

October 27, 2015

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

Re: **340B Drug Pricing Program Omnibus Guidance [RIN 0906-AB08]**

Dear Sir or Madam:

The National Family Planning & Reproductive Health Association (NFPRHA) is pleased to comment on the proposed guidance for participation in the 340B Drug Pricing Program.

NFPRHA is a national membership organization representing providers and administrators committed to helping people get the family planning education and care they need to make the best choices for themselves and their loved ones. NFPRHA's members operate or fund a network of nearly 5,000 health centers and service sites that provide high-quality family planning and other preventive health services to millions of low-income, uninsured, or underinsured individuals in 50 states and the District of Columbia. Services are provided through state, county, and local health departments as well as hospitals, family planning councils, Planned Parenthoods, federally qualified health centers, and other private non-profit organizations.

NFPRHA appreciates the strong commitment of the Health Resources and Services Administration (HRSA) to ensure that ongoing implementation of the 340B program considers the needs of Title X-funded health centers and the individuals that they serve. Since its establishment in 1992, the 340B Drug Pricing Program (340B) has provided safety-net health centers and hospitals access to important prescription drugs at a reduced cost. The program

has allowed Title X family planning health centers to reach more patients and do more with their limited funds.

NFPRHA appreciates HRSA's efforts to provide clarifying guidance on the 340B Drug Pricing Program and to address ongoing concerns about accountability and transparency in the program. However, NFPRHA has broad concerns that this proposed guidance marks a fundamental change in HRSA's interpretation and implementation of the program. Language in the preamble and guidance text indicate an intent to significantly limit the types of drugs covered entities can purchase at 340B prices. The 340B program was designed by Congress to allow safety-net providers "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Key to achieving that goal is the flexibility to ensure that covered entities can receive 340B pricing on any drug they prescribe to eligible patients. NFPRHA encourages HRSA to maintain that existing flexibility moving forward.

Of primary concern are the proposed changes to the patient definition. To reflect the primacy of those concerns, we are addressing that section of the proposed guidance first in our comments. All other comments are in the order of the guidance document.

PART C – INDIVIDUALS ELIGIBLE TO RECEIVE 340B DRUGS

NFPRHA urges HRSA to retain the existing standard of patient eligibility tied to the service received, rather than eligibility tied to the drug prescribed

The current patient definition allows Title X-funded health centers to offer prescriptions to patients at the 340B discounted price, provided that those patients receive health care services at the site delivered by a health care professional employed or contracted by or affiliated with the health center, and as long as the patient receives a service or range of services consistent with the Title X grant. While Title X requires its providers to offer a schedule of discounts for individuals whose income is at or below 250% of the federal poverty level (an amount equal to \$29,425 for an individual in 2015), access to 340B pricing allows Title X-funded entities to provide drugs that would often otherwise be too expensive out of pocket for all of their patients. The current patient definition affords Title X-funded health centers the ability to offer contraceptive methods and any other appropriate drugs (for example, antibiotics to treat an infection found during the course of an exam) to patients regardless of their ability to pay full cost for prescriptions.

NFPRHA has significant concern about the proposed changes to the patient definition and their impact on the ability of Title X-funded health centers to serve their patients. The proposed patient definition expressly states that it should "include all patients that meet all of the following criteria on a *prescription-by-prescription or order-by-order basis*" [emphasis added].

This marks a significant change in policy with potentially far-reaching implications. If a patient meets the criteria of the patient definition, it is unclear why that would change on a prescription-by-prescription basis, unless HRSA is moving towards tying patient eligibility to the drug prescribed rather than to the service provided.

NFPRHA strongly opposes tying 340B patient eligibility to the drug prescribed. If a clinician at a Title X-funded health center is providing services within their scope of practice and consistent with all applicable state laws, then he or she should have the flexibility to obtain 340B pricing for any and all medically appropriate prescriptions, provided that the patient is otherwise eligible.

Four in 10 patients seeking care at Title X-funded sites say that their Title X provider is their **only** source of health care. In recognition of this fact, many Title X-funded health centers offer limited primary care services in order to better serve the needs of those patients. 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.

Furthermore, Title X grants do not explicitly delineate the services or drugs that fall within their scope. If the patient definition were to be tied to the drug prescribed and require that that drug be "consistent with the scope" of the Title X grant, it is unclear which drugs would qualify. Furthermore, it is unclear which agency or authority would determine which drugs would be included under each type of 340B-qualifying grant.

Any effort to tie 340B patient eligibility to the drug prescribed would have a significant negative impact on the patients served at Title X-funded health centers. NFPRHA urges HRSA to remove from the guidance all references, similar to the examples below, to 340B patient eligibility being tied to the drug prescribed.

- Part C(a): HHS interprets this section to include all patients that meet all of the following criteria on a prescription-by-prescription or order-by-order basis.
- Preamble Section C(1): The use of telemedicine involving the issuance of a prescription by a covered entity provider is permitted, as long as the practice is authorized under State or Federal law *and the drug purchase otherwise complies with the 340B Program.*
- Part A(c)(2): If a child site loses eligibility for one of the multiple covered entity types for which it is registered, it may continue purchasing and using 340B drugs only for the registered covered entity type(s) which remains eligible for the 340B Program.

