THE HEMOPHILIA ALLIANCE

October 27, 2015

Captain Krista Pedley
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Mail Stop: 08W05A
Rockville, MD 20857

Submitted via regulations.gov.

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

Dear Captain Pedley:

The Hemophilia Alliance and its members thank you for this opportunity to provide comments on the proposed omnibus guidance. The Hemophilia Alliance is a non-profit organization comprised of approximately 100 hemophilia treatment centers (HTCs) across the United States that provide comprehensive specialized diagnostic and treatment services to patients with hemophilia and other bleeding and clotting disorders and participate in the 340B Drug Pricing Program. The Hemophilia Alliance serves as a group purchasing organization for participating HTCs and provides analytic, operational, and advocacy services to its members.

The Alliance's comments are organized into three sections, which follow this cover letter:

Executive Summary
Background on Hemophilia and the Hemophilia Treatment Center Network
Specific Comments on Proposed Omnibus Guidance

We look forward to working with HRSA to increase the integrity of the 340B program, while ensuring that HTCs can continue to participate in the program to benefit the thousands of patients with bleeding and clotting disorders that they serve.

If you have any questions or would like to discuss these comments further, please contact me by e-mail at joe@hemoalliance.org or by phone at 215-279-9236.

Sincerely yours,

Joe Pugliese,
President
The Hemophilia Alliance

Executive Summary

The National Network of Hemophilia Diagnostic and Treatment Centers were included as original covered entities in the 1992 legislation authorizing the 340B Program. Hemophilia Treatment Center (HTC) participation in the 340B program has provided a critical means of financial support for HTC services and maintaining comprehensive care for all patients seen at the center.

In reviewing the proposed omnibus guidance, our concerns and suggested revisions are focused on ensuring the continued participation of HTCs in this important program while supporting HRSA's efforts to prevent duplicate discounts and drug diversion. The Hemophilia Alliance is concerned that the proposed guidance does not recognize the current and varied structure of HTCs participating in 340B and sets up requirements that would hinder the ability of HTCs to serve their patient population. Our areas of greatest concern are as follows:

1. ***Provide clear eligibility for sub-recipients of Federal grants to be non-hospital covered entities***

The Hemophilia Alliance asks that the eligibility of sub-grantees and their responsibilities for compliance for all program requirements be clearly stated in the guidance. We believe that the simplest way to do this would be to be to add the term "Federal sub-grant" to the list of eligible non-hospital covered entities and include the term Federal sub-grant throughout the guidance wherever the term "Federal grant" is used. As an alternative we would suggest making it clear in the guidance that sub-recipients of Federal grants as defined in section 340B (a) (4) (G) (the statutory reference to HTC participation in the 340B program) are eligible non-hospital covered entities.

2. ***Revise patient definition criteria to accommodate HTC Network structure.***

The proposed guidance creates a six part test to determine patient eligibility for 340B drugs on a prescription-by-prescription/order-by-order basis. The Alliance has several concerns with the proposed criteria outlined in the guidance and suggests specific changes to recognize the broad scope of services provided by HTCs, including telemedicine and telepharmacy; the variety of relationships between HTC covered entities and their service providers; and the role that HTCs play in coordinating care for patients with co-morbidities of hemophilia. With the suggested changes highlighted **(in bold)** below we believe that HTCs can continue to serve their patients while meeting the requirements of the guidance.

> **Criterion 1:** The individual receives a health care **or clinical** service at a facility or clinic site **or a site that is approved under the scope of the grant, sub-grant, or project of** the non-hospital covered entity **and is** provided by a covered entity which is registered for the 340B Program and listed on the public 340B database.
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> **Criterion 2:** The individual receives a health care service from a health care provider who is employed by the covered entity or who is an independent contractor for the covered entity~~, such that the covered entity may bill for services on behalf of the provider~~ **or a provider who performs the services pursuant to a written agreement with the 340B covered entity. Faculty practice arrangements and established residency, internship, locum tenens, and volunteer health care provider programs are examples of covered entity-provider relationships that would meet this standard.**
>
> **Criterion 3:** An individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service described in (2). **The service delivery may**

include the use of telemedicine, telepharmacy, remote, or other health care arrangements. An individual will not be considered a patient of the covered entity if the only health care received by the individual from the covered entity is the infusion or dispensing of a drug.

Criterion 6: The individual has a relationship with the covered entity such that the covered entity maintains access to ~~auditable~~ health care records which demonstrate that the covered entity has a provider-to-patient relationship~~, that the responsibility for care is with the covered entity~~ and that each element of this patient definition in this section is met. ~~for each 340B drug~~.

3. Audits

The Alliance is concerned about a number of the audit provisions in the guidance, including the fact that the term "auditable records" is never clearly defined. The Alliance believes that HRSA's 340B audits of covered entities should be conducted in accordance with Government Auditing Standards, permit extensions of time, and provide an opportunity to appeal final decisions.

