October 27, 2015

Captain Krista Pedley
Director, Office of Pharmacy Affairs (OPA)
Health Resources and Services Administration
5600 Fishers Lane, Mail Stop 08W05A
Rockville, Maryland 20857

Submitted via www.regulations.gov

RE: Joint "Grantee" Comments on 340B Drug Pricing Program Omnibus Guidance, Federal Register, Vol. 80, No. 167, 52300, (August 28, 2015)

Dear Captain Pedley:

We, the nine undersigned organizations, are pleased to submit the following comments on the Health Resources and Services' (HRSA's) proposed guidance on the 340B Program published in the Federal Register on August 28, 2015. Jointly, we represent the majority of "grantee" covered entities – meaning those covered entities that are not hospitals – including (in the order in which they are presented on HRSA's webpage): Federally Qualified Health Centers (FQHCs), including both grantees and Look-Alikes[1]; Ryan White HIV/AIDS Program grantees and subgrantees; Comprehensive Hemophilia Diagnostic Treatment Centers; Title X Family Planning Clinics; and Sexually Transmitted Disease Clinics.

We believe that our members fulfill a vital role in the 340B Program and can provide a unique perspective on the draft guidance. We begin with a summary of our comments, and then address each one in detail.

Summary of Comments

Cross-Cutting Comments

- The proposed one-size-fits-all approach to managing covered entities does not take into account each grantee's unique, statutorily-mandated structure and goals, and as a result is often detrimental to HRSA grantees and their patients. We therefore request that, when establishing expectations and processes for the 340B Program, HRSA take into account the specific organizational structures, program requirements, Federal oversight, and statutory goals that apply to each type of "HRSA grantee" which is eligible for the program.

[1] Officially, FQHC Look-Alikes are not grantees, as they do not receive direct grant support from HRSA. However, they are subject to the same requirements and oversight as FQHCs who receive grants, so for simplicity we include them in the category of "grantees."

- A critical example of the shortcomings of this one-size-fits-all approach is the proposed revisions to the "patient definition," which will have significant negative impacts on grantees and their patients.
- The guidance should not create large administrative burdens in an attempt to rectify small issues of non-compliance.

The "one-size-fits-all" patient definition is contrary to the statute and will have significant negative impacts on grantees and their patients.

HRSA's proposed 6-part "patient definition" raises serious concerns for our grantee organizations, as follows:

- Statutory: It is contrary to 340B statute, which defines eligibility on a person-by-person basis, not a script-by-script basis.
- Operational: It would severely weaken the ability of many grantee types to achieve their statutorily-mandated purpose, for a variety of reasons depending on the grantee type.

The proposed one-size-fits-all patient definition is a very blunt tool which fails to recognize the unique structures and purposes of the range of eligible covered entities. As a result, while it may address concerns in some areas of the program, if applied uniformly to all covered entities it would have significant, negative impact on grantees and their patients. In Section C.2., we provide examples of the significant negative impact which each prong of the proposed "patient definition" would have on one type of grantee. Please note that ***this is far from an exhaustive list of ways in which the proposed definition will harm grantees and their patients.*** (For detailed discussions of how it will impact each grantee type, and how these concerns can best be addressed, see our individual organizations' comments.) Rather, it is only a sample of the negative impacts, intended to demonstrate that:

- While grantee types vary enormously in structure and purpose, we share a major concern that the proposed definition will cause significant harm.
- There is no single cause of concern, or "easy fix" that will resolve all these issues. Rather, while some of our issues do overlap, our concerns – and the parts of the definition that raise them – vary almost as much as our organizations do.

Part A - Eligibility and Registration of Covered Entities

Our organizations jointly recommend that HRSA:

- Streamline and accelerate the site registration process to avoid multi-month delays in 340B access for eligible grantees and their patients.
- Indicate that subrecipients are eligible for the 340B Program by virtue of the subgrants awarded by the direct grantee, by giving them their own eligibility definition.
- Clarify that a group of parent and child sites that share common ownership and control may transfer inventory among all their sites.
- Ensure that the guidance and registration system are appropriate for the full range of eligible sites used by grantees.
- State in the guidance that entities who receive in-kind contributions are eligible.

- Permit 340B sites to replenish drugs provided to eligible patients prior to their termination date.

Part B. Eligible Prescription

- We recommend that HRSA incorporate language into the final guidance, as appropriate, prohibiting manufacturers from unilaterally denying 340B sales based on compliance with HRSA's interpretation of the "covered outpatient drug" definition.

Part C – Additional Comments

Our organizations support HRSA's continuation of the unique patient definition for AIDS Drug Assistance Programs (ADAPs), as this definition is appropriate to the unique structure and purpose of ADAP programs. In addition, we recommend that HRSA:

- Expand Guidance to incorporate the broad definition of employed or contracted providers.
- Incorporate language about telemedicine, etc. into the Guidance.
- Clarify that Expedited Partner Therapy (EPT) is permissible under the 340B Program (specifically under Criterion #3 of the proposed patient definition).

Part D - Requirements on Covered Entities

With regard to Medicaid, our organizations jointly recommend that HRSA:

- Clarify that the Medicaid Exclusion File (MEF) currently applies only to Fee-for-Service.
- Permit covered entities to vary carve-in/ carve-out decisions based on individual drugs.
- Remove the requirement for a state or MCO to sign a contract with each contract pharmacy in order to carve out.
- Encourage or require States to develop a mechanism for grantees to identify 340B drugs to States/ MCOs.

With regard to audit standards, our organizations jointly recommend that HRSA:

- Conduct audits in accordance with the government audit standards, including the "Yellow Book."
- Provide covered entities with more time to respond to audit findings.
- Provide covered entities with opportunities for oral hearings and appeals.
- Publish HRSA/OPA's audit protocol, to assist covered entities in knowing how compliance will be evaluated, and increase consistency across auditors.
- Implement the proposed requirement to maintain auditable records for 5 years on prospective basis.

Part E - Contract pharmacy arrangements

Our organizations jointly support HRSA's proposals to:

- Not limit number of pharmacies with which a grantee may contract.
- Instruct covered entities to ensure their contract pharmacy arrangements are consistent with the intent of the 340B Program.

Part F – Manufacturer Responsibilities

- Our organizations support HRSA's proposals to require manufacturers to ensure that limited distribution networks do not discriminate against 340B covered entities.
- We request that HRSA state in the guidance that 340B prices apply to drugs sold via Limited Distribution Networks.

Part G – ADAP Rebates

Our organizations jointly recommend that HRSA:

- Clarify that the proposed qualified payment definition requires the ADAP to pay only the portion of the insurance premium that is attributable to the client.
- State explicitly that manufacturers may not withhold rebates from ADAPs due to issues related to the qualified payment definition (or other compliance issues).

Part H – Program Integrity

Our organizations jointly support HRSA's proposals to:

- Permit covered entities to be subjected to no more than one audit at a time.
- Ensure that appropriate parameters are in place around manufacturers' audit practices.

Our organizations jointly recommend that HRSA:

- Ensure that consequences for findings of non-compliance are commensurate with the scope, intention, and impact of the violation.
- Provide for clarity and consistent interpretation among auditors of what constitutes "auditable records."
- Incorporate the current requirement for manufacturers to follow GAGAS ("Yellow Book") standards into the Guidance.
- Exempt findings from manufacturer audits from the requirement to be reported to HRSA/OPA if both the manufacturer and covered entity agree they are not significant.

Introductory Comments

- **The proposed one-size-fits-all approach to managing covered entities does not take into account each grantee's unique, statutorily-mandated structure and goals, and as a result is often detrimental to HRSA grantees and their patients.** HRSA grantees recognize that hospitals account for the majority of 340B covered entities, and an even larger majority of the total drugs purchased under 340B. Therefore, it is understandable that HRSA would offer proposals – both policy-related and administrative – that reflect hospitals' operational structure.

  However, we have serious concerns about this one-size-fits-all approach to managing covered entities. We recognize that from an administrative standpoint, a one-size-fits-all approach is much easier than having different standards for different types of covered entities. However, given how different grantees can be from hospitals, a proposal that may be appropriate in a hospital setting is often counterproductive in a grantee setting.

