EMPLOYED BY OR UNDER CONTRACT WITH THE HOSPITAL**

Proposed new restrictions on who must have treated an individual qualifying as a 340B patient, and who can write prescriptions to be filled with 340B drugs, are of particularly great concern to 340B hospitals because of the artificial and essentially arbitrary distinctions between “patients” and “non-patients” that such restrictions would create in many instances. Under the proposed guidelines, an individual may be considered a patient qualified to receive 340B drugs only if the individual receives or is prescribed the drugs as part of diagnosis and treatment from a health care “provider” either employed by or providing health care under a “valid, binding, and enforceable contract” with the covered entity. Missing from this new formulation is the flexibility (included in the previous and still current patient definition guidelines) for the prescriber of 340B drugs or the professional providing health care services incident to which 340B drugs are furnished to be connected with the covered entity through some “other arrangement” distinct from an employment or contractual relationship.

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<sup>1</sup> 61 Fed. Reg. 55,156.

<sup>2</sup> *Id.* at 55,158.

We comprehend HRSA's apparent view that the current guidelines, arguably allowing any "other arrangement" between a medical practitioner and a covered entity to serve as a basis for recognition of a patient relationship between the entity and those treated or diagnosed by the practitioner, may be too open-ended and may be an invitation to program abuse. Nevertheless, it should be equally apparent that in today's health care system, and especially in hospitals, direct employment and contractual relationships represent a relatively limited subset of the myriad arrangements between health care facilities and the medical practitioners who treat patients of those facilities. Physician interns and residents, for example, are characteristically neither employed by nor under contract with the hospitals in which they are on-staff. Visiting physicians may temporarily serve on the staff of university or other teaching hospitals, without forming new contractual or employment relationships. Safety net institutions and facilities often deliver services through volunteer physicians or other professional staff who serve without pay or formal contracts. Hospitals commonly contract with physician practice groups, rather than individual physicians, to staff hospital departments and clinics providing direct patient care.<sup>3</sup> DSH hospitals are often part of larger health systems, or of other entities (such as universities or private, non-profit corporations) that employ or contract with medical staff assigned to the DSH hospital, such that the discrete hospital specifically designated as a 340B entity has no direct employment or contractual relationship with any of the doctors treating patients at the facility.

In other situations, an individual may plainly receive health care services as a patient of a hospital, even though the physician directly responsible for diagnosing or treating the individual has no employment or contractual relationship with the facility beyond admitting or other limited, hospital "privileges." An individual experiencing chest pain might, for example, be admitted to a hospital for inpatient observation or might undergo a period of observation on an outpatient basis at a hospital clinic, upon referral by a cardiologist or primary care physician with privileges at the hospital. The individual in such a case would receive services from hospital staff, including administrative, nursing, dietary, medical technician, and probably other services, and might be prescribed some medication by his or her doctor in the course of or as a follow-up to that observation. A medical record would be created and maintained by the hospital, and there can hardly be any doubt that the individual, by any reasonable measure, would be regarded as the hospital's patient. Under the proposed "employed by or under contract with" standard, however, such an individual would not qualify as a "patient" for 340B program purposes and could not receive 340B outpatient drugs to stabilize his or her condition. This cannot possibly be considered consistent with Congress' intent in creating the 340B program.

Indeed all of the above-mentioned medical staffing mechanisms are sufficiently common and widespread in hospital operations and administration that the proposed

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<sup>3</sup> It is unclear from the guidelines as currently drafted whether a hospital's contract with a physician practice group, members of which furnish care to hospital patients but are not directly employed or under contract with the hospital, would satisfy HRSA's new "contract" test. We submit that this very common means of staffing hospitals with treating physicians should be regarded to meet the test, and that this should be made clear in revised guidelines when they are published in final form.

guidelines threaten to create a class of hospitals that – for 340B purposes – are regarded to have no “patients” at all.

We therefore believe that HRSA should revise its proposed guidelines to permit recognition of 340B patient status in connection with “other arrangements” beyond contractual and employment relationships between covered entities and individuals’ treating or prescribing physicians. Since a completely unrestricted “other arrangements” standard may not adequately preserve program integrity, however, we urge HRSA and OPA to adopt a modified “other arrangements” standard that would encompass legitimate facility/patient relationships, but would exclude arrangements inconsistent with program goals. We suggest that an appropriate formulation of the standard might define a patient to receive care from:

...a health care professional<sup>4</sup> who is employed by the covered entity, provides health care to patients of the covered entity under a valid binding and enforceable contract, or has such other arrangement with the covered entity as results in the health care professional providing health care services on the premises of the covered entity’s physical facility or an integral part thereof, in the delivery of health care services to such health care professional’s patient by members of the covered entity’s (or it’s parent legal entity’s) employees or contracted staff, or in participation by the health care professional in providing services to a defined population on behalf of or under the direction of the covered entity in order to effectuate the covered entity’s legal obligation to provide care for that population.

We believe the above standard would encompass situations where genuine patient relationships exist, but would exclude circumstances in which an attempt is made to use 340B drugs in a scheme primarily for private gain or for purposes outside the proper boundaries of the program.

**C. SERVICES PROVIDED BY NURSES, CASE MANAGERS, SOCIAL WORKERS AND OTHER NON-PHYSICIANS SHOULD BE SUFFICIENT TO ESTABLISH A PATIENT RELATIONSHIP**

In addition to the above-discussed need for expansion of the proposed standard as to professional care of a qualifying 340B “patient,” we think other related revisions and clarifications of the guidelines’ language are necessary. One confusing element, for example, is use of the term “provider” to refer to the entity using or prescribing drugs in diagnosing or treating a patient. It is unclear whether use of the word “provider” rather than “health care professional” is intended to narrow the scope of caregivers recognized by HRSA as establishing bona fide patient relationships and authorized to order 340B drugs. We note that under the Medicare program, “provider” typically refers to a health care facility such as a hospital, nursing home, or hospice that makes claims for

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<sup>4</sup> We think use of the term “health care professional” would be more clear and accurate than reference to a “provider” as appears in the proposed guidelines. See discussion at pp. 9-10 *infra*.

reimbursement from the Medicare Trust Fund. Thus the term has an uncertain application to individual physicians or caregivers, and may be read to imply some limitation connected with billing Medicare. On the other hand, in a 340B program context, the term could be interpreted more broadly to include anyone who provides a health care service: physicians, physician assistants, nurse practitioners, clinical nurse specialists, nurse midwives, clinical social workers, dieticians, and others.