Background on Hemophilia and the Hemophilia Treatment Center Network

Hemophilia is a rare, chronic bleeding disorder affecting approximately 20,000 people in the US, who infuse high-cost clotting factor therapies to replace missing or deficient blood proteins. These therapies are safer and more effective than ever, but are also very expensive. Drug costs for a person with severe hemophilia can be $250,000 a year or more. Developing an inhibitor (an immune response to treatment) can increase those costs to $1 million. In addition, co-morbidities such as HIV/AIDS, hepatitis and joint disease, or bleeding as a result of trauma or surgery, can further impact clotting factor utilization and costs. Due to the high costs of treatment and the volatile nature of hemophilia and its complications and comorbidities, the hemophilia community is extremely medically vulnerable. HTCs also serve patients with other congenital and acquired bleeding and clotting disorders.

Most individuals with bleeding disorders receive care at HTCs, which provide comprehensive, multi-disciplinary, patient-centered care for bleeding disorders and their long-term complications. Studies have shown that mortality and hospitalization rates are 40% lower for people who use HTCs than in those who do not, despite the fact that more severely affected patients are more likely to be seen in HTCs.

According to the Centers for Disease Control and Prevention's most recent data from the Hemophilia Universal Data Collection system, almost half of the hemophilia population is on Medicaid, covered by high-risk insurance pools, or uninsured. These individuals with bleeding disorders would face significant barriers to good health and appropriate medical care if denied access to HTCs. The availability of the 340B drug discounts for high-cost clotting factor can dramatically reduce the comprehensive life-long health care costs for patients seen at the HTCs.

Federal funding for the National Network of Hemophilia Diagnostic and Treatment Centers is authorized by §501(a) (2) of the Social Security Act, the Maternal and Child Health Federal Set-Aside Program: Special Projects of Regional and National Significance (SPRANS) (42 U.S.C.

701(a) (2)), as amended.[1] There are approximately 140 HTCs that receive Federal funding as part of the Federal network, which is currently funded at approximately $4 million, with most HTCs receiving less than $30,000 annually. The network was established as a regional network of eight regional center grantees that oversee and provide sub-grants to the HTCs in their region.

In 1992, Congress included all HTCs funded by MCHB as covered entities in the 340B program as eligible grantees in order to stretch their Federal grant funding to provide comprehensive care without increasing Federal appropriations.[2] HTC participation in the 340B program has provided a critical means of financial support for HTC services and maintaining comprehensive care for all patients seen at the center.

Under the HHS grant regulations at 45 CFR part 75, all revenue generated by HTCs from the 340B discounted factor delivery programs is defined as "program income" because it is "earned as a result of the Federal award" under 45 CFR 75.2. The "program income" earned by an HTC is restricted under 45 CFR 75.307 so that it may only be used to supplement its activities consistent with the MCHB grant, and its expenditure must be in compliance with the HHS grant regulations, HHS Grant Policy Statement, and the terms of the Federal grant. This grant restriction ensures that the 340B revenue is used as intended by Congress and only benefits the 340B covered entities and the patients they serve as intended by the 340B program.

Specific Comments on Proposed Omnibus Guidance

General Comments: In general the Alliance is concerned that the one-size-fits-all approach taken in the guidance, with one set of requirements for hospital and non-hospital covered entities, has significant potential to be detrimental to the participation of HTCs and other grantees in the program. The mission and administrative set up of most grantees differs greatly from hospitals that participate in the 340B Program, and there are also significant differences among the grantees. **We ask that that HRSA recognize these differences and allow for some variance in the requirements outlined in the guidance based on the specific program requirements and organizational structure of each type of grantee.**

We also urge HRSA to comply with the Paperwork Reduction Act[3] as it relates to the many reports and record-keeping requirements in the proposed guidance. The Paperwork Reduction Act[4] clearance process provides an opportunity for comment on the necessity of the reports and record-keeping, evaluates the time, effort and financial resources necessary to comply, and to assess whether there are less burdensome ways to implement the requirement. We ask that all participants in the 340B program be afforded this opportunity as we find multiple requirements overly burdensome.

Part A – Eligibility and Registration of Covered Entities

1. **The proposed guidance definitions and non-hospital covered entity eligibility does not adequately describe HTC participation in the 340B Program and needs revision.**

[1] HTCs also receive grant funds from the Centers for Disease Control and Prevention, although that funding and the number of grants have been significantly reduced.
[2] H.R. Rep. No. 102-384 at 12.
[3] 44 USC §3501 et seq.

HRSA has structured the eligibility requirements in the proposed guidance such that only recipients of Federal grants, contracts, designations or projects will be considered eligible non-hospital covered entities. Most HTCs are sub-recipients of federal grants or sub-grantees; in fact, there are only eight grantees in the HTC network; the remaining 100 HTCs in the 340B program are sub-grantees. The guidance itself has no reference to sub-grantees and the definitions of "associated sites" and "child sites" do not adequately describe sub-recipients of Federal grants.