(Examples that we will discuss below include, but are not limited to: patient definition; registration requirements; some telemedicine models; and definition of parent-child-associated sites.) Thus, this one-size-fits-all approach will often lead to outcomes that are contrary to the 340B Program's congressional intent to enable providers "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[2]

Also, in the same way that grantees can vary enormously from hospitals, they also vary enormously among themselves. Each grantee's program was established individually by Congress to operate in unique ways and serve unique goals. Thus, it is also inappropriate to apply a one-size-fits-all approach to all grantees, as the same request can have vastly different impacts depending on how the grantee is structured. HRSA has already recognized this reality by creating a definition of "eligible patient" that is unique to AIDS Drugs Assistance Programs.

We therefore request that, ***when establishing expectations and processes for the 340B Program, HRSA take into account the specific organizational structures, program requirements, Federal oversight, and statutory goals that apply to each type of "HRSA grantee" which is eligible for the program.***

- **A critical example of the shortcomings of this one-size-fits-all approach is the proposed revisions to the "patient definition," which will have significant negative impacts on grantees and their patients.** As we will discuss, the Proposed Guidance does not define eligibility on a patient-by-patient level but rather on a prescription-by-prescription level. We recognize that this approach might make sense in a hospital environment, in which a provider sees a patient once, refers them to other outside providers, and never sees them again. However, in the various grantee environments, it will have significant negative implications, many of which are in direct contradiction of the 340B Program's purpose of enabling safety net providers to "stretch scarce Federal resources."

- **The Guidance should not create large administrative burdens in an attempt to rectify small issues of non-compliance**. The Guidance outlines a wide range of practices and outcomes which result in non-compliance. These practices vary widely in their intention, scope, and impact. Some may be very significant, involving diversion or duplicate discounts that the covered entity knew about (or should have known about) and substantial amounts of money. In contrast, other findings result from small, unintentional paperwork errors, which – while requiring correction – led to no diversion or duplicate discounts, and are easily fixed. In addition, other findings of non-compliance have resulted from issues where HRSA/OPA's statutory authority is debatable (e.g., failure to produce certain records requested during HRSA/OPA audits).

[2] H.R. Rep. No. 102-384(III), at 12 (1992).

Despite this range of potential violations, the Guidance generally applies the same consequences to every instance of non-compliance regardless of how small or easily corrected. Specifically, the covered entity must proactively report *every* violation to HRSA/OPA and/or the manufacturer, and repay the manufacturer. We are concerned about this approach because:

- It is significantly different from current HRSA policy, which requires covered entities to report *material* noncompliance to HRSA, but not *immaterial* noncompliance.
- It will create an enormous administrative burden (for HRSA/OPA as well as covered entities and manufacturers) if every instance of non-compliance – no matter how small – will need to be reported.

For these reasons, we recommend that HRSA/OPA maintain its current policy of limiting reporting to those violations that rise to the level of being "material." Alternatively, HRSA/OPA could define an "allowable rate of error" below which errors do not need to be reported. Additionally, we recommend that instances of non-compliance not be required to be reported to HRSA/OPA if both the covered entity and the manufacturer agree that they are not significant. We give specific recommendations on this issue below.

Part A. Eligibility and Registration of Covered Entities

A1. Site Registration: ***Streamline and accelerate the site registration process to avoid multi-month delays in 340B access for eligible grantees and their patients.***

Issue: Our organizations recognize the need for HRSA to maintain a standardized, publicly-accessible system for identifying covered entities that are approved to participate in the 340B Program. We also recognize that, in the interest of program integrity, HRSA should verify that covered entities have met all eligibility requirements prior to listing them in the system. However, the current enrollment timelines require a new or relocated grantee medical site to be operational – meeting all program requirements and actively seeing patients - for a minimum of 3 months and potentially as long as 6 months before prescriptions written at that site are eligible for the 340B Program. The extended timeframe results because once the site becomes operational, the site must wait until the next quarterly enrollment period to register, and then wait an additional 3 months for the approval to become effective.

Recommendation: Given the negative impact of these delays on grantees and their patients, we recommend that HRSA/OPA:

- Accept applications from grantee sites on a rolling basis, as opposed to a quarterly basis.
- If unwilling or unable to accept applications on a rolling basis, accept them on a monthly basis.
- Process applications as quickly as possible, as opposed to requiring a 3-month delay for all applications.

- To the extent possible, accept the "due diligence" performed by other HHS agencies (including other parts of HRSA) who have independently verified that the grantee meets all eligibility requirements for 340B. Those applications where other HHS or HRSA divisions have already verified eligibility should receive a much faster "turnaround" than those where HRSA/OPA must make an independent assessment of eligibility.

A2. Parent-Child Structure for Registration: ***Indicate that subrecipients are eligible for the 340B Program by virtue of the subgrants awarded by the direct grantee, by giving them their own eligibility definition.***

Issue: The parent-child structure for registrations outlined in the guidance is one example of how the proposed one-size-fits-all approach is poorly suited to the structures of many types of grantees.

HRSA incorrectly characterizes the relationship between direct grant recipients and their subrecipients to be similar to the parent-child relationship between hospitals and their outpatient clinics. The Federal assistance programs exist completely independent of the 340B Program. Unlike hospital outpatient clinics which are a part of the hospital, a subrecipient can be a completely distinct legal entity for which the direct recipient has no legal authority or liability to direct subrecipient activities outside of the grant program. Subrecipients are eligible for the 340B Program because they receive "subgrants" from the direct Grantees of the programs listed at 340B(a)(4)(A) through (K) of the PHSA.

There are many reasons why "subrecipients" should not be classified as children of the direct grantees. First, not every grantee or subgrantee under the HRSA financial assistance programs has drug programs. Second, even if a direct grantee has a drug program, it may not be enrolled in the 340B Program. Plainly stated, there may not be a "parent" to enroll its "child." Third, subrecipients may be separate legal entities from the grantee, so there is no legal ownership, affiliation, or organizational relationship between a direct recipient and its subrecipient. Without any legal control over the subrecipient organization, the direct recipient cannot be liable for compliance with another government program. Fourth, many of HRSA's financial assistance awards contain no terms regarding the 340B Program[3] and HRSA cannot require the recipients of these Federal grants to be liable for a subrecipient's compliance with some other government program. If the direct grantee wishes to be liable for its subrecipient's 340B Program, the agreements must include terms that create that liability. The terms of grant awards and subrecipient agreements generally only require compliance with the grant program requirements and HHS grant regulations. "Parent" liability cannot be inferred.

[3] The Consolidated Health Centers Program is an exception – every Notice of Award and Notice of Designation issued under the Health Center program contains a standard term requiring health center who provide prescriptions to participate in 340B via the Prime Vendor or else a similar program that provides the same or larger discounts.

Recommendation: To fix this problem, "Subrecipient" should be defined and added as a category of eligible non-hospital covered entity. "Subgrantees" should also be added to the list of non-hospital eligible covered entities wherever they are referenced in the Final Omnibus Guidance. As is currently done, all subrecipients can show OPA their Federal subawards to establish eligibility for the 340B Program. If it is HRSA's intent to merely have an identifying number in the OPA database that links the subrecipient with a direct recipient, then HRSA can work with the grant program offices to develop an identifier for the direct recipients of each of the financial assistance programs at 340B(a)(4)(A)-(K) that will be applied to each enrolled subrecipient entity.

As subrecipients are eligible for the 340B Program by virtue of the subgrants awarded by the direct grantee, we recommend that HRSA add the following language to the Guidance, giving subrecipients their own eligibility definition:

(a) *Eligibility of Subrecipients of Federal grants as defined in section 340B (a) (4) (A)-(K). A subrecipient of a Federal grant as defined in section 340B (a) (4)(A)-(K) of PHSA will be listed on the public 340B database if it registers and establishes that it receives a qualifying Federal subgrant. HHS will assign a unique 340B identification number to represent each subrecipient of a 340B (a) (4) (A)-(K) grant that registers and demonstrates eligibility, and list the entity accordingly on the public 340B database. A subrecipient of a Federal grant as defined in section 340B (a) (4) (A)-(K) 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 their direct Federal grantee does not participate in the program and is not registered on the 340B database.*

A.3. Clarify that a group of parent and child sites that share common ownership and control may transfer inventory among all their sites.