If the term “provider” is to be used, it is important that it be expressly defined with sufficient breadth to encompass the range of health care professionals whose provision of services establish patient relationships. For example, services furnished by many types of non-physicians establish patient relationships in hospitals justifying the use of 340B drugs. Among these non-physician services are those provided by nurses, medical technicians, case managers, social workers and others.

Defining (or revising) the reference to a “provider” is especially important to clarifying the future status of covered entities’ case management programs as bases for patient relationships. It is unclear from the guidelines whether case management services may still be regarded as health care services sufficient to create a patient relationship when they consist of more than mere administrative and record keeping functions (such as, for example, face-to-face health case assessments of the patient and ongoing monitoring of treatment and health status), and are furnished by non-physician health care professionals such as nurses or licensed case managers. The guidelines as proposed suggest (we think improperly) that case management services cannot be regarded as health care services in and of themselves sufficient to establish a patient relationship.

We do not doubt that there may be some case management programs developed primarily as a mechanism for obtaining 340B discounts and which are so exclusively administrative in character as not to qualify as “health care.” But we nevertheless believe that case management, appropriately configured and staffed, can be a valid and indeed vital health care service that preserves individual health and conserves provider resources by minimizing emergent medical crises and preventable acute-care needs. In fact, it should not be overlooked that community health centers are required to provide case management services. It would be anomalous indeed for the federal government to require covered entities to provide a specific health care service to their patients, because it is recognized as valuable and important to patients’ health care, but refuse to support provision of that same service through the 340B program. Pharmaceutical care in conjunction with case management is an appropriate use of 340B drugs, and we urge HRSA to further clarify in its final guidelines that case management services can legitimately be regarded to comprise health care, and under what circumstances this may be the case.

#### **D. HRSA SHOULD PERMIT DISCHARGE PRESCRIPTIONS TO BE FILLED WITH 340B DRUGS**

A similar objection applies to proposed guideline provisions restricting health care services on which “patient” status may be based exclusively to “outpatient” services.

This represents a significant change from current policy, which recognizes persons admitted to hospitals for inpatient treatment as patients of the treating hospitals, and therefore permits those patients to be dispensed 340B drugs when, upon discharge from hospitalization, they seek to fill prescriptions for outpatient drugs prescribed in connection with their prior inpatient treatment that may have been prescribed in anticipation of or to facilitate their discharge and follow-up care. The proposed guideline appears to confuse the character of drugs permissibly purchased and used in the 340B program (covered outpatient drugs) with the character of health care services that create a patient relationship (inpatient or outpatient). The consequence is a "patient" standard that drastically restricts and alters the scope of the 340B program as expressly established by statute.

Current guidelines only require that the prescriptions be for "covered outpatient drugs," which relates to how the drugs are billed rather than the kind of services that give rise to the prescription. Because discharge prescriptions are generally filled by outpatient pharmacies and billed as outpatient drugs, DSH hospitals have routinely used 340B drugs to fill discharge prescriptions since the inception of the program. Elimination of this practice, through adoption of HRSA's newly proposed test for patient status, would undermine a legitimate and important use of 340B drugs. Similarly, other common and entirely legitimate uses of 340B drugs, such as for residents of hospital-based nursing homes, rehabilitation units, and other long term care components of DSH hospitals, would also be threatened to the extent the services underlying the use of 340B drugs might be viewed as inpatient services rather than outpatient services.

The 340B statute prohibits resale or transfer of 340B drugs to any person other than a "patient" of a covered entity, but contains nothing to suggest that only an outpatient qualifies for the "patient" designation. To the contrary, absent any statutory language or legislative history indicating a specific Congressional intent to restrict the meaning of "patient" to less than its ordinary meaning, the term "patient" can only be understood to have its usual meaning in common parlance – *i.e.* to encompass "patients" who receive inpatient or outpatient care at health care facilities.<sup>5</sup> This reading is supported, moreover, not only by common sense and the ordinary usage of the word "patient" in the English language, but by the structure and purpose of the 340B statute as well.

The 340B program was established to provide support to safety net health care facilities serving large numbers or high proportions of indigent patients, and to enable those facilities to better stretch their scarce resources to care for their indigent patient populations. A major element of the test that qualifies a hospital for 340B participation, therefore, is its character as a "disproportionate share hospital," *i.e.* a hospital serving a disproportionate share of indigent patients, and the specific percentage of such patients that the hospital serves. However, both DSH hospital status and the disproportionate share adjustment percentage that determine hospital eligibility to buy 340B drugs are

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<sup>5</sup> We note that a well-established tenet of statutory construction requires words to be given their natural and ordinary meanings unless there is a specific indication of Congressional intent to the contrary. See, e.g. Smith v. United States, 508 U.S. 223, 228 (1993), and other authorities cited therein.

based on the hospital's *inpatients* that are regarded as indigent. It is clear, therefore, that these populations – the indigent inpatients of a DSH hospital – are among the individuals Congress intended to help DSH hospitals serve through the savings achieved by 340B discounts.

If this were not the case, it would have been nonsensical to use inpatient days of indigent persons as the principal measure of a hospital's need for 340B assistance in stretching its resources. By purporting to define "patient" to exclude inpatients, the guidelines fly directly in the face of the underlying rationale of the statute and of clear Congressional intent. Hospitals would be prevented from purchasing 340B drugs and realizing 340B savings on outpatient prescriptions for the very indigent patient populations that justify the hospitals' participation in the 340B program in the first place. There is, in short, no question that Congress intended 340B drugs to be available to fill outpatient prescriptions (such as discharge prescriptions) for individuals who are "patients" of a hospital based on their *inpatient* stays and treatment.