The guidance's preamble states: "HHS will list sites (in the 340B database) that are sub-recipients of Federal grants, but seeking their own 340B identification (ID) numbers separate from a parent entity if those entities provide information demonstrating their receipt of eligible Federal funds … as well as their grant number under which they receive those funds." This language makes clear that sub-recipients of Federal grants can register for the 340B program and receive a unique ID number from their Federal grantees, but the guidance does not clearly state that the responsibilities for program registration, operation and compliance lies with the individual participating sub-grantee, not the Federal grantee.

Alliance suggested change to eligibility language:

The Hemophilia Alliance asks that the eligibility of sub-grantees and their responsibilities for compliance for all program requirements be clearly stated in the guidance. **The simplest way to do this would be to be to add the term "Federal sub-grantee" to the list of eligible non-hospital covered entities and include the term Federal sub-grant throughout the guidance wherever the term "Federal grant" is used.**

Non-Hospital Covered Entities

(a) *Eligibility.* A non-hospital entity will be listed on the public 340B database if it registers and establishes that it receives a qualifying Federal grant, **Federal sub-grant,** Federal contract, Federal designation, or Federal project as defined in sections 340B(a)(4)(A) through (K) of the PHSA. HHS will assign a unique 340B identification number to represent each entity type for which a non-hospital covered entity registers and demonstrates eligibility, and list the entity accordingly on the public 340B database.

In addition, we suggest adding a separate paragraph to address the responsibilities of grant sub-recipients as defined in 340B (a) (4) (G) (the HTC regional network) as follows:

Non-Hospital Covered Entities

(b) *Eligibility.* A non-hospital entity will be listed on the public 340B database if it registers and establishes that it receives a qualifying Federal grant, **Federal sub-grant**, Federal contract, Federal designation, or Federal project as defined in sections 340B(a)(4)(A) through (K) of the PHSA. HHS will assign a unique 340B identification number to represent each entity type for which a non-hospital covered entity registers and demonstrates eligibility, and list the entity accordingly on the public 340B database.

(c) *Eligibility of Sub-recipients of Federal grants as defined in section 340B (a) (4) (G).* A sub-recipient of a Federal grant as defined in section 340B (a) (4) (G) of PHSA will be listed on the public 340B database if it registers and establishes that it receives a qualifying Federal sub-grant. HHS will assign a unique 340B identification number to each sub-recipient of a 340B (a) (4) (G) grant that registers and demonstrates eligibility, and list the entity accordingly on the

public 340B database. A sub-recipient of a Federal grant as defined in section 340B (a) (4) (G) of PHSA is responsible for its compliance with all requirements in this guidance as related to its participation in the 340B program and can register for the program even if its regional Federal grantee does not participate in the program and is not registered on the 340B database.

Justification for separate eligibility language for sub-recipients of grants

The guidance's language regarding associated and child sites is inadequate to cover the structure of the HTC network. The guidance defines an "associated site" as "a health care delivery site which is not located at the same physical address" as the covered entity, "but is a part of" the covered entity and "delivers outpatient health services for the non-hospital covered entity." The guidance goes on to say that an associated site once enrolled in the 340B Program is referred to as a child site.[5] The definition of "child site" includes a non-hospital covered entity associated site that is derived from an enrolled parent site, is enrolled in the 340B Program, and is listed on the public 340B database.

There are multiple ways in which this language is inadequate for HTCs:

First, there are only eight grantees in the HTC network; the remaining 100 HTCs in the 340B program are sub-grantees. The eight direct recipients of the MCHB grants under the Hemophilia Treatment Center Network program are responsible for distributing sub-grants to the HTCs in their region and for assuring that sub-grantees meet the requirements of the MCHB Hemophilia grant program, but they do not have responsibility for ensuring compliance with 340B requirements.

Second, there is no requirement that HTCs participate in the 340B program and two of the eight Federal grantees do not participate in 340B. As a result, forcing all of the grantees and sub-grantees inappropriately into a parent-child structure will cause the ineligibility of numerous HTCs whose regional grantee is not a 340B participant. In these two regions (Great Lakes Region: Indiana, Michigan, Ohio; and the Northern Region: Illinois, Minnesota, Wisconsin, North Dakota, and South Dakota), no parent-child relationship as defined in the guidance can exist. Since the inception of the 340B program in 1992, both the direct recipients of MCHB grants designated as "Regional Centers" and their HTC sub-recipients have historically independently registered as 340B covered entities.

Third, HTCs are not a part of their regional grantee's organization - there is no legal ownership, affiliation, or organizational relationship between the direct recipient of the HTC grants and its sub-recipient grantees. In addition, the regional grantees in the hemophilia program are not in any way responsible for 340B compliance for any HTC but the one they operate. Without any legal control over the sub-recipient organization, the direct recipient cannot be liable for their sub-recipients' compliance with the 340B program. HRSA's HTC grant awards contain no terms regarding compliance with the 340B Drug Discount program and HRSA cannot direct that the recipient of a Federal grant be liable for a sub-recipient's compliance with 340B. The terms of the HTC grant awards and sub-recipient agreements only require compliance with the MCHB grant program requirements and HHS grant regulations, not with the 340B program. Parent liability as outlined in the guidance simply cannot apply to the Regional Centers.