Issue: It is our understanding that if a group of sites with common ownership and control are registered as parent/ child sites, then the parent is able to transfer inventory among its affiliated child sites without raising issues about diversion. However, this is not stated in the proposed Guidance.

Recommendation: We recommend that HRSA/OPA clearly state in the Guidance that sites which are under common ownership and control and are registered as parent/child sites on the 340B database are permitted to transfer inventory among themselves without such transfer being viewed as diversion. HRSA should ensure its covered entity database can accommodate this type of registration for all HRSA grantee types.

A.4. Ensure that the Guidance and registration system are appropriate for the full range of eligible sites used by grantees.

Issue: We are concerned that HRSA/OPA's current registration system, as well as the language in this Guidance, may be too rigid to reflect the full range of sites that grantees use to provide services. The current system works well for a traditional "four walled" entity that provides all services in a standard office; whose locations are all legally part of the same organization; and whose service locations can be predicted in advance (e.g., a hospital system). However, this does not reflect the reality – in statute or in practice – of how many grantee organizations operate. For example, grantees often provide services from mobile vans, in homeless shelters, at educational or community facilities, etc.

Recommendation: The following are specific examples of non-traditional sites, and how HRSA/OPA can address this concern:

- Some grantees have sites that are approved under their Scope of Project, but are not legally "part of" their organization. HRSA could address this by revising the Guidance to define an associated site as follows:

  "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 Project of* ~~and delivers outpatient services for~~ the non-hospital covered entity *and delivers outpatient services on its behalf or pursuant to an agreement with the non-hospital covered entity*."
- Many sites lack a fixed address. HRSA/ OPA should ensure that these sites are not prevented from enrolling.
- Grantees, including but not limited to FQHCs, often must set-up sites to address emergent community needs that could not have been foreseen. HRSA/OPA should allow these sites to enroll on a rolling basis, retroactive to the date of the emergent need.

Finally, we urge HRSA/OPA to consider whether each non-traditional site needs to be registered separately in the 340B database, including those that are not a legal part of the covered entity. It is our view that if these sites have been approved under a grantee's Scope of Project and the grantee has been determined to be eligible for 340B, then the non-traditional sites should be deemed eligible as well, without needing to each be enrolled independently.

A.5. In-Kind Contributions*: State in the Guidance that entities who receive in-kind contributions are eligible for the 340B Program.*

Issue: We are pleased to see included in the draft guidance preamble (p.52301) that entities receiving "in-kind contributions purchased with eligible Federal funds" will continue to be eligible for the 340B Program. However, we are concerned that this language is not included in the Guidance.

Recommendation: We request that language around in-kind contributions be included in the "Proposed Guidance" section -- not just the Summary -- to ensure this eligibility option. In addition, to clarify HRSA's intent, we request that the language in bold be added as follows:

> "…*if those entitled provide information demonstrating their receipt of eligible Federal funds, or in-kind contributions purchase with eligible Federal funds, as well as the* ***original Federal*** *grant number under which they received those funds. Direct grantees should be required to provide this information to any subrecipients when the grant, designation, project or contract is executed."*

A.6. Replenishment: ***Permit 340B sites to replenish drugs provided to eligible patients prior to their termination date.***

Issue: The Guidance requires that a covered entity site, contract pharmacy, etc., must stop purchasing drugs under the 340B Program immediately upon being terminated from the program. We think this prohibition is entirely consistent with program integrity, with one small exception. As you are aware, many grantee organizations have arrangements with contract pharmacies under which they use a "replenishment model." Under this model, the pharmacy maintains a single inventory for both 340B and non-340B customers, and only purchase drugs under 340B when their system indicates that they have dispensed a full package's worth of a specific drug to 340B eligible patients. In other words, drugs for 340B-eligible patients are purchased on a retroactive basis, rather than a prospective one. We are concerned that covered entities with replenishment-model contract pharmacies could be short-changed 340B-priced drugs at the end of their eligibility period. This is because some drugs will only be determined to be 340B eligible after the termination date, at which time it will not be possible to purchase them at the 340B price. Instead, the grantee will be required to pay full price for them.

Recommendation: To address this concern, we recommend that HRSA/OPA revise the proposed Guidance to permit small quantities of drugs to be purchased by terminated covered entities if the entity can demonstrate that those drugs are replenishing 340B-eligible drugs that were dispensed prior to the termination date and filled with regular-priced drugs. Specifically, the Guidance should be revised as follows:

- *(b) Termination. "*Upon loss of eligibility…, the covered entity must immediately notify HHS and stop purchasing and using 340B drugs*, except for those drugs which it can demonstrate will be used to replenish 340B-eligible drugs that were dispensed prior to the termination date and filled with drugs purchased outside the 340B Program*.… A covered entity is liable to manufacturers for repayment for the 340B discounts on any drugs purchased for itself, any child site, or any contract pharmacy when the covered entity was ineligible for the 340B Program for any reason*, except for those drugs purchased for replenishment purposes, as outlined above*."*
- *(c) Loss of eligibility.* "A non-hospital covered entity and its child sites are immediately ineligible for the 340B Program upon closing of the covered entity or upon loss of the parent covered entity's qualifying Federal grant, Federal project, Federal designation, or

Federal contract. The entity may be liable to impacted manufacturers for 340B drug purchases made when the entity was ineligible for the 340B Program, and this information may be made available to the public*, except for those which the covered entity can demonstrate were purchased to replenish 340B-eligible drugs that were dispensed prior to the termination date and filled with drugs purchased outside the 340B Program "*

- *Annual Recertification:* "The covered entity is responsible for repayment to manufacturers in the amount of the discounts for 340B Program drug purchases made after the date the covered entity or child site became ineligible for the 340B Program, *except for those which the covered entity can demonstrate were purchased to replenish 340B-eligible drugs that were dispensed prior to the termination date and filled with drugs purchased outside the 340B Program "*

Part B. Eligible Prescription

B.1. Expand draft Guidance to incorporate prohibition on manufacturers denying 340B sales based on compliance with this definition (as discussed in the Summary).

Issue: The Summary of the draft guidance reads:

> **"**In accordance with section 340B(a)(1) of the PHSA, a manufacturer may not condition the sale of a covered outpatient drug on covered entity compliance with this provision. Remedies for violations would be imposed under the enforcement provisions of the 340B Program, but manufacturers may not unilaterally deny sales based on such violations."

If HRSA determines in the final version of guidance that the "limiting definition" does not apply, then the language quoted above is no longer relevant. However, if the final guidance maintains HRSA's proposed position that the limiting definition does apply, then this is an important clarification, as it indicates that the authority for determining compliance with this provision lies with HRSA/OPA rather than manufacturers. As such, we are concerned that this language in not included in the actual text of the Guidance.

Recommendation: We recommend that the Guidance be expanded to include this provision, as discussed in the Summary. Specifically, the following sentence (which is copied directly from the Summary) should be added to the end of the Guidance for this section: *"Manufacturers may not condition the sale of a covered outpatient drug on covered entity compliance with this provision."*

Part C. Patient Definition

C1. Overall Concerns: The proposed 6-part definition raises serious concerns for our grantee organizations, for both statutory and operational issues, as follows:

- ***<u>Statutory</u>: The proposed definition is contrary to 340B statute, which defines eligibility on a person-by-person basis, not a script-by-script basis.*** The 340B statute states that the only drugs not eligible to be purchased at the 340B price are those provided to "a *person* who is not a patient of the [covered] entity." (42 USC 256b(a)(5)(B)) (emphasis added.) Thus, eligibility is to be determined on a person-by-person basis, according to whether the person is truly a patient of the covered entity. In contrast, HRSA/OPA's proposed "patient definition" does not define eligible patients/persons – rather, it defines eligible scripts. Thus, a single person is eligible for 340B-priced drugs in some circumstances, but not others, depending on the particular script that he or she is presenting. This is contrary to the explicit wording of the statute, which states that eligibility is to be based on the status of an individual person.
- ***<u>Operational:</u> The proposed definition would severely weaken the ability of many grantee types to achieve their statutorily-mandated purpose, for a variety of reasons depending on the grantee type.*** In our discussion of the individual criterion, we provide examples of how the proposed patient definition would weaken many grantees' ability to achieve their statutorily-mandated purposes; we also refer you to the comments submitted by our individual organizations (and grantees) for further details.