Accordingly, we think the proposed guidance limiting 340B drug use and prescriptions to treatment of persons who have received outpatient care from a covered entity, to the exclusion of patients discharged from an inpatient stay, is inconsistent with the law. Even if not regarded as literally in conflict with section 340B, moreover, the proposed guideline represents a sufficient change and substantive restriction of the statutory provision to constitute, at a minimum, a substantive or "legislative" rule, of the type HRSA and OPA cannot impose through mere policy "guidelines," and issuance of which we think would require statutory authority beyond what has been conferred on HRSA by the 340B statute.

It should also be noted that a rule prohibiting the use of 340B drugs to fill discharge prescriptions would create enormous administrative burdens and complexities for hospital pharmacies, OPA, and State Medicaid agencies. To comply with this prohibition, a "closed" hospital pharmacy would either have to turn hospital patients away when they seek to fill prescriptions needed upon discharge, or would have to maintain a double-inventory of drugs, incurring expense that many safety net pharmacies cannot afford. Since, assuming implementation of the prohibition, discharge medications would be subject to Medicaid rebates, but the rest of the pharmacy's 340B inventory would be excluded from rebates to avoid a duplicate discount problem, the hospital pharmacy would need to utilize two different provider numbers to bill Medicaid drugs. OPA would need to somehow differentiate in its exclusion file for States between the pharmacy when billing Medicaid for discharge drugs and the same pharmacy when billing Medicaid for other outpatient drugs purchased at 340B discounts. These practical and administrative difficulties, therefore, further buttress SNHPA's view that the proposed "outpatient only" definition of a 340B "patient" is ill-advised and unworkable.

**E. HRSA SHOULD USE A CONTINUUM-OF-CARE STANDARD IN DETERMINING WHETHER PRESCRIPTIONS WRITTEN BY OUTSIDE PRESCRIBERS CAN BE FILLED WITH 340B DRUGS**

Another problem with the proposed guidelines is the new limitation on who may write prescriptions to be filled with 340B drugs. Whereas the current “patient” test does not address or set limits on who may prescribe 340B drugs, the proposed new test does. Under current guidelines, it does not matter who is writing the prescription as long as standards of record maintenance and care by a medical professional properly associated with the covered entity are satisfied. By contrast, we read the proposed notice to require that a prescription can only be filled with 340B drugs if it is written by a health care “provider” employed by or under contract with the covered entity. This means that hospitals would be forced to reorient their approach to compliance with anti-diversion requirements by focusing on individual prescriptions rather than the hospital’s relationship to various categories of potential patient populations.

We think such an approach is objectionable from both practical and legal perspectives. On the practical side, a “patient” test hinging on the identity of the drug prescriber would impose an unreasonable burden on hospital pharmacists by requiring them to know, research, or interrogate individuals presenting a prescription about, a multiplicity of facts surrounding the prescription (including not only the prescriber’s identity, but where he or she practices, and what the prescriber’s specific relationship is with the hospital, as well as what illness or condition gave rise to the prescription, and where, by whom and at what facility that illness or condition was diagnosed and/or treated). It is likely that often the individual presenting a prescription (who may be an authorized family member instead of the actual patient) will not know all of this information, and will be unwilling or unable to accommodate the delay necessary for the pharmacist to research the matter. In other situations (and on an increasingly frequent basis as technological advances proceed) there may be no individual presenting the prescription and available to answer questions, because the pharmacist may receive an “e-script.”

From a legal perspective, the 340B statute places no limitation on who may prescribe 340B drugs and contains no provision even arguably suggesting that “patient” status with a covered entity hinges on the source of prescriptions or the specific nature of the health care services furnished by a facility to its “patient.” To impose such a “prescriber identity” test as a mandatory criterion of patient status goes beyond interpreting the meaning of the commonly used term “patient” in the statute, and extends well into a zone of substantive rulemaking for which HRSA has been given no apparent statutory authority in the 340B arena.

In addition, we question the appropriateness and wisdom of the extent to which the proposed policy narrows the circumstances under which 340B drugs may be used to fill prescriptions written by “outside” prescribers – that is, by prescribers that are not affiliated with the covered entity in any manner recognized by the guidelines. HRSA’s proposal would preclude the use of 340B drugs to fill outside prescriptions unless (1) the

covered entity's health care "provider" refers the patient to the outside prescriber for follow-up care relating to the same condition treated by the covered entity, and (2) the covered entity maintains ongoing responsibility for the outpatient health care service that results in the use of, or prescription for, 340B drugs. But discerning when such circumstances are present will often be difficult or impossible from a practical standpoint, especially because it is not always easy to tell when pre-referral and post-referral care is for the same condition or whether and when an individual referred to an outside provider may return to the hospital for further treatment.

In fact, the provision of the guidelines limiting use of 340B drugs to fill prescriptions by an outside prescriber to instances where the patient will return to the covered entity for further care or treatment within 12 months of the patient's referral to the outside provider/prescriber is unrealistic and impossible to administer. A pharmacist at an outpatient pharmacy counter cannot foresee the future and cannot reasonably be expected to decide whether to fill a prescription with 340B drugs based on a determination of what a patient will or will not do in the coming year. Moreover, when there is a longstanding relationship between a hospital and an outside provider in caring for a common population, requiring a patient to go to the covered entity first to get a referral to the outside provider is overly burdensome for the patient and contrary to the efficient operation of a health system.

This last point underscores what we believe is one of the most problematic aspects of the proposed guidance. Most 340B hospitals operate in health systems in which the responsibility for delivering care is shared among the providers participating in the system. The rights and obligations of each participating provider are typically well-defined and reflected in binding contracts or, if the parties are components of the same legal entity, in the entity's internal governance structure. Patients generally enter the health system through a participating primary care provider (PCP), and most referrals emanate from the patient's PCP. The proposed conditions under which non-entity prescriptions can be filled with 340B drugs appear to be based on a model in which the covered entity is the patient's PCP. Although this approach may make sense for community health centers and other covered entities that generally only provide primary care, it does not fit well within the reality of DSH hospital operations, especially since many such hospitals provide little or no primary care.