[5] 80 Fed. Reg. 52316.

For these reasons, sub-recipient HTCs must be able to operate independently in the 340B program and not be considered or classified as "associates" or "children" of the "parent" regional grantee.[6] Alliance members are extremely concerned that approximately 90 sub-recipient HTCs might be construed under this language as "associated sites" or "child sites" of the eight regional grantees. We urge you to accept our suggested language specific to grant sub-recipient under the Hemophilia Network to rectify this situation.

We recognize that it may be HRSA's intent to have the public database identify the direct recipients under 340B (a) (4) (G) by a special number or designation in order to link to its sub-recipient enrolled covered entities. We believe that this can be created within the system without requiring the regional grantees to enroll in the 340B program or to become responsible for the sub-recipients' compliance with the 340B program. The sub-recipient HTC can provide a copy of its sub-recipient agreement that can be verified by MCHB and the Office of Financial Assistance Management. If there is a number or letter assigned to each of the Regions, then that identifier can be added to the registered sub-recipient's 340B identification number on the database.

2. Definition of an Associated Site

The Alliance, along with the other grantee participants in the 340B program, is also concerned with the definition and registration requirements for so-called "associated sites." We do not believe that the current definition adequately accounts for the various ways and different types of sites utilized by HTCs to provide services to their patients. Many HTCs serve their patients at sites approved under the scope of their grant or sub-grant that are not legally part of the 340B covered entity. These sites of service may be temporary, lack a fixed address, and can change at the last minute. The Alliance would ask that sites approved under the scope of the Federal grant or sub-grant be eligible sites for serving patients and not be required to be separately registered entities.

Alliance suggested change to the definition of an associated site:

> **Associated site** is a health care delivery site which is not located at the same physical address as a non-hospital covered entity, but is part of **or is approved under the scope of the grant, sub-grant, or project of** ~~and delivers outpatient services for~~ the non-hospital covered entity **and delivers outpatient services on its behalf or pursuant to an arrangement with the non-hospital covered entity.**

Part C- Individuals Eligible to Receive 340B Drugs

3. Patient Definition changes needed to accommodate HTC Network structure.

The proposed guidance creates a six-part test to determine patient eligibility for 340B drugs on a prescription-by-prescription/order-by-order basis. For patients with a chronic disease like hemophilia who receive healthcare services from the HTC throughout their lives, it doesn't make sense to determine patient eligibility on a script-by-script basis. An HTC patient's eligibility will remain fairly constant throughout his lifespan. For patients who move or transition from

[6] We understand that every HTC registering as a covered entity is verified by the HRSA Office of Financial Assistance Management (OFAM) and MCHB to be either a direct recipient of a Federal MCHB grant or a sub-recipient.

pediatric to adult centers resulting in a change in HTC, this change in patient care responsibility is always well-documented. **The Alliance urges HRSA not to require that the patient definition six-criteria test be implemented for non-hospital covered entities on a per prescription or order basis.**

In addition, the Alliance has several concerns with the proposed criteria outlined in the guidance and suggests changes to each criterion to enable HTCs to continue to serve their patients while meeting the requirements of the 340B Program, which are listed in order below:

Alliance suggested change to Criterion 1: The individual receives a health care **or clinical** service at a facility or clinic site **or a site that is approved under the scope of the grant, sub-grant, or project of** the non-hospital covered entity **and is** provided by a covered entity which is registered for the 340B Program and listed on the public 340B database.

HTCs provide a broad array of healthcare services to patients by an inter-disciplinary team of providers. The inclusion of the term "clinical" should encompass the work of nurses, physician assistants, pharmacists, and clinical social workers, who are an integral part of the comprehensive care team. These professionals train patients to self-infuse, assure patients are complying with medication adherence, and provide appropriate psychosocial support. For this reason, we seek the addition of the term "clinical" to the description of services provided or at the very least ask that HRSA accept a broad definition of healthcare services under criterion 1.

The second issue with criterion 1 is the limitation that a patient must receive services at a facility or site that is registered for the 340B program. This requirement is fine for the permanent locations at which HTCs provide healthcare services, since these sites would be relatively easy to register with HRSA. The Alliance is more concerned with the significant outreach services provided by HTCs at multiple locations, which often change on a monthly or weekly basis. Outreach is an important element of the HTCs' grant requirements, mentioned more than 20 times in the Regional Hemophilia Network program requirements published by MCHB (HRSA-12-133) and included in the scope of the Federal grants and sub-grants.

Some off-site clinics are regularly scheduled, but many are just single events or only occasionally offered. Since outreach locations sometimes change at the last minute, the sites would not be able to comply with the registration process outlined in the guidance and 340B drugs could not be provided to patients. The sort of places that HTCs conduct patient outreach would not meet the definition of an associated or child site because they are typically not a part of the covered entity – they can be community centers or a rural physician's office that has worked cooperatively with the HTCs for many years. In addition, the site of service will sometimes be the patient's home. Ideally, we would suggest eliminating the on-site requirement in criterion 1.