  However, at this time we wish to highlight a critical point, which echoes our introductory comments: each grantee type is unique in its statutorily-mandated structure and purpose, and as a result, the proposed definition would impact each of us in different ways. Thus, while we share some common concerns and recommendations, we often have concerns that are unique to our grantee type. In other words, ***the one-size-fits-all approach to defining an eligible patient is a very blunt tool which fails to recognize the unique structures and purposes of the range of eligible covered entities; as a result, while it may address concerns in some areas of the program, if applied uniformly to all covered entities it would have significant, negative impact on grantees and their patients.***

<u>C.2. Examples of Negative Impact of Each of the Six Criteria of Patient Definition across Different Grantee Types</u>

In this section, we provide a few examples of the significant negative impacts which the proposed "patient definition" would have across multiple grantee types. Please note that ***<u>this is far from an exhaustive list</u> of ways in which the proposed definition will harm grantees and their patients.*** (For detailed discussions of how it will impact each grantee type, and how these concerns can best be addressed, see our individual comments.) Rather, it is only a sample of the negative impacts, intended to demonstrate that:

- While grantee types vary enormously in structure and purpose, we share a major concern that the proposed definition will cause significant harm.
- There is no single cause of concern, or "easy fix" that will resolve all these issues. Rather, while some of our issues do overlap, our concerns – and the parts of the definition that raise them – vary almost as much as our organizations do.

To demonstrate the wide variety in our concerns, and the part of the definition which raises them, the following sections give one example of how each of the criterion will negatively impact a particular grantee group.

Criterion #1 – Site: Negative Impact on Hemophilia Treatment Centers

While a requirement to register permanent locations at which Hemophilia Treatment Centers (HTCs) provide healthcare services can be met, The Hemophilia Alliance is concerned that HTCs will not be able to register sites where outreach services are provided as required by the guidance, since these sites 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.

Outreach clinics are held in remote rural sites where members of the HTC team travel to provide services. In addition, HTCs serve patient populations, such as the Amish in OH, MI, and IN, in their own communities since they are not willing to come to the main HTC facilities.

Some of these 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. Also, 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.

Please see the comments submitted by The Hemophilia Alliance for more details on these and other concerns with the patient definition.

Criterion #2 – Provider: Negative Impact on STD and TB Clinics

This criterion, if implemented, would severely weaken the impact of programs designed to protect public health, such as Sexually Transmitted Disease (STD) and Tuberculosis (TB) programs. Frequently, these programs provide necessary public health medications purchased under the 340B Program to patients who have not received a prescription from a provider associated with the STD/TB program. Under these arrangements, the STD/TB program administers necessary STD/TB treatment after being contacted by a private provider who diagnosed the patient and prescribed treatment, but the provider did not stock the necessary treatment. Following best public health practice[4], the STD/TB program immediately provides

[4] *See* Anderson RM, Transmission dynamics of sexually transmitted infections. In: Holmes K, Mardh P-A, Sparling P, et al, eds. Sexually Transmitted Diseases, 3rd ed. New York: McGraw-Hill; 1999:24-29. *See also* "Gonorrhea: Other

the necessary treatment before the patient leaves the private provider's care, limiting the further spread of infectious disease; the STD/TB program continues to provide the necessary medications for the patient under the private provider's care, as often any barriers to prescription access can reduce medication adherence, threatening the public health.[5] In these instances, the STD/TB program maintains a health care record for the patient after providing services within the scope of the STD/TB program's grant, consistent with the existing patient definition.

Under the proposed patient definition, however, STD/TB patients diagnosed in private practice would need to undergo a second visit and diagnosis by a provider of the STD/TB program and receive a second prescription – an administrative barrier that would reduce treatment access and compliance, furthering the spread of infectious disease.

When STD/TB programs provide necessary treatment to patients diagnosed by a private provider, they act differently from most 340B covered entities, paying for the entire cost of the medication purchased at the 340B price rather than receiving the "spread" between the 340B cost and the payer reimbursement. In these instances, STD/TB programs operate more like ADAPs than other covered entities, as they fulfill core public health functions that facilitate treatment compliance, reducing disease incidence. Without the ability to purchase drugs at the 340B price, STD/TB programs would be unable to provide these drugs at no cost to patients, threatening the public health.

Please see the comments submitted by the National Coalition of STD Directors and the National Alliance of State and Territorial AIDS Directors (NASTAD) for more details on this and other concerns with the patient definition.

Criterion #3 – Service: Negative Impact on AIDS Service Organizations (ASOs)

This provision, as written, effectively eliminates all AIDS Services Organizations (ASOs) from participating in the 340B Program. ASOs and their teams of medical case managers work with patients to stay on their medications and to stay healthy. Medication adherence is critical for AIDS patients, given the complicated nature of treatment regimens, and it may take significant supports and services for patients to be fully compliant with their prescription.

Management Considerations" Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines, 2015. MMWR Recomm Rep 2015;64(No. RR-3): 1-137.

[5] *See* Limitations to Treatment Safety and Efficacy: Cost Considerations and Antiretroviral Therapy, Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents, April 8, 2015. Available at https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/459/cost-considerations-and-antiretroviral-therapy. *See also* Goldman DP, Joyce GF, Zheng Y. Prescription drug cost sharing: associations with medication and medical utilization and spending and health. *JAMA*. 2007;298(1):61-69; Maciejewski ML, Farley JF, Parker J, Wansink D. Copayment reductions generate greater medication adherence in targeted patients. Health Affair. 2010;29(11):2002-2008.

The language included in the proposed guidance requires that a covered entity provider (employed by the CE) must be the prescriber for the individual to be an eligible patient. AIDS Services Organizations do not necessarily have a physician or nurse practitioner on staff to write the prescription. The services provided directly result in the prescription—but the employed provider of the covered entity does not write the prescription.

Maintaining relationships with providers that specialize in working with people living with HIV and AIDS improves the quality of care delivered to this population and improves adherence rates to complex drug protocols. However, these relationships do not necessarily require employment arrangements. As a result, as drafted, this guidance will eliminate AIDS Services Organizations from participating in 340B and put the health and health care of HIV/AIDS patients at risk.

Please see the comments submitted by the Pharmaceutical Access for Community-based Service Providers (PACSP) for more details on this and other concerns with the proposed Guidance.

Criterion #4 – Scope: Negative Impact on Title X Family Planning Providers

The wording of the fourth prong of the proposed patient definition differs only slightly from the current patient definition. However, these slight changes in wording could translate to very large changes in practice which could severely limit the ability of Family Planning providers to effectuate the intent of the 340B Program – to enable safety net providers to stretch scarce resources to provide more comprehensive health care services to more patients.

The current patient definition requires an individual to receive "a health care service or range of services from the covered entity which is consistent with the *service or range of services for which grant funding … has been provided to the entity*." The proposed patient definition states that the individual receives "health care [that] is consistent with the *scope of the Federal grant, project, designation, or contract*." (emphasis added)

Family planning providers are concerned that this new reference to "scope of the grant" could be interpreted to mean that the service must be explicitly enumerated in the grant, project, designation, or contract (herein, referred to collectively as "grant") in order for the resulting prescription to be 340B eligible. This interpretation would limit qualifying services to only those explicitly named within the scope of the grant, and thereby would drastically hinder the ability of Family Planning providers to meet the needs of their patients.