HRSA's seemingly PCP-based perspective in defining appropriate patient relationships may explain why, as a pre-condition for using 340B drugs to fill outside prescriptions, the agency proposes to require covered entities to make formal referrals to any outside prescriber and maintain ongoing responsibility for care rendered pursuant to such referrals. Under a PCP-based model, it might be more reasonable to withhold 340B coverage of prescriptions written by "unaffiliated" providers and expect covered entities to have "primary" responsibility for patients. The proposed DSH-specific requirement that the patient return to the hospital for continuing care within 12 months of any referral also seems to assume that hospitals fit into the PCP paradigm of health care, of which annual exams are a routine part. But since in fact very few hospitals actually function

according to a PCP paradigm, aspects of the proposed guidelines seemingly predicated on a PCP model are a poor fit with the reality of how DSH hospitals care for their patients.

The result is that the proposed conditions for filling outside prescriptions are so restrictive that in virtually all instances of non-hospital prescriptions, most hospitals would be prevented from using 340B drugs. This restrictiveness drastically reduces the extent to which 340B drugs can be used to stretch safety net providers' resources and assist in addressing the health care needs of indigent and underserved communities. Importantly, part of what is (we think unwisely) restricted is the role 340B entities can play and heretofore have played in offering affordable drugs to indigent, uninsured, or otherwise vulnerable populations in the local communities where the entities are located. Individuals in these communities often rely on safety net pharmacies as a source of affordable prescription drugs, even when the doctors who have written their prescriptions are not affiliated with the safety net providers of which the pharmacies are a part. Thus, while we do not suggest that use of 340B drugs to fill outside prescriptions should be entirely unconstrained, we suggest the following as a more reasonable and practical standard that would permit 340B drugs to be used for such prescriptions in appropriate circumstances:

340B drugs may be used to fill a prescription at a covered entity outpatient pharmacy if the prescription or refill is presented within one year of the patient's encounter at the covered entity and the encounter is part of the continuum of care that gives rise to the prescription. A continuum of care is defined to exist if the covered entity makes a referral to the outside provider for follow-up care or if there is an established pattern of the covered entity and non-covered-entity provider working together to serve a common patient population or populations.

**F. THE PROPOSED MEDICARE PROVIDER-BASED TEST SHOULD BE FLEXIBLY APPLIED AND SHOULD NOT BE THE EXCLUSIVE TEST OF A FACILITY'S INTEGRAL RELATIONSHIP WITH A DSH**

In articulating a new "patient" definition under the 340B program, HRSA has also proposed to redefine the standard for determining what facilities may be considered part of a DSH, and therefore qualified to receive and use or dispense 340B drugs. In this section, we first discuss our understanding of the proposed new "provider-based" standard for qualifying additional sites of a DSH to participate in the 340B program. We then explain the basis of our concern that the new standard will not adequately serve the purposes of the program, and will improperly exclude from program participation facilities and sites that are genuinely integral parts of 340B-qualified DSH hospitals, if the standard is used as an exclusive measure of "integral" relationship between a DSH hospital and other facility components or sites.

In addition to proposing the above discussed changes to the previous record maintenance and professional care test for patient status, HRSA has proposed an entirely

new requirement specifically for DSH hospitals. This proposed requirement would be incorporated into the third prong of the existing definition of patient (which currently does not apply to DSH hospitals). The third prong of the patient definition relates to the scope of a covered entity's federal grant, which is the basis on which all covered entities, except for DSH hospitals, qualify for the 340B program. HRSA has proposed to supplement the third element of the definition with a unique test that seems designed as a DSH counterpart to the scope-of-the-grant requirement applicable to non-DSH covered entities. Under this proposed DSH-specific requirement, outpatient services received by a patient that result in the use of or prescription for 340B drugs must be provided by a DSH hospital or by another location that has qualified as a "provider-based" facility within the DSH hospital under the Medicaid provider-based regulations (42 C.F.R.413.65). The facility's provider-based status would also have to be reflected in the hospital's Medicare cost report. In essence, the proposal is to adopt Medicare provider-based regulations as the measure for determining whether a facility or off-site location constitutes an "integral part" of a DSH hospital for purposes of its participation in the 340B program.

The provider-based regulations state that, in order for a site to be deemed provider-based, its relationship with the main provider must meet the following eight criteria: (1) joint licensure; (2) integration of clinical services, including main provider oversight and administration of (and responsibility for) the clinical services rendered at the provider-based site; (3) integration of medical records; (4) integration of financial operations; (5) holding the provider-based site out to the public as part of the main provider; (6) compliance by the provider-based site with federal rules and regulations applicable to the main provider; (7) billing of services rendered at the provider-based site to Medicare patients as hospital services; and (8) integration of administrative and managerial functions.

The Centers for Medicare and Medicaid Services (CMS) has established a voluntary process by which hospitals and other providers can apply for and receive a determination by Medicare that a given site is provider-based. The process involves a provider submitting an attestation explaining how the site in question meets each of the eight provider-based standards described above. However, there are several categories of providers – including ambulatory surgical centers, home health agencies, ESRD facilities and skilled nursing facilities – which are excluded from this attestation process and are not subject to designation as "provider-based," even though they may meet the eight regulatory standards of eligibility for this status. Moreover, our understanding is that the Medicare program does not make provider-based determinations for facilities that treat exclusively non-Medicare patients, such as children or uninsured adults who are neither disabled nor elderly. For example, an off-site pediatric clinic may meet all the criteria for provider-based status but be ineligible for a determination of provider-based status because none of the clinic's patients are entitled to Medicare benefits.

SNHPA is very concerned that the proposed application of Medicare provider-based regulations in defining a 340B-eligible patient could result in denying 340B drugs to patients who receive services at the kinds of facilities to which the provider-based

determination process does not technically apply. Such an application of the guidelines would likely have a devastating impact on 340B hospitals because they would have to discontinue their use of the 340B program for hospital-based ambulatory surgical centers, home health agencies, ESRD facilities, nursing homes, and the like. They would also have to terminate their use of the program for indigent care clinics, pediatric units, prison infirmaries, and other sites that do not serve Medicare beneficiaries, but do serve indigent or vulnerable populations and provide care of the type the 340B program was specifically designed to support. We are hopeful that HRSA does not intend to limit DSH hospital utilization of the 340B program to only those provider-based sites that are technically eligible to submit attestations and to receive provider-based determinations under the Medicare program, and that HRSA intends, instead, to allow use of 340B drugs in hospital facilities that meet the eight provider-based criteria regardless of whether they are eligible or choose to apply for Medicare provider-based designation. This flexibility is crucial to application of provider-based criteria so as not to improperly exclude sites and facilities that are genuinely part of qualifying DSH hospital from 340B participation, and should be expressly incorporated into HRSA's guidelines.