However, if HRSA is interested in creating a new registration requirement for off-site healthcare services conducted by HTCs, the Alliance would ask that the terminology we suggest for the associated site definition be repeated in criterion 1. We believe that it should be the responsibility of the HRSA department awarding grantees to approve sites of service recognizing the needs of the patients and the operation of the program.

Alliance suggested change to Criterion 2: The individual receives a health care service from a health care provider who is employed by the covered entity or who is an independent contractor for the covered entity~~, such that the covered entity may bill for services on behalf of the provider~~ **or a provider who performs the services pursuant to a written agreement with**

the 340B covered entity. Faculty practice arrangements and established residency, internship, locum tenens, and volunteer health care provider programs are examples of covered entity-provider relationships that would meet this standard.

The second criterion requires that patients receive healthcare services from a provider who is "employed" or is an "independent contractor" with the covered entity and suggests that the covered entity be able to bill for their services. In the proposed guidance, HRSA has eliminated the current patient definition allowing for "other arrangements" between covered entities and providers. There are many different ways that HTCs engage with the providers that serve their patients. In the academic setting (a frequent model for HTCs), the HTC may be owned and operated by a university or a hospital, but the hematologists and other physicians prescribing medications will be part of the physician group practice plan that serves the hospital's patients. Other arrangements exist between HTCs and physicians in rural areas serving in outreach clinics and for the treatment of comorbidities of hemophilia such as HIV and Hepatitis C. While an HTC can have written agreements with these providers, they are often not "employed by" the HTC and are not necessarily defined as "independent contractors," which denotes the HTC pays them for their services. Some provide their services at no charge to the HTC and others bill directly for their services.

It is critically important that HRSA allow for additional arrangements between covered entities and physicians, or at the very least between HTCs and their providers. We recognize that HRSA would like to be able to verify that these arrangements exist and the Alliance would support a requirement that a written agreement exist between the covered entity and the providers serving the covered entity's patients. We also suggest that the language from the preamble of the guidance be restated under criterion 2 to assure that this list of acceptable provider arrangements are clearly available to covered entities.

Alliance suggested change to Criterion 3: An individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service described in (2). **The service delivery may include the use of telemedicine, telepharmacy, remote, or other health care arrangements.** An individual will not be considered a patient of the covered entity if the only health care received by the individual from the covered entity is the infusion or dispensing of a drug.

The guidance preamble provides additional explanation regarding what qualifies a prescription received "as a result of a service" to include the delivery of health care services by "telemedicine, telepharmacy, remote, and other health care service arrangements (e.g., medication therapy management) involving the issuance of a prescription by a covered entity is permitted." HTC patients are often remotely located from the clinic, and may be in situations where the quickest consultation with the provider is by telephone. These alternative deliveries of health care services are essential for the comprehensive care of hemophilia patients. While we believe that HRSA intends to consider these methods of delivery of health care services as qualifying for 340B drug prescriptions, the guidance should explicitly include them so that it would not be questioned or misinterpreted.

Proposed Guidance Criterion 4: The individual's health care is consistent with scope of the Federal grant, project, designation, or contract.

The Alliance has no concerns about criterion 4 in the patient definition.

Proposed Guidance Criterion 5: The individual is classified as an outpatient when the drug is ordered or prescribed.

The Alliance is concerned that this criterion could impact prescriptions written upon a patient's discharge from the hospital. Most patients are not admitted for their hemophilia, but for orthopedic surgery (to treat joint damage due to hemophilia), treatment for comorbidities such as HIV, Hepatitis C/liver disease or for other more common issues such as cardiac care. The HTC physician is usually involved in the patient's care while he is hospitalized, but is not the attending or physician responsible for the patient's discharge from the hospital. Most patients following hospitalization will need a new prescription from the HTC provider and for ease of patient care it should be written on the day of hospital discharge. The Alliance has recommended that HTCs contact patients immediately following hospital discharge to go over the patient's hemophilia care and consider any changes in clotting factor treatment. We believe that current practice can be maintained under this criterion with this understanding.

Alliance suggested change to Criterion 6: The individual has a relationship with the covered entity such that the covered entity maintains access to ~~auditable~~ health care records which demonstrate that the covered entity has a provider-to-patient relationship~~, that the responsibility for care is with the covered entity~~ and that each element of this patient definition in this section is met. ~~for each 340B drug~~.

The Alliance has concerns with the requirement that "auditable" health care records be maintained when no definition of the term "auditable" is provided. It is not clear what kind of records a covered entity is being required to maintain.

Patients with hemophilia experience co-morbidity issues such as HIV and Hepatitis C and other common problems that are treated collaboratively by HTC personnel and other specialists. HTC patients may be seen by other physicians, but care is closely coordinated. The HTC doctor or the collaborating physician may write the prescription for drugs to treat both diseases, which would be eligible for 340B discount. HRSA should not construct unnecessary barriers to this kind of comprehensive care provided by the HTCs. We suggest, therefore, striking "responsibility for care is with the covered entity." The HTC will have access to all patient records, establishing its "provider to patient relationship," but the "responsibility for the care" of the patient could be shared and not solely be the responsibility of the covered entity.