To demonstrate this impact, it should be noted that four in ten patients seeking care at Title X funded sites say that health center is their **only** source of health care. In response, many Title X-funded health centers offer limited primary care services in order to better serve these patients' needs. Consider a scenario in which a patient presents at a Title X-funded health center for a well-woman visit and asks to initiate hormonal contraception. Upon examination,

the patient is found to have an infection that requires antibiotics. The clinician performing the exam should be able to use 340B drugs not only for that patient's contraceptive method of choice, but also for the antibiotics necessary to treat the infection. The same would be true for a patient who is interested in a drug to assist with smoking cessation, given that smoking in women over 35 years old is a contraindication for some hormonal contraceptives. However, under the proposed wording for this criterion, neither the antibiotics nor the smoking cessation drug would be eligible for 340B, since neither identifying infections nor tobacco counseling are explicitly mentioned in Title X grantees' scope of grant. As a result, these women would be required to make a separate visit to a 340B-eligible provider in order to receive a 340B-eligible prescription.

Our concerns about the proposed changes are elevated by the examples set forth in the preamble language, as these examples seem even more restrictive than the proposed criteria language. In one example, HRSA specifies that a hospital's outpatient clinic enrolled in 340B as a Title X provider (not as a hospital) cannot access 340B drugs for patients receiving care *outside the scope of the Federal family planning project*. HRSA's example is inconsistent with the actual Guidance language which requires that a service be *consistent with* the scope of the grant, not that it be *within* the scope of the grant.

HRSA's other example provides that an FQHC limited in its scope of grant to treating pediatric individuals can provide 340B drugs to only individuals "receiving pediatric care meeting the limitations specified in the child site scope of grant." Like the example above, it appears that an individual must receive a service *in* the scope of the grant – not a service that is *consistent* with the scope of the grant. Moreover, this example limits the eligible population that can receive 340B drugs to only those specified in the grant.

Please see the comments submitted by the National Family Planning & Reproductive Health Association and Planned Parenthood for more details on these and other concerns with the patient definition.

Criterion #5 – Outpatient: Negative Impact on Federally Qualified Health Centers

The draft Guidance states that in order for a drug to be eligible to be filled under 340B, "The individual [must be] classified as an outpatient when the drug is ordered or prescribed." All grantee groups support this statement to the extent that it ensures that inpatient drugs – namely, those that are prescribed and *taken while the patient is in the hospital* - are ineligible for 340B. However, FQHCs have significant concerns about the fact that HRSA defines prescriptions that a patient is given *upon being discharged from the hospital, to be filled and taken at home* – as inpatient, and therefore ineligible for 340B.

Classifying discharge prescriptions as inpatient—and therefore ineligible for 340B – is both inconsistent with long-standing medical practice and harmful to FQHC patients, finances, and

clinical operations. First, long-standing practice has consistently defined services as "inpatient" or "outpatient" based on the time and location where the service is actually received. In the case of discharge prescriptions, the service – filling and taking the medication – occurs in the community and in the patient's home. Neither the time when the medicine is taken (after coming home) nor the location (in the patient's home) overlaps with the hospital or other inpatient facility. If this broad definition of "inpatient" were applied to other services, the results would be inconsistent with current medical practice. For example, consider the case of a patient who is admitted to the hospital for heart surgery. Upon discharge, he will be told to see his cardiologist for follow-up care. Under HRSA's definition, this follow-up appointment (which takes place in the doctor's office) would be considered inpatient, since it was prescribed to the patient while he was an inpatient.

Second, FQHCs are required by statute to coordinate all their patients' care, and to provide them with access to appropriate pharmaceutical services. They are also held publicly accountable – with data posted on-line for each Health Center– for the quality of care their patients receive and outcome measures related to chronic conditions. Under this criterion, Health Center patients who leave the hospital will no longer be able to get their discharge prescriptions filled with 340B drugs. Given that nearly two-thirds of Health Center patients have incomes below the poverty line, it is doubtful they will be able to pay full price. So one of two outcomes is likely – either the patient goes without the medication[6], and their health (and the Health Center's quality measures) suffer, or the Health Center will offer a discount on the drug. Given that Health Centers generally operate on margins of less than 1%, these discounts will need to be financed by cutting services elsewhere under the Health Center's scope of grant.

Please see the comments submitted by the National Association of Community Health Centers for more details on these and other concerns with the patient definition.

Criterion #6 – "Auditable Records": Impact on all grantees

As a general matter, we agree that a covered entity is responsible to demonstrate (on audit, or otherwise) that it has met the key 340B compliance requirements, namely:

- That 340B drugs are dispensed only to individuals who meet the definition of a patient;
- That the covered entity has taken the appropriate measures (under state Medicaid law and otherwise) to identify its utilization of 340B drugs for Medicaid beneficiaries; and
- That the covered entity has a compliant contract in place with any contract pharmacy.

[6] Medication underuse (also called non-compliance or non-adherence) is already a significant national issue, and disproportionately impacts the types of populations that FQHCs target. A 2014 study by Harvard Medical School researchers found that 23.4% of adults with chronic illnesses reported "taking less medication than prescribed, or none at all, due to costs." The study also highlighted the strong correlation between medication underuse and food insecurity, indicating that many individuals often must choose between medicine and food.

We also agree that covered entities should maintain records demonstrating this compliance, and be able to produce these records for inspection and oversight purposes.

However, we are extremely concerned with HRSA's proposed requirement for covered entities to maintain "auditable records," for several reasons.

First, HRSA characterizes the maintenance of "auditable records" throughout the proposed guidance as an eligibility requirement. That simply is not the case. The eligibility requirements are set out in Section 340B(a)(4) of the PHSA which makes no mention of record keeping requirements. We recognize that Section 340B(a)(5)(C) of the PHSA requires a covered entity to permit the Secretary to audit a covered entity's compliance with the requirements of 340B (a)(5)(A) (pertaining to diversion) and 340B(a)(5)(B) (pertaining to so-called "duplicate discounts"). Clearly, a covered entity that refuses to make itself available for an audit or refuses to make any records available for audit would violate the statute. Whether that would be grounds for removal from the 340B Program is not addressed in the Proposed Guidance and we will not discuss it here (although we do observe that the only statutory basis for removal is set forth in Section 340B(d)(2)(B)(v)(II), added by the Affordable Care Act Amendments, which authorizes removal for a systematic, egregious, and knowing and intentional diversion of 340B drugs).

Second, not maintaining adequate records (in the view of an auditor) is much different than not allowing an audit at all. We note that Section 340B(a)(5)(C) does not specifically authorize an audit of a covered entity's record-keeping practices *per se.* It stands to reason that an auditor who finds that a covered entity's records are insufficient to document a compliance requirement has had an opportunity to audit the covered entity so that there is no possibility that the covered entity could have violated Section 340B(a)(5)(C). In short, HRSA's proposal to treat the lack of "auditable records" as an eligibility requirement is not supported by the statute. Moreover, this overreach is compounded by the absence of any definition or description of what HRSA considers to be an "auditable record."

The potential negative consequences of this approach, if adopted as policy, are not a matter of conjecture. Grantees that have undergone HRSA audits report widely divergent findings on what is considered to be an "auditable record." They also report having been reviewed by auditors who refuse to accept alternative evidence of patient eligibility. Moreover, HRSA sometimes disallows all 340B claims for the audit period – on the false premise that maintenance of auditable records is an eligibility requirement – solely because some of the claims in the audit sample were not documented.

We will return to the topic of auditable records in H.3., below. In the meantime, these examples have demonstrated that:

- While grantee types vary enormously in structure and purpose, we share a major concern that the proposed definition will cause significant harm.

- There is no single cause of concern, or "easy fix" that will resolve all these issues. Rather, while some of our issues do overlap, our concerns – and the parts of the definition that raise them – vary almost as much as our organizations do.

C.3. Comments on other Part C provisions

- ***Support for unique patient definition recognizing the unique structure and purpose of ADAP programs.*** As discussed previously, we strongly encourage HRSA/OPA to establish policies that reflect grantees' unique structures and purposes, as opposed to applying a "one-size-fits-all" approach. Therefore, we support HRSA's continued recognition that AIDS Drug Assistance Program (ADAP) clients categorically meet the patient definition, (80 FR 52307) as this provision is appropriate to the unique character of ADAPs.