However, even if applied with appropriate flexibility, the provider-based test has inherent limitations stemming from the fact that it was developed for application in the very specific context of the Medicare system. Although Medicare principles and procedures can sometimes be instructive in assessing administrative and operational issues in the 340B program, it is nevertheless the case that Medicare and 340B are two very different programs, governed by different statutes, and many of the statutory and regulatory technicalities of the Medicare program have no proper application in a 340B program context.

We agree that a facility meeting the criteria for "provider-based" status in connection with a DSH hospital is properly regarded as part of the hospital and should be permitted to use 340B drugs to treat and dispense to its patients. However, there will be some instances where a facility or site fails to meet some technical aspect of the Medicare provider-based test, but is in fact still genuinely a part of the hospital, and properly qualifies for 340B participation. For example, depending on the specific function of an off-site facility and the make-up of its patient population, the DSH hospital might not actually engage in billing services rendered at the site to Medicare patients, as hospital services or otherwise; but failure to meet this Medicare criterion would not have any real relevance to the question of whether the facility's relationship to the DSH hospital warrants recognition of the facility as a 340B-qualified site. In other words, too strict and exclusive application of Medicare, provider-based criteria to the question of 340B facility/site qualification would produce an arbitrary and improper result in certain scenarios.

This problem needs to be addressed, and could be solved in at least two ways. First, the "provider-based" test should not be employed as the exclusive test of whether a secondary hospital location qualifies as part of the DSH hospital allowed to participate in 340B drug receipt and utilization. Instead, we believe provider-based standards should be used to supplement, not supplant, the previous "cost report test" for alternative-site,

340B eligibility. The “cost report test” has admittedly been difficult to apply in some circumstances, especially to the extent it is construed to require inclusion of a facility’s costs on an already-filed cost report of a DSH hospital, and newly established facilities cannot realistically be assessed through that mechanism. However, as a general rule, the cost-report test worked well through 15 years of 340B program administration, and there are many scenarios in which that test will still be a better measure of a site’s relationship to a DSH hospital than the more technically detailed provider-based regulation. Thus we believe fairness and accuracy in determining which facilities are part of 340B-qualified DSH hospital can best be achieved through a policy permitting sites to establish 340B participation eligibility through meeting *either* the cost report test *or* provider-based criteria. In the alternative, a policy might be developed recognizing a site’s 340B eligibility if it meets at least six, but not necessarily all eight, of the Medicare provider-based criteria. However, we think the former option – utilizing the cost report test *or* provider-based criteria, depending on which is more appropriate to the situation and the facility – is the preferable course.

Finally, we wish to note that under our reading of the proposed guidelines as currently drafted, if an off-site, freestanding facility affiliated with a 340B-qualified DSH hospital does not meet provider-based criteria, it could nevertheless use 340B drugs to the extent the drugs are furnished incident to professional services of a physician or other “provider” meeting HRSA’s professional care standards (*i.e.*, under the current proposal, a “provider” employed by or under contract with the hospital). This aspect of the policy, however, should be more clearly and expressly explained in any final publication of the guidelines.

**G. EMPLOYEES RECEIVING SERVICES THROUGH A COVERED ENTITY’S SELF-INSURED HEALTH PLAN SHOULD BE CONSIDERED 340B-ELIGIBLE PATIENTS**

SNHPA believes the proposed new guidelines require further revision insofar as they would prohibit use of 340B drugs to fill prescriptions of hospital employees covered under a hospital’s self-insured employee health plan. Under the terms of many hospitals’ self-insured employee health benefit plans, a hospital provides its employees and their dependents with health care services under what is essentially a managed care arrangement, utilizing a network of physicians and providers with whom the hospital contracts for participation in the network. Under the previous and currently effective guidelines, this model of care was permitted as one that establishes valid 340B patient relationships. A change in this policy would represent an extremely serious problem for a high percentage of SNHPA member hospitals.

We believe managed care for hospital staff and their dependants under a self-insured employee insurance program should be recognized as a valid context for using 340B drugs and a legitimate structure for a hospital’s care of “patients” within the meaning of 340B. It is important to note that the capacity to offer the benefit of prescription drugs to employees at discounted prices at the employees’ jobsite assists a hospital to retain and conserve important staff resources. Some categories of hospital

personnel, for example nursing and pharmacist staff, are in short supply nationwide, and staff retention is a critical element in maintaining the hospital's continued capacity to provide adequate patient care. Also, the on-site availability to hospital staff of low-cost prescription drugs is a convenience that conserves staff time. For both reasons, affording hospital employees access to 340B drugs under a self-funded insurance program is a significant mechanism for conserving a hospital's limited staff resources, and is therefore entirely consistent with the core purposes of the 340B program, that is, assisting qualified DSH hospitals to stretch their scarce resources.

Furthermore, we believe employees and their dependants served under a properly configured employee managed care model would meet the core elements of a reasonable 340B patient definition. Under this model, employee-patients would receive care solely from medical professionals either employed by or under contract with the hospital,<sup>6</sup> and the hospital would maintain records of those patients' medical care, albeit in some cases something less than patients' full medical records. Of particular importance, the hospital would plainly retain financial responsibility for patient care under the plan. We therefore urge HRSA to revise its proposed patient definition guidelines to better accommodate an employee/patient model, consistent with the policy and practice developed over the last 15 years of 340B program administration.