4. Patient Definition Exceptions: Recognizing local and patient specific emergencies beyond those declared as Public Health Emergencies by the Secretary of HHS.

Alliance suggested change to Public Health Emergency exception:
(2) ***Public health and other emergencies*** ~~***declared by the Secretary***~~**.** If normal healthcare operations are disrupted due to a public health emergency declared by the Secretary **or a local health or other emergency**, **a covered entity may request, and HHS may authorize**, a covered entity to temporarily follow alternate patient eligibility criteria. A covered entity must maintain ~~auditable~~ records that document the alternate patient eligibility criteria used and the exact dates for which alternate patient eligibility criteria are in effect.

An HTC might experience some calamity, such as a local fire or flooding, which impacts its ability to provide healthcare services and to dispense drugs to their patients. When HTCs have faced this in the past, upon request, HRSA has allowed the HTC affected by the emergency to work with another HTC to dispense drugs to its patients. HTCs generally have documented

operation plans for such events and we recommend they register alternative pharmacies just for such emergencies. We request, however, for the flexibility that has been provided in the past to be included in the guidance and ask that the Public Health Emergency exception to the patient definition allow covered entities to request HRSA approval in local and site specific emergencies that may not be designated by the Secretary. This is needed to meet the needs of patients without exposing the HTC to 340B non-compliance.

5. Revision to replenishment language is needed to recognize emergency situations.

Alliance suggested change to replenishment language:
(c) Replenishment. To avoid a violation of the statutory prohibition on diversion, a covered entity that utilizes a drug replenishment model may only order 340B drugs based on actual prior usage for eligible patients of that covered entity as defined by this guidance**, unless the order is to meet a patient's emergency needs.**

Not many HTCs utilize the replenishment model, but for those that do, there must be an exception for emergency situations. HTCs monitor their patients' usage very well and orders are based upon that knowledge. However, there are also situations where a patient may have suffer an accident or an internal bleed or be on extended travel, and the HTC must be able to significantly increase the order to meet that patient's needs. We also question how ordering drugs for the covered entities' patients could be determined to be "diversion" as long as it was provided to the HTC patient.

Part D- Covered Entity Responsibilities

6. Prohibition of Duplicate Discounts – Flexibility should be maintained with regards to agreements with Medicaid Managed Care Organizations and Contract Pharmacy Agreements.

Our members appreciate the flexibility to choose whether or not to provide 340B drugs depending upon the Medicaid managed care organization (MCO). HTCs have been successful in working with State Medicaid Offices to identify when 340B drugs are provided to MCO patients to prevent duplicate discounts, including some HTCs who utilize contract pharmacies. While we support HRSA's implementation of a mechanism for States and MCOs to identify when 340B drugs have been billed, the Alliance does not support the provisions in the guidance that would require prior approval by HRSA for every contract pharmacy agreement. This would interrupt current arrangements HTCs have entered into for contract pharmacies dispensing drugs for both Medicaid FFS and MCO patients. Drafting these newly required agreements with a State Medicaid agency or MCO is time consuming and unnecessary if there is already an agreed-upon process that is working. We do not oppose including the procedures in our contract pharmacy agreements, but requiring prior review and approval of every agreement by HRSA before drugs can be dispensed would unnecessarily burden covered entities, interrupt current operations, and cause extended delays.

Therefore, we request that HRSA not interrupt current agreements between covered entities, MCOs, and State Medicaid Offices. Similarly, we do not believe that HRSA should review and approve every agreement, though it could review them upon request. If HRSA is intent on requiring covered entities to have signed agreements with MCOs and State Medicaid Offices, then time should be allowed for their preparation without prohibiting current claims processing. The Alliance recommends that HRSA:

(1) allow the continuation of arrangements reached between the parties to date,
(2) ask covered entities to document those arrangements, rather than have a contract signed by all parties, and
(3) ask covered entities to make all agreements available for HRSA review upon request as it deems necessary.

Alliance suggested change to Prohibition of Duplicate Discounts (c.) Contract pharmacy:

(c) *Contract Pharmacy.* Unless otherwise noted on the public database, contract pharmacies will not dispense 340B drugs for Medicaid FFS or MCO patients. If a covered entity wishes to purchase 340B drugs for Medicaid FFS or MCO patients and dispense 340B drugs utilizing a contract pharmacy, the covered entity will ~~provide~~ **maintain** a written agreement with its contract pharmacy and State Medicaid agency or MCO that describes a system to prevent duplicate discounts **and provide a copy for review and approval upon request by** ~~for~~ HHS ~~approval~~,

7. Maintenance of Auditable Records Should Not Be an Eligibility Requirement.

Alliance suggested change to language on Maintenance of Auditable Records:

Part D – Covered Entity Responsibilities/Maintenance of ~~Auditable~~ Records.
A covered entity must maintain ~~auditable~~ records demonstrating compliance with all 340B Program requirements for itself, any child site, and any contract pharmacy for 5 years from the date the 340B drug was ordered or prescribed, regardless of whether the entity continues to participate in the 340B Program. 340B Program records must be made available to HHS at any time and to certain manufacturers pursuant to an audit. If an entity, any child site, or any contract pharmacy terminates its 340B Program participation, an entity must maintain applicable ~~auditable~~ records for 5 years after the date of termination.