- ***Expand Guidance to incorporate the broad definition of employed or contracted providers.***

  Issue: In reference to the standard that eligible providers must be either employed by or a contractor of the covered entity, the Summary states:

  > "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."

  We appreciate this clarification, but are concerned that it is not incorporated into the Guidance.

  Recommendation: We request that HRSA/OPA include the Summary language verbatim into the Guidance, as follows (new language in *underlined italics*):

  > "The individual receives a health care service from a health care provider employed by the covered entity or who is an independent contractor of the covered entity such that the covered entity may bill for services on behalf of the provider. *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."*

- ***Incorporate language about telemedicine, etc. into the Guidance.***

  Issue: The Preamble provided 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."

  Many covered entities' patients are often remotely located from the clinic given the large service areas they cover, and may have situations when the quickest consultation with the provider is by telephone, telemedicine, or other online modalities. (For example, patients

served by Hemophilia Treatment Centers (HTCs) are located all over the country, and due to the limited number of HTCs, telephone and telemedicine are often the fastest way for them to reach a qualified provider.) In addition, other grantees use telemedicine and telehealth to provide the patients with access to providers who are not available in their geographic area. (For example, health centers use telemedicine to provide patients with access to mental health services when culturally and linguistically-appropriate providers are not available in the immediate geographic area.) In all these cases, these alternative delivery methods are essential for the comprehensive care of their patients. While we believe that HRSA intends to consider these methods of delivery of health care services as qualifying for 340B drug prescriptions, it would not be questioned or misinterpreted if it was inserted into the Final Guidance.

Recommendation: We therefore suggest the following language from the Preamble be added verbatim into the Guidance, as follows *(*new language in *italics and underlined)*:

> "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."

- ***Clarify that Expedited Partner Therapy (EPT) is permissible under the 340B Program (specifically under Criterion #3 of the proposed patient definition).***

Issue: This draft guidance was a missed opportunity by HRSA to strongly and publicly support the practice of Expedited Partner Therapy (EPT) for grantees to decrease re-infection rates of public health program patients. EPT provided to an index patient who meets the patient definition is an appropriate use of 340B drugs and providers will continue to operate under that assumption, absent clear and explicit guidance from HRSA to the contrary.

EPT is the practice of providing antibiotics or a prescription for antibiotics to a patient who tests positive for an STD for their partner(s) without a medical examination of their partner(s). EPT is a legally-specified, clinical option to ensure effective patient treatment. Ensuring a patient who tests positive for an STD is treated is not enough; to ensure that patient is not re-infected and to stop the spread of STDs, a patient's partner(s) must also be treated. Recommended by the Centers for Disease Control and Prevention (CDC) since 2006, the 2015 STD Treatment Guidelines support the use of EPT by all providers if the provider cannot confidently ensure that all of a patient's sex partners from the prior 60 days will be treated.

Any attempt to limit 340B drugs for use in EPT would be an unnecessary burden on entities working to reduce STD rates and ensure their patients are not re-infected. EPT is part of the

index patient's medical management, ensuring that their treatment is effective and successful, and a form of prophylaxis for the covered entity's patient.

While the majority of EPT is being implemented by Section 318 grantees across the country, EPT access for patients is also a concern of other 340B grantees as well, notably Ryan White grantees, family planning, and FQHCs. As noted above, the CDC encourages all providers to implement EPT to ensure that the index patient will not be re-infected.

Recommendation: HRSA should include a strong support of EPT in its final Guidance to ensure that grantees can continue to use 340B drugs for this proven public health practice. Specifically, in section (3) of the Patient Definition, HRSA should clarify that Expedited Partner Therapy (EPT) is permissible under the 340B Program. As noted above, not providing these prescriptions would be detrimental to the health of the patient.

- ***Provide additional flexibility in the event of Public Health Emergencies:*** *(Please see related comments in sections A and E.)*

Issue: As discussed in Section A, we are concerned that proposed flexibilities in the event of a Public Health Emergency are not broad enough to reflect the full range of emergencies to which grantees are called and expected to respond. Specifically, we request that these flexibilities be expanded to:

- Broaden the definition of public health emergencies to include those declared by a state or local authority;
- Permit covered entities to petition HRSA to approve specific situations as a Public Health Emergency; and
- Make flexibility in the case of Public Health Emergencies retroactive.

Recommendation: To address these recommendations, we recommend that HRSA/OPA make the following changes (new language in *italics and underlined)* to the Guidance:

Part C, (b)(2): "*Public health emergency declared by ~~the Secretary~~ a governmental body:* If normal health care operations are disrupted due to a public health emergency declared by ~~the Secretary~~ *a governmental body,* a covered entity may request, and HHS may authorize, a covered entity to temporarily follow alternate patient eligibility criteria*…. HRSA may also permit a covered entity to temporarily follow alternative patient eligibility criteria in response to other events which HRSA determines, on a case-by-case basis, qualify as public health emergencies. The ability to apply alternate patient eligibility criteria may, at HRSA's discretion, be retroactive to the date that the emergency began."*

D. Requirements on Covered Entities

Medicaid

D.1. Clarify that the Medicaid Exclusion File (MEF) currently applies only to Fee-for-Service.

Issue: Section D.a.1. of the Guidance refers to the use of the MEF for fee-for-service patients. The final sentence reads:

> "If a covered entity's provider number or NPI is not listed on the 340B Medicaid Exclusion File, all drugs billed under the Medicaid provider number or NPI are purchased outside of the 340B Program."

We are concerned that this sentence could be taken out of context (independently from the heading "Medicaid Fee-for-Service") it could be interpreted as meaning that the MEF applies to all Medicaid MCO patients as well as FFS ones. As HRSA/OPA is aware, there have already been issues with states and MCOs misinterpreting the MEF as applying to managed care.

Recommendation: We recommend the following additions *(in italics and underlined)* to the Guidance language at D.a.(1) (under Prohibition of Duplicate Discounts):

> "If a covered entity's provider number or NPI is not listed on the 340B Medicaid Exclusion File, all drugs billed under the Medicaid provider number or NPI *for fee-for-service patients* are purchased outside of the 340B Program."

D.2. Support for permitting covered entities to vary carve-in/ carve-out decisions based on site and MCO.

We support HRSA/OPA's proposal to not force covered entities into a "one-size-fits-all" approach to carving in or out, as outlined at D.a.(2) of the Guidance. We appreciate HRSA/OPA's recognition that covered entities are best able to comply with and benefit from the program if they are permitted to make different decisions based on the unique circumstances of each site and MCO.

D.3. Permit covered entities to vary carve-in/ carve-out decisions based on individual drug.

Issue: As stated above, covered entities are best able to benefit from the 340B Program if they are permitted to make different carve-in/out decisions based on specific circumstances. In the same way in which benefits and responsibilities may differ between sites and MCOs, they can also differ between different drugs. For example, some covered entities find it easier to carve in drugs that are provided in the clinic (i.e., during a visit) than those which patients get filled to take at home.

Recommendation: HRSA/ OPA should revise the Guidance language at D.a.(2) as follows (*new language underlined and in italics):*

"The covered entity may make differing selections by covered entity site, ~~and~~ managed care organization*, and drug* so long as such distinction is made available to HHS."

D.4 Remove requirement for state or MCO to sign contract with each contract pharmacy.

Issue: HRSA proposes that a covered entity and its contract pharmacy outline how they will prevent duplicate discounts AND have either the State Medicaid agency or the MCO sign the contract. HRSA grantees are community-based non-profits and true providers of last resort. Contract pharmacies expand the capacity of our organizations and allow us to provide 340B drugs to our patients. Larger organizations and those with significant political support in the state may have an easier time negotiating the political and bureaucratic silos needed to get the state or an MCO to sign the contract, but small grantees are unlikely to easily or quickly navigate these waters.