### III. CONCLUSION AND SUMMARY OF RECOMMENDATIONS

SNHPA has both corresponded and met with OPA extensively over the past two years in connection with anticipated changes to HRSA's patient definition guidelines. During one of the meetings between SNHPA and OPA, we were asked to recommend specific changes to the guidelines which, in our view, would protect the program from potential abuses. We reviewed the guidelines, solicited input from our members and developed eight specific suggestions for tightening up the guidelines in order to promote the integrity of the program. A copy of our eight suggestions is attached. SNHPA firmly believes that implementation of these eight recommendations would achieve HRSA's goal of tightening up the definition in order to prevent abuses without compromising legitimate uses of the program. We therefore resubmit these recommendations with the hope that HRSA will drop its current proposal to overhaul the definition of patient in favor of a less disruptive approach that, in our view, would still protect program integrity.

We recognize, however, that HRSA has proposed specific changes to the patient definition and that, notwithstanding SNHPA's general concerns that the proposal is much too restrictive, we should provide specific feedback on HRSA's proposal. A summary of our comments is set forth below.

***Recommendation One: Only limited changes to the current record keeping standard are necessary to improve 340B program integrity.*** SNHPA has articulated several reasons why the proposed requirement that a covered entity own, control and

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<sup>6</sup> We do not endorse including in the patient definition employees who receive care solely from providers who are not part of the health plan's network and are not otherwise employed by, under contract with or in other arrangements with the covered entity.

possess a patient's records is problematic. We recommend an alternative standard requiring (1) that the covered entity incur real and reportable costs in connection with maintaining patient records, (2) that the records reflect the services giving rise to the 340B order or prescription, and (3) that the use of pharmacy records alone to meet the record keeping test is insufficient.

***Recommendation Two: Hospital medical staff should be authorized to write 340B prescriptions even if they are not employed by or under contract with the hospital.*** 340B prescribers should not be limited to employees and contractors of the covered entity. Although SNHPA can support removal of the term "other arrangements" in describing 340B-compliant patient relationships, it is essential that HRSA recognize services provided by professionals other than those who are employed by or under contract with the covered entity. SNHPA recommends that, in describing services that give rise to a 340B-compliant patient relationship, HRSA recognize services provided by:

...a health care professional who is employed by the covered entity, provides health care to patients of the covered entity under a valid binding and enforceable contract, or has such other arrangement with the covered entity as results in the health care professional providing health care services on the premises of the covered entity's physical facility or an integral part thereof, in the delivery of health care services to such health care professional's patient by members of the covered entity's (or its parent legal entity's) employees or contracted staff, or in participation by the health care professional in providing services to a defined population on behalf of or under the direction of the covered entity in order to effectuate the covered entity's legal obligation to provide care for that population.

***Recommendation Three: Services provided by nurses, case managers, social workers and other non-physicians should be sufficient to establish a patient relationship.*** SNHPA opposes HRSA's proposal to replace the term "health care professional" with "provider." The term "provider" could be construed narrowly so as to preclude the services provided by nurses, case managers, social workers and other non-physician professionals from establishing a patient relationship within the meaning of the 340B anti-diversion provision. We recommend that HRSA continue to use "health care professional" in the 340B definition of patient.

***Recommendation Four: HRSA should permit discharge prescriptions to be filled with 340B drugs.*** SNHPA objects to the proposed guideline provision restricting health care services on which patient status may be based exclusively to "outpatient" services. This proposed change would exclude discharge prescriptions from being filled with 340B drugs even though such drugs would clearly be "covered outpatient drugs" within the meaning of both the Medicaid rebate and 340B programs. We recommend that the word "outpatient" be deleted every time it appears in the term "outpatient health care services" in HRSA's proposed patient definition.

**Recommendation Five:** *HRSA should use a continuum-of-care standard in determining whether prescriptions written by outside prescribers can be filled with 340B drugs.* HRSA's proposal would preclude the use of 340B drugs to fill outside prescriptions unless (1) the covered entity's health care "provider" refers the patient to the outside prescriber for follow-up care relating to the same condition treated by the covered entity, and (2) the covered entity maintains ongoing responsibility for the outpatient health care service that results in the use of, or prescriptions for, 340B drugs. SNHPA believes that such a narrow test for using 340B to fill non-covered entity prescriptions is unwarranted and would be virtually impossible to implement by safety net pharmacists. We recommend that HRSA replace this test with the following alternative for using 340B to fill outside prescriptions:

340B drugs may be used to fill a prescription at a covered entity outpatient pharmacy if the prescription or refill is presented within one year of the patient's encounter at the covered entity and the encounter is part of the continuum of care that gives rise to the prescription. A continuum of care is defined to exist if the covered entity makes a referral to the outside provider for follow-up care or if there is an established pattern of the covered entity and non-covered entity provider working together to serve a common patient population or populations.

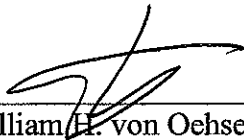
**Recommendation Six:** *The proposed Medicare provider-based test should be flexibly applied and should not be the exclusive test of a facility's integral relationship with a DSH hospital.* There will be occasions when a hospital facility fails to meet a technical aspect of the Medicare provider-based requirements but is still an integral part of the DSH hospital. HRSA should give hospitals the choice of meeting either the provider-based regulations or the Medicare cost report test. HRSA should also make clear that 340B drugs may be used outside provider-based facilities if they are used in connection with hospital services that comply with the first two elements of the definition of patient.

**Recommendation Seven:** *Employees receiving services through a covered entity's self-insured health plan should be considered 340B-eligible patients.* Employees and dependents should not automatically qualify for 340B-discounted drugs even though hospitals have historically filled employee prescriptions. Rather, use of the 340B program to fill employee prescriptions should be limited to only those employees and dependents (1) who are enrolled in a covered entity's employee health plan that is self-insured, (2) who receive in-network services from participating physicians and other providers under contract with the plan, (3) who present prescriptions written in connection with such services, and (4) for whom the entity owns and/or maintains the health plan's records.

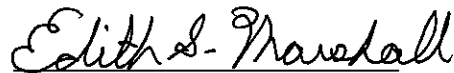
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Again, SNHPA would like to thank HRSA for the opportunity to comment on the proposed changes to the definition of patient. Please do not hesitate to contact us if you have any questions.