(a) Failure to maintain records. If a covered entity cannot produce records pertaining to compliance with any specific 340B Program requirement during an audit or pursuant to a request from HHS, the covered entity could be presumed to be out of compliance with that 340B Program requirement and subject to the penalty applicable to the requirement. If a covered entity systematically ~~fails to maintain auditable records, which is a statutory eligibility requirement, or~~ ~~fails~~ **refuses** to provide **their records** ~~them~~ as requested by HHS or a manufacturer authorized to conduct an audit, the covered entity will be removed from the 340B Program after a notice and hearing process as described in this guidance. A covered entity deemed ineligible and removed from the 340B Program for ~~failure to maintain auditable records~~ **refusal to provide records for audit** ~~would~~ **may** be liable for repayment to manufacturers. ~~for periods of ineligibility.~~

Justification for suggested language
HTCs that participate in the 340B Program understand that they must maintain records establishing their compliance with the program. The Alliance is concerned that HRSA does not define the term "auditable" in the guidance, nor does it specify what types of records covered entities would be required to maintain. Greater guidance is needed with regard to this requirement so that covered entities can comply. Without defining the terms or describing what records are required, we suggest deleting the adjective "auditable" and simply state that records must be kept demonstrating program compliance as suggested in the revised language.

What causes more concern is that HRSA states that having auditable records is a "statutory eligibility requirement." There is no reference in Section 42 USC 256b that says covered entities can lose their eligibility if they do not maintain "auditable records." Under the statute, HRSA and manufacturers clearly have the right to conduct an audit of a covered entity, which would include the review of documentation. The Alliance asserts that HRSA cannot tie a covered entity's eligibility to having auditable records, since 340B eligibility of HTCs is provided at 42 USC 256b (a) (4) (G). Obviously, to be prepared for a HRSA or manufacturer audit, the HTC will have to provide documentation, but this is not a condition of eligibility.

Audits are permitted under the statute for the purpose of determining two things - whether the covered entity is responsible for duplicate discounts under 42 USC 256b (a) (5) (A), and for diversion of a 340B drug at 256b (a) (5) (B). The sanction for noncompliance in the statute is clearly stated at 42 USC 246b (a) (5) (D), which stipulates that the covered entity shall be liable to the manufacturer for the covered outpatient drug for an amount equal to the 340B reduction in price of the drug.

The other sanctions in the statute are found at 256b (d) (2) (B) (v), which only apply to the diversion of 340B drugs where there was a "knowing and intentional" violation by the covered entity which requires the payment of a monetary penalty to the manufacturer;[7] or if there was a "systematic and egregious" as well as "knowing and intentional"[8] diversion[9] with the sanction of removal from the program. The 340B statute does not authorize removal from the program for failure to have records. HRSA should significantly revise this section to simply state the record-keeping requirements, including the need to provide access to those records by HRSA or manufacturers for purposes of audits, and remove all sanctions related to recordkeeping.

Part E – Contract Pharmacy Arrangements

8. Contract Pharmacy Oversight Requirements Are Too Burdensome

Alliance suggested change to contract pharmacy language:

> ***Part E – Contract Pharmacy Arrangements (b) Compliance with statutory requirements***
> *(3) Contract pharmacy oversight.* The covered entity is expected to conduct ~~quarterly~~ **periodic** reviews and ~~annual~~ independent audits **as necessary**, of each contract pharmacy location; the results of these reviews are included in the records' requirements of section 340B(a)(5)(C) of the PHSA. Any 340B Program violation detected through ~~quarterly~~ reviews or ~~annual~~ audits of a contract pharmacy should be disclosed to HHS. Covered entities are subject to the applicable penalties for instances of duplicate discounts and diversion.

First, we would like to echo our prior comments related to public health and local emergencies and the need for HTCs to request HRSA approval for additional pharmacy locations. HTCs need the flexibility to request approval for additional contract pharmacies in emergency situations to serve patients.

[7] 42 USC 256b(d)(2)(B)(v)(I).
[8] 42 USC 256b(d)(2)(B)(v)(II).
[9] 42 USC 256b(a)(5)(B).

In addition, many HTCs are very small organizations that simply don't have the staff or financial resources to conduct quarterly contract pharmacy reviews and annual independent audits of contract pharmacies. It is expensive to hire an outside audit firm and annual audits would be extremely time-consuming. HTCs usually have a manager that routinely reviews pharmacy transactions as a self-monitoring tool and this should continue to be an acceptable practice. HRSA should not impose the requirement to use outside auditors annually, especially when the requirement is not statutorily based, and the government is not funding the audits. Please allow an HTC flexibility to determine when it should engage an outside firm and expend the funds on an independent audit.