Recommendation: HRSA must acknowledge the significant resource challenges faced by small covered entities, as well as the difficulty of directing state or MCO participation; this burden must not fall on the covered entity. HRSA should modify this section to allow the covered entity to register their intent to use a contract pharmacy with HHS without requiring the approval of the state or MCO. Specifically, we recommend the following changes to the Guidance language (*new language in italics and underlined):*

> (c) Contract pharmacy…If a covered entity wishes to purchase 340B drugs for its Medicaid FFS or MCO patient and dispense 340B drugs utilizing a contract pharmacy, the covered entity will provide a written ~~agreement~~ *notice to* ~~for~~ HHS ~~approval~~ with its contract pharmacy ~~and State Medicaid agency or MCO~~ that describes a system to prevent duplicate discounts.

D.5. Encourage or require States to develop a mechanism for grantees to identify 340B drugs to States/ MCOs.

Issue: Grantees often contract with multiple Medicaid MCOs. If each MCO establishes its own methodology for how grantees are to identify 340B drugs, the grantee is forced to work with several distinct systems, creating a significant administrative burden.

Recommendation: HRSA/OPA should encourage – and if possible, require – states to establish a standardized system for all covered entities to identify drugs purchased under 340B to the state or MCOs, provided that the a state protects the right of the covered entity to decide whether to use 340B on a drug-by-drug basis. This will reduce administrative burden on covered entities, and also on states.

Audit Standards:

D.6. Conduct audits in accordance with the government audit standards, including the "Yellow Book."

Issue: Federal grantees and subgrantees are familiar with other government audits such as Medicaid, Medicare, and annual financial assistance audits performed under 45 CFR 75 Part F. Most government audits are required to be performed in accordance with the Generally Accepted Government Auditing Standards (GAGAS), the "Yellow Book."[7] HRSA 340B audits are not being conducted in accordance with the Yellow Book. 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.[8] We believe that the 340B compliance audits should be conducted in accordance with the Yellow Book because they qualify as "performance audits" to assess the covered entity's compliance with applicable law and regulations governing the 340B Program.[9] It is essential that the auditor's findings provide the specific facts and circumstances regarding their findings, along with the specific citation to the violated statute or regulation. In fact, HRSA provides in the Draft Omnibus Guidance and stated in the Federal Register notice for Manufacturer Audit Guidelines that they should follow Government Auditing Standards because "Compliance with these standards will also ensure audit uniformity and consistency and adequacy of documentation to permit independent review in cases where disputes arise."[10]

Recommendation: We recommend that 340B audits be conducted in accordance with the government audit standards, including the "Yellow Book."

D.7. Provide covered entities with more time to respond to audit findings.

Issue: The proposed guidance only provides 30 calendar days for covered entities to respond to audit findings. This only provides about 20 work days excluding weekends, and even fewer if there are intervening holidays. Also, the response period currently starts on the date that the audit findings were issued by HRSA, not the date they are received by the covered entity. This very short period of time is further exacerbated if there was not a full and complete disclosure of the auditor's concerns during the Exit Conference.

Recommendation: We suggest that at a minimum, the auditor should provide 45 – 60 days' response time, and that this response period begin the day that the covered entity receives the report, not the date of the report.

[7] The Yellow Book is published at: http://www.gao.gov/yellowbook/overview.
[8] *Id.* Section 1.01, 1.02, and 1.07(c).
[9] *Id.* Sections 1.04 and 2.10-11.
[10] 61 Fed. Reg. 65,406 at 65,409 (December 12, 1996).

D.8. Provide covered entities with opportunities for oral hearings and appeals.

Issue: We are also concerned that there is no opportunity for an oral hearing or an appeal from the final decision. The 340B statute clearly requires that after audit and prior to the imposition of sanctions for noncompliance, there shall be "notice and hearing." 42 U.S.C. 256b(a)(5)(D). We feel the due process procedures for 340B audits are inadequate. Adequate due process is required when there is a constitutionally protected interest within the meaning of the Constitutional Due Process Clause. Federal courts have consistently held that some form of hearing is required before a person or entity can be deprived of its protected property[11] and liberty[12] interests. These sanctions and corrective actions may include the loss of 340B eligibility, financial liability to the manufacturer, or referral to the OIG Office of Investigations.[13] The Supreme Court directed that the sufficiency of due process procedures consider the private interest affected by the official action, the risk of an erroneous deprivation of such interest through the procedures, and the probable value of additional procedures regarding the affected entity and the Government's interest in fiscal and administrative burden.[14]

Recommendation: At a minimum, there should be an opportunity for an oral hearing when there are facts in dispute, and an appeal to another official outside the Office of Pharmacy Affairs. We suggest an attorney in Office of General Counsel could conduct such review or the HHS Departmental Appeals Board which hears other audit appeals. We also urge HRSA to consider providing additional administrative due process procedures, because the only recourse covered entities have is to file a lawsuit in Federal court, which is expensive and time-consuming.

D.9. Publish HRSA/OPA's audit protocol, to assist covered entities in knowing how compliance will be evaluated, and increase consistency across auditors.

Issue: At present, the HRSA/OPA audit process is a "black box" for grantees. Unlike the audit requirements for Federal grants, covered entities have no clear, consistent information about what auditors will do, or how compliance will be evaluated. In addition, there appears to be significant variation in the standards applied by individual auditors. As a result, covered entities are unclear how to best ensure that their policies and practices are complying with HRSA/OPA's expectations. Given the variability in how audits are conducted and the findings, even if covered entities confer with other entities who have already undergone audits, they cannot be confident that they will be held to the same standards.

[11] Protected property interest stems from the financial liability and the increased cost of drugs. *Mathews v. Eldridge*, 424 U.S. 319, 335 (1961).
[12] Protected liberty interest stems from the denial of its eligibility as a "covered entity" to participate in the 340B program. See Old Dominion Dairy Products, Inc. v. Sec'y of Defense, 631 F.2d 953 (D.C. Cir. 1980) where a contractor was denied eligibility for federal contracts without minimum due process).
[13] See 42 U.S.C. § 256b (a)(5)(D) and (d)(2)(v).
[14] *See Mathews v. Eldridge*, *supra at footnote 6.*

Recommendation: For all these reasons, we strongly urge HRSA/OPA to issue its audit protocol for all covered entities. Ideally, this protocol should be subject to a public review and comment process.

D.10. Support for HRSA/OPA discretion in situations of non-systemic failure to produce records.

We appreciate and support the following proposal:

> "HHS proposes to use discretion for those entities whose failure to retain records is non-systematic. A non-systematic recordkeeping violation would occur if the covered entity generally has available records but cannot produce a certain specific record demonstrating compliance with a 340B Program requirement."

As discussed in our introductory comments, instances of non-compliance of 340B requirements vary enormously in their impact and their intention, and it is critical that the repercussions for specific violations reflect these variations. With this language, HRSA/OPA is indicating that it understands that small, non-systematic lapses in record keeping do not necessarily indicate a major issue which should lead to drastic consequences such as removal from the program.

D.11. Implement requirement to maintain auditable records for 5 years on prospective basis.

Issue: We appreciate HRSA/OPA's establishment of an explicit standard for how long covered entities must maintain auditable records, and agree that 5 years is an appropriate timeframe. However, we are concerned that if this expectation is effective immediately upon the publication of a Final Guidance, some covered entities may not be able to comply immediately, as in the absence of guidance, some covered entities currently keep records for fewer than five years. In addition, some auditors currently request records for more than a five-year period.

Recommendation: We recommend that the 5-year requirement be made effective on a prospective basis, as of the date the Final Guidance is published. We also request that auditors be instructed that they may not penalize a covered entity for failure to keep records for time periods that are not required under the Final Guidance.

Part E - Contract pharmacy arrangements.

E1. Support for Request to not limit number of contract pharmacies: We appreciate that HRSA/OPA is not proposing to limit the number of pharmacies that a grantee can contract with to dispense 340B drugs to its eligible patients. Each grantee has unique operational needs and its patients face unique challenges in getting to pharmacies, so we commend HRSA/OPA for maintaining grantees' ability to rely on contract pharmacies as most appropriate for their patients.

E2. Support for instructing covered entities to ensure their contract pharmacy arrangements are consistent with the intent of the 340B Program. The Summary states that:

> "Congress intended the benefits of the 340B Program to accrue to participating covered entities. Each covered entity should carefully evaluate its relationships with contract pharmacies (i.e., cost/benefit analysis) to make certain that the relationship benefits the covered entity and is in line with the intent of the Program."