Sincerely,



William H. von Oehsen  
President and General Counsel



Edith Marshall  
Special Counsel and Director of  
Legal Affairs



## Public Hospital Pharmacy Coalition

[www.phpcrx.org](http://www.phpcrx.org)

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(A Coalition of the National Association of Public Hospitals and Health Systems)

July 13, 2006

Mr. Jimmy R. Mitchell, R.Ph., MPH, MS  
Director  
Office of Pharmacy Affairs  
Health Resources and Services Administration  
Parklawn Building  
5600 Fishers Lane  
Mail Stop 10C-03  
Rockville, MD 20857

**VIA PDF AND U.S. MAIL**

Re: Indigent Care Policy for Private Non-Profits

Dear Jimmy:

The Public Hospital Pharmacy Coalition (PHPC) represents a majority of the public and private non-profit hospitals participating in the 340B drug discount program. Last September, PHPC recommended to the Health Resources and Services Administration (HRSA) and the Office of Pharmacy Affairs (OPA) a number of clarifications to the 340B definition of patient that, in PHPC's view, would help prevent both intentional and unintentional incidents of diversion. Included in our recommendations was a request that the government ensure that private non-profit hospitals that apply for the 340B program demonstrate that they are providing significant levels of indigent care. PHPC indicated that it would be following up with a proposal to help address this issue. We are writing today to submit the proposal.

As you know, a private non-profit hospital can only qualify for the 340B program if it has a Medicare disproportionate share hospital (DSH) adjustment percentage of 11.75 or greater and "has a contract with state or local government to provide health care services to low income individuals who are not entitled to benefits under [Medicare] or eligible for assistance under [Medicaid]."<sup>1</sup> While we are confident that a significant majority of private non-profit hospitals participating in the 340B program are providing substantial levels of indigent care, PHPC believes that the government should establish more specific federal standards to ensure program integrity. PHPC therefore urges HRSA to specify language that must be included in all state or local contracts on which non-profit hospitals rely for their participation in the 340B program.

PHPC has attached to this letter proposed language that, if incorporated into 340B-qualifying contracts, would address any questions about indigent care obligations

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<sup>1</sup> 42 U.S.C. § 256b(a)(4)(L)(i).



**NATIONAL ASSOCIATION OF PUBLIC HOSPITALS & HEALTH SYSTEMS**

1301 Pennsylvania Avenue, N.W. Suite 950, Washington, DC 20004, 202-585-0100, FAX 202-585-0101, [www.naph.org](http://www.naph.org)

PHPC Counsel: Powers, Pyles, Sutter & Verville PC, 1875 Eye Street, NW 12th Floor, Washington, DC 20006,

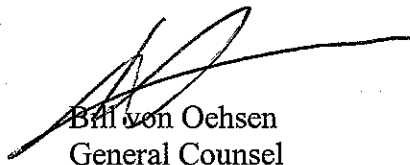
202-466-6550, FAX 202-785-1756, [www.ppsv.com](http://www.ppsv.com)

by private non-profits in the 340B program. PHPC's proposed language mandates that the contracting hospital have an indigent care policy in place whereby (1) hospital patients who are low income and uninsured would be entitled to discounts on their care (based on, for example, a sliding fee schedule) and (2) uninsured patients in the lowest income bracket would pay little or nothing for hospital services. Because 340B private non-profit hospitals would be contractually obligated to implement this proposed policy, HRSA could feel confident that the hospitals are meeting their indigent care obligations. Likewise, because PHPC's proposed language explicitly requires the hospital to utilize the 340B program in accordance with the policy, low income uninsured patients could never be denied access to pharmacy services based on an inability to pay. HRSA should therefore require that, with respect to every state and local contract that private non-profit hospitals rely on to qualify for the 340B program, the attached indigent care policy must be included in the contract.

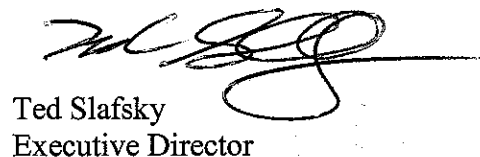
PHPC supports current efforts by HRSA and OPA to tighten up the 340B definition of patient in order to prevent diversion of discounted drugs. PHPC has provided OPA with specific recommendations on how the existing guidelines can be strengthened. However, it is important to recognize that tightening up the definition of patient will not prevent the possibility of a private non-profit hospital enrolling in the 340B program based on inadequate indigent care contracts. No matter how stringent HRSA and OPA make the patient definition guidelines, such steps will not solve this problem because the real issue relates to the payer mix of a hospital's outpatient population, not how a patient is defined. Hence, PHPC would much rather see HRSA and OPA devise guidelines to ensure that hospitals provide significant levels of indigent care as a condition of participation in 340B, and further, that the guidelines be constructed in a way that jeopardizes a hospital's 340B status if it does not provide adequate levels of indigent care. We believe that inclusion of the attached indigent care policy in 340B-qualifying contracts with private non-profit hospitals will achieve both of these objectives. PHPC therefore urges HRSA and OPA to include the attached proposal in the patient definition guidelines that are currently under development and scheduled to be published later this year.

PHPC hopes that you agree with its firm belief that adoption of the above proposal will significantly improve the integrity of the 340B program. Please do not hesitate to contact us if you have any questions or comments regarding the proposal and/or the attached indigent care policy.

Sincerely,



Bill von Oehsen  
General Counsel



Ted Slafsky  
Executive Director

Enclosure

**PROPOSED CHARITY CARE POLICY  
FOR PRIVATE NON-PROFIT 340B HOSPITALS**

The hospital agrees to have a charity care policy whereby non-Medicare, non-Medicaid indigent patients who meet hospital-defined eligibility requirements would receive their care for free or at nominal cost. For patients who fall outside the charity care eligibility requirements but meet broader standards of being indigent, the hospital agrees to offer discounts on such care based on, for example, a sliding scale. Use of the 340B drug discount program shall be implemented in accordance with this policy. The hospital also agrees to provide, upon request by the federal government, a copy of its charity care policy and documentation that the policy applies to the hospital's 340B pharmacy program.