HRSA requires notification of any and all 340B program violations, even in those cases where the HTC corrected the violation through its own oversight. The Alliance does not agree that each and every error that is corrected in a timely manner should require notification to HRSA. The notification of "material violations" will occur at annual re-certification. Notifying HRSA of all errors corrected is not supported by the statute, which only speaks to "material violations" requiring sanctions.

We strongly urge HRSA to provide more flexibility on the timing of the reviews, eliminate the self-disclosure of errors that have been corrected, and allow an internal audit in lieu of an independent audit. If HRSA retains the requirement for independent audits, we ask the Final Guidance to extend the frequency to at least every two or three years.

Part H – Program Integrity

9. HRSA's 340B Audits of Covered Entities Should Be Conducted in Accordance with the Government Auditing Standards, Permit Extensions of Time, and Provide an Opportunity to Appeal Final Decisions

Alliance suggested change to program integrity language:

Part H – Program Integrity - HHS audit of a covered entity.
Pursuant to section 340B(a)(5)(C) of the PHSA, a covered entity participating in the 340B Program, including all its child sites and contract pharmacies, is subject to audit by HHS to determine if it is complying with all 340B Program requirements. **HHS shall conduct the audit in accordance with the Generally Accepted Government Auditing Standards (GAGAS).** HHS will ensure that only one 340B Program audit of a covered entity, its child sites, and contract pharmacies is in process at any given time, including a 340B Program audit by a manufacturer. HHS will notify the covered entity of its intent to audit. HHS will have the option to conduct an on-site review, a review of documentation submitted to HHS, or both.

(a) Provision of ~~auditable~~ records. At HHS's request, the covered entity shall provide or arrange for access to all specified records pertaining to 340B Program compliance on behalf of the parent covered entity site, its child sites, and its contract pharmacies by the deadline specified. Failure to provide records or respond to requests for information within HHS-specified deadlines may result in the penalties specified in this guidance for **systematic and egregious** failure to maintain ~~auditable~~ records and termination from the 340B Program.

(b) Notice and hearing. HHS will initiate a notice and hearing process under which a covered entity has the opportunity to respond to adverse audit findings and other instances of noncompliance or to respond to the proposed loss of 340B Program eligibility. HHS

initiates the process by providing written notice that will specify a ~~30~~ **45 day** response deadline. The covered entity responds in writing to each issue of noncompliance, providing supporting documentation as necessary, including but not limited to a revised or amended cost report accepted for filing. **If there is a factual dispute, HHS may conduct an oral hearing.** HHS will issue a final written notice with is final determination regarding noncompliance. If the final determination of noncompliance includes a finding that the covered entity is no longer eligible, HHS will determine the removal date. The covered entity is liable for repayment to affected manufacturers for purchases made after the date the entity loses its eligibility. **The covered entity may appeal the final decision within 45 days of the date of the final decision.**

Justification for suggested language

Non-hospital covered entities participating in 340B are accustomed to Medicaid, Medicare, and financial assistance audits, all of which are conducted in accordance with Generally Accepted Government Auditing Standards (GAGAS). In fact, HRSA requires that manufacturers' audits of covered entities be performed in accordance with GAGAS as well, but does not require it for HRSA audits of covered entities. The Yellow Book contains requirements and guidance dealing with ethics, independence, auditors' professional judgment, competence, quality control, standards for performance of the audit, and issuing reports and findings.[10] We believe that 340B compliance audits should be conducted in accordance with the Yellow Book because they qualify as "performance audits" which are defined to assess the covered entity's compliance with applicable law and regulations governing the 340B program.[11]

Additionally, we believe that the 30 days response time is completely inadequate to provide for a complete response with supporting documentation. We suggest that HRSA allow at least 30-45 business days or 60 calendar days. At minimum, covered entities should be able to request an extension of time. Additionally, the guidance does not provide any opportunity for appeals of final audit decisions. Most government audits provide for an appeal of the final decision to an independent official who is not within the same office as the final decision-maker. We encourage HRSA to provide such opportunity for appeals. Such appeals could be considered by the HHS Departmental Appeals Board, or perhaps by an attorney in HRSA's General Counsel's office.

HRSA states that a result of an audit can include a finding that a covered entity is no longer eligible and determine a removal date. We would like the final guidance to reference "that such finding of ineligibility is based upon the statutory eligibility criteria under the PHSA at 45 USC 256b (a) (4) (A)-(O), or for findings of sanctions defined at 340B (d) (2) (B) (v)." This clarifies that eligibility under the law is not based on an auditor's finding that the covered entity does not have "auditable records."

[10] *Id.* Section 1.01, 1.02, and 1.07(c).
[11] *Id.* Sections 1.04 and 2.10-11.