We strongly support this expectation, as we are concerned that contract pharmacy arrangements that are inconsistent with program intent could raise concerns about the use of contract pharmacies, and potentially about the entire 340B Program. Therefore, ensuring that all contract pharmacy arrangements are consistent with program intent will help to protect this important option, and the program overall. For these reasons, we encourage HRSA/OPA to include this language in the Guidance.

Part F – Manufacturer Responsibilities

F1. Support for requiring manufacturers to ensure that limited distribution networks do not discriminate against 340B covered entities. We support the proposed requirements to ensure that manufacturers who use limited distribution networks for specific drugs do not make accessing these drugs more difficult for 340B providers than for other providers. Several of HRSA/OPA's Requests will help avoid such discrimination, including the requirement for manufacturers to submit a detailed distribution plan to HRSA assuring that restrictions will be applied equally to 340B and non-340B providers, and the online posting of such plans.

F2. Request to state in the Guidance that 340B prices apply to drugs sold via Limited Distribution Networks.

Issue: We are hearing anecdotal reports of grantees who have been told by limited distribution networks that while they are willing to sell these drugs to grantees, they are not required to sell them at the 340B price. HRSA/OPA addresses this issue directly in the Summary, stating "340B Program pricing requirements apply to such sales." (p.52312). However, this statement is not included in the Guidance.

Recommendation: Given the confusion that already exists around this issue, we recommend that HRSA/OPA state this requirement explicitly in the Guidance by adding the following language *(in italics*):

> "(c) Limited Distribution Plan: A manufacturer's limited distribution plan is expected to include… *An assurance that the product subject to restricted distribution will be made available to covered entities at the 340B price.*

Part G – ADAP Rebates

G.1. Clarify that the proposed qualified payment definition requires the ADAP to pay only the portion of the insurance premium that is attributable to the client.

Issue: We understand the proposed "qualified payment definition" to be met when the ADAP pays the portion of the insurance premium *attributable to the client*. However, it appears that certain manufacturers are asserting that only those policies for which the ADAP pays 100% of the premium would meet the proposed definition. This interpretation would eliminate over 80 percent of insured ADAP clients from the qualified payment definition, as only those clients with Standard Benefit Medicare Part D and clients with incomes greater than 400 percent of the Federal Poverty Level enrolled in Marketplace plans would qualify. (All patients who receive an Advanced Premium Tax Credit through the Marketplace or an employer contribution to a policy would be eliminated.) Moreover, this runs contrary to long-standing HRSA policy encouraging ADAPs to enroll clients in marketplace plans, undermining the success of ADAPs in maintaining viral suppression and broadening access to care.

Recommendation: HRSA should state explicitly in Part G (b)(2) of the Guidance that a qualified payment entails the portion of the insurance premium *attributable to the client*, as follows *(new language in italics and underlined)*:

(1) A payment by the AIDS Drug Assistance Program of the *portion of* health insurance premiums *attributable to the client for the policy* that cover the covered outpatient drug purchases at issue and payment of a copayment, coinsurance, or deductible for the covered outpatient drug.

G.2. State explicitly that manufacturers may not withhold rebates from ADAPs due to issues related to the qualified payment definition (or other compliance issues).

Issue: The proposed Guidance states that manufacturers "may not condition the offer of the 340B ceiling price on a covered entity's assurance of compliance with the 340B Program." However, manufacturers often withhold disputed rebate payments to ADAPs rather than use HRSA-recommended dispute resolution procedures after making rebate payments.

Recommendation: Given concerns about manufacturers' interpretation of the qualified payment definition, we request that HRSA clarify this expectation of manufacturers in final guidance, as absent this clarity, manufacturers may perceive that they are allowed to withhold rebates to force ADAPs to initiate disputes.

Part H – Program Integrity

H1. Ensure that consequences for findings of non-compliance are commensurate with the scope, intention, and impact of the violation. To date, HRSA/OPA audits of covered entities have resulted in findings of non-compliance that vary enormously in their scope, intention, and impact. Some might be very significant, involving diversion or duplicate discounts that the covered entity knew about (or should have known about) and which involve substantial amounts of money. In contrast, other findings result from small, unintentional paperwork errors, which – while requiring correction – led to no diversion or duplicate discounts. In addition, other findings result from issues where HRSA/OPA's statutory authority is unclear (e.g., failure to maintain records that meet HRSA/OPA definition of "auditable.")

We strongly urge HRSA/OPA to ensure that the consequences for any findings are commensurate with the scope, intention, and impact of the violation, and to recognize that removing a covered entity from the 340B Program results in a minimum 3-6 months gap in their eligibility (due to the timeframes for re-enrollment, discussed above.) For example, failure to list the appropriate contact person on the 340B database is an error that must be corrected; however, it is certainly not significant enough to merit disenrollment from the program.

H.2. Support for permitting only one audit at a time: We support HRSA/OPA's statement that "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." We appreciate this provision, as it indicates that HRSA/OPA recognizes the administrative demands that audits impose on covered entities.

H.3. Need for clarity and consistent interpretation among auditors of what constitutes "auditable records."

Issue: As discussed in C.2. above, we are extremely concerned with HRSA's proposed requirement for covered entities to maintain "auditable records," for several reasons:

- HRSA has mischaracterized the maintenance of "auditable records" throughout the proposed guidance as an eligibility requirement.
- Not maintaining adequate records (in the view of an auditor) is much different than not allowing an audit at all.
- There is no description of what HRSA considers to be an "auditable record."

Recommendation: For all these reasons, ***we strongly encourage HRSA/OPA to publish guidance explaining exactly what records a covered entity is expected to maintain. To the extent that a covered entity's record keeping practices are subject to audit, HRSA should ensure that all auditors adhere to the same standards.*** (See further discussion of audit process in D, above.)

H.4. Comments on manufacturer audit process.

- ***Support for appropriate parameters around manufacturers' audit practices:*** We appreciate and support HRSA/OPA's Request to ensure that appropriate parameters are placed around the audit practices of manufacturers. These include the requirements to: seek to resolve the issue informally before proceeding to a formal audit; demonstrate "reasonable cause" to HRSA prior to starting an audit; and limiting the scope of the audit to potential diversion and/or duplicate discounts of their drugs over the past five years. We also appreciate the statement that manufacturers must continue to sell covered outpatient drugs at no more than the 340B ceiling price to the covered entity until HHS makes a determination of a 340B Program violation.

- ***Incorporate the current requirement for manufacturers to follow GAGAS ("Yellow Book") standards into the Guidance:***

  Issue: HRSA/OPA currently requires manufacturers to follow GAO's published standards for government performance audits ("GAGAS" or the "Yellow Book") when auditing covered entities. This is also stated in the Summary (p. 52314), but is not incorporated in the Guidance.

  Recommendation: Therefore, we request that the expectations that manufacturers adhere to Yellow Book standards be stated explicitly in the Guidance.

- ***Exempt findings from manufacturer audits from the requirement to be reported to HRSA/OPA if both the manufacturer and covered entity agree they are not significant:***

  Issue: As discussed above, violations identified during a manufacturer or HRSA/OPA audit vary significantly in terms of their scope, intention, and impact. However, the Guidance currently requires that all instances of non-compliance identified by a manufacturer audit must be reported to HRSA/OPA. As a result, even very small, insignificant errors must be reported to HRSA/OPA, resulting in a paperwork burden that it disproportionate to the size of the finding.

  Recommendation: To avoid creating unnecessary paperwork in the case of minor violations that can be easily remedied, we recommend that covered entities not be required to report violations if both the manufacturer and the covered entity agree that they are not significant. This would be similar to the HRSA/OPA's policy around repayments, which states: "A manufacturer retains discretion as to whether to request repayment based on its own business considerations…" (p. 52308)

In closing, we thank HRSA for the opportunity to comment on this proposed guidance, and we appreciate your consideration of these concerns. If you have any further questions, please contact any of us listed below.

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