# PHPC

## Public Hospital Pharmacy Coalition

www.phpcrx.org

(A Coalition of the National Association of Public Hospitals and Health Systems)

### SUGGESTIONS FOR TIGHTENING UP PATIENT DEFINITION GUIDELINES<sup>1</sup>

1. ***Clarify that in order for a contractual relationship to satisfy the 340B professional care test,<sup>2</sup> the contract must be legally binding such that adequate “consideration” is given by both the covered entity and the professional.*** This will prevent contracts being used to extend 340B drugs to patients of non-entity physicians and other providers that really cannot be said to be providing services on behalf of the covered entity. For example, in order for a covered entity to dispense 340B-priced drugs to an individual receiving services from a physician who is not an employee of the covered entity, the covered entity should pay the non-employee physician fair market value for his or her services and such services must be medical rather than administrative in nature.
2. ***Tighten up the “other arrangements” provision<sup>3</sup> by formally incorporating the standards articulated in HRSA’s January 26, 2001 letter and by adding other limitations.*** Most disproportionate share hospitals have built their 340B programs around application of HRSA’s January 26, 2001 letter.<sup>4</sup> HRSA’s letter basically allows a hospital to fill non-hospital prescriptions only if the non-hospital care giving rise to the prescriptions is proximate in time and scope to the hospital care received by the patient. We recommend that these standards be explicitly applied to any individual who seeks 340B-priced drugs based on receiving care from a professional who is in a referral relationship or has other arrangements with the covered entity. We further recommend (1) that a service cannot be considered “hospital care” unless the cost of such care appears on a reimbursable line of the Medicare cost report and (2) that the non-hospital care cannot be considered to be proximate in time if more than a year has passed since the hospital care took place. The new guidelines should also make clear that, even if an individual satisfies the proximate relationship test established under HRSA’s letter, (1) the 340B drugs must be dispensed by a hospital pharmacy that is reimbursable on the hospital’s cost report (or by a contract pharmacy in compliance with the contract pharmacy guidelines) and (2) ownership of the drug may not be transferred to a third party, including the treating physician or other provider furnishing the non-hospital care, before the patient receives the drug.
3. ***For covered entities that use the “other arrangements” language to extend 340B pricing to employees and dependents, limit this practice to only those individuals who meet specific criteria.*** Employees and dependents should not automatically qualify for 340B-discounted drugs even though hospitals have historically filled employee prescriptions in accordance with the Robinson-Patman “own use” standard. Rather, use of the 340B program to

<sup>1</sup> 61 Fed. Reg. 55,156 (Oct. 24, 1996).

<sup>2</sup> *Id.* at (C)(2).

<sup>3</sup> *Id.*

<sup>4</sup> Letter from Thomas G. Morford, HRSA Deputy Administrator, to William H. von Oehsen, PHPC Counsel (January 26, 2001).



fill employee prescriptions should be limited to only those employees and dependents (1) who are enrolled in a covered entity's employee health plan that is self-insured, (2) who receive in-network services from participating physicians and other providers under contract with the plan, (3) who present prescriptions written in connection with such services, and (4) for whom the entity owns and/or maintains the health plan's records. The first two requirements are necessary to meet the 340B professional care test.<sup>5</sup> Responsibility for employee care remains with the covered entity because the health plan is self-insured, which means that the entity is ultimately responsible for arranging and reimbursing for such care. The third requirement is necessary to meet the proximate relationship test set forth in HRSA's January 26, 2001 letter. The last requirement is necessary to satisfy the maintenance-of-record test.<sup>6</sup>

4. ***Tighten up the reference to "health care services" in the professional care test<sup>7</sup> by requiring that the services be clinically meaningful, not duplicate existing care, involve face-to-face visits with a professional, and reflect ongoing care rather than a single encounter.***

This step would guard against covered entities providing one-time, superficial or unnecessary services to individuals as a basis for making them 340B-eligible. Telemedicine services, for example, would not create a patient relationship recognizable under 340B if the services simply involve a consultation via telephone or videoconferencing.

5. ***Define what kinds of case management and disease management services constitute "health care services" within the meaning of the patient definition professional care test.<sup>8</sup>*** Case management is a required service for community health centers, so it is important that an individual not be at risk of losing his or her 340B eligibility based on receiving case management services from a health center, even if those are the only services that the individual receives. With respect to case management services provided by hospitals and other types of covered entities, we recommend that HRSA rely on the distinction between direct patient services versus administrative services articulated in recent CMS guidelines and that HRSA only recognize the former type of case management for patient definition purposes.<sup>9</sup>

6. ***Clarify that a covered entity cannot be said to "maintain" a health care record<sup>10</sup> unless it incurs costs in performing such maintenance and the costs appear on a reimbursable line of the Medicare cost report.*** This limitation would prevent a covered entity from claiming that it maintains patient records that are simply copies of records generated by outside parties and supplied to the entity for the sole purpose of satisfying the maintenance-of-record test.

7. ***Clarify that whatever record is relied upon to satisfy the 340B maintenance-of-record test,<sup>11</sup> it must reflect the services giving rise to the order or prescription that the covered entity wants to fill with 340B drugs.*** Besides providing evidence that an individual is a *bona fide* patient of the covered entity, the maintenance-of-record requirement can serve a secondary purpose, namely, to provide an audit trail reflecting how a particular 340B-discounted drug is

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<sup>5</sup> 61 Fed. Reg. 55,156 at (C)(2) (Oct. 24, 1996).

<sup>6</sup> *Id.* at (C)(1).

<sup>7</sup> *Id.* at (C)(2).

<sup>8</sup> *Id.*

<sup>9</sup> CMS, Letter to State Medicaid Directors, SMDL # 04-002 (Feb. 25, 2004).

<sup>10</sup> 61 Fed. Reg. 55,156 at (C)(1).

<sup>11</sup> *Id.*

used by the provider. With respect to prescriptions written by outside physicians, the records should reflect that a referral to the prescribing physician was made or that the outside physician and covered entity are working together in caring for the patient.

8. ***Mention that pharmacy records alone cannot satisfy the maintenance-of-record test.*** The current guidelines specify that the dispensing of drugs to an individual is insufficient by itself to establish a patient relationship that would allow the covered entity to use 340B-priced drugs for that individual.<sup>12</sup> Consistent with this exclusion is the suggestion that a covered entity must maintain more than a pharmacy record to meet 340B standards.

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<sup>12</sup> Id. at 55,158.