NFPRHA recommends that the examples of provider arrangements in the preamble be moved to guidance text

The second element of the patient definition requires that patients receive a health care service from a provider 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.” In the preamble text, HRSA specifies that this “independent contractor” relationship could include “faculty practice arrangements and established residency, internship, locum tenens, and *volunteer health care provider programs*” [emphasis added]. Many Title X-funded health centers rely upon providers who donate their time to the health center. NFPRHA appreciates the clarification that it is appropriate to use 340B drugs for eligible patients if those patients are seen by clinicians providing care under a volunteer arrangement. However, these relationships are unique and would not necessarily be interpreted as independent contractors by future administrations. Thus, NFPRHA requests that these examples be included in guidance text, and not just in the preamble.

NFPRHA requests that HRSA provide additional clarification on how 340B drugs may be used in the context of services provided through telemedicine

NFPRHA applauds the inclusion of telemedicine services in the preamble language of the proposed patient definition. Particularly in remote, rural areas, telemedicine is the most viable and efficient method of delivering health care services. To that end, NFPRHA requests that HRSA clarify that no in-person visit is required to establish the patient-provider relationship prior to services being provided through telemedicine. In addition, NFPRHA requests clarification that telemedicine services or the “provider-to-patient encounter” (referenced in the third prong of the proposed patient definition) do not have to occur at a facility or site such as a mobile van.

NFPRHA urges HRSA to modify the third prong of the patient definition to include confirmation that 340B drugs may be used for expedited partner therapy

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 HRSA should provide clear and explicit guidance to that effect.

EPT is the practice of providing antibiotics or a prescription for antibiotics to a patient who tests positive for an STD to provide to their partner(s) without a medical examination of their partner(s). EPT is a legal, 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 the correct use of 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, an explicit contradiction to public health guidelines. 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 for Title X-funded health centers, as well as HIV prevention grantees and federally qualified health centers. As noted above, the CDC encourages all providers to implement EPT if they cannot ensure that the index patient will not be re-infected. In support the provision of EPT, HRSA should not limit which 340B covered entities be permitted to utilize it as a covered service, as it is in the scope of a number of grantees' grants. HRSA should also clarify that EPT is permissible under the 340B program. As noted above, not providing these prescriptions would be detrimental to the health of the patient and be against the scope of the grants of the grantees providing these services.

NFPRHA requests clarification that the service provided must be consistent with the grant rather than explicitly included in the scope of the project

The wording of the fourth prong of the proposed patient definition is only slightly different from the current patient definition. However, this slight change in wording could translate to very large changes in practice which could severely limit the ability of Title X-funded health centers and their patients to properly benefit from the 340B program. The current patient definition requires that the patient "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 patient "receives a health care service that is consistent with the covered entity's *scope* of grant, project, or contract" [emphasis added].

NFPRHA is concerned that this change in wording could be interpreted to mean that the service is explicitly enumerated in the Title X project. That concern is elevated by the examples set forth in the preamble language. Limiting 340B drugs to those that are within the scope of the grant would hinder the ability of Title X-funded health centers to meet the needs of their patients, as well as limit the benefit of the program for the health center itself.

Title X dollars make up approximately 20% of the revenue at Title X-funded health centers. Ultimately, family planning administrators have to prioritize limited Title X funds where they will be of most use. Limiting 340B drugs to those drugs that are within the *scope* of the project

could have a serious negative impact on patient access. There are many situations in which Title X projects focus on specific populations (e.g., the uninsured, the Latina population, teens, etc.) or activities (e.g., outreach, education, etc.). In addition, some Title X-funded health centers have to make a decision to carve out specific contraceptive methods from their Title X project. Title X requires that services be available on a discounted fee schedule for patients under 250% of the federal poverty line (FPL). All patients under 100% FPL must receive services free of charge. Furthermore, Title X-funded health centers must provide all services outlined in the project to all patients regardless of ability to pay. Because of the high upfront cost of stocking long-acting reversible contraceptives (LARCs) such as intrauterine devices or contraceptive implants, some Title X-funded health centers are financially unable to offer these methods at no cost to the patient. In those instances, LARCs are carved out of the Title X project so that they can recoup at least some of the cost of these methods.

PART A – 340B PROGRAM ELIGIBILITY AND REGISTRATION

NFPRHA requests clarification on registration for Title X grant sub-recipients and service sites

The preamble of the proposed guidance makes reference to sub-recipients of federal grants, stating that:

“HHS will list sites that are sub-recipients of Federal grants, but seeking their own 340B identification numbers separate from a parent entity, if those entities provide information demonstrating their receipt of eligible Federal funds, or in-kind contributions purchased with eligible Federal funds, as well as the grant number under which they receive those funds.”

That same section of the guidance also refers to the ability of non-hospital covered entities to register “associated health care delivery sites” as child sites. It is unclear how these two statements interact, particularly in the context of the Title X program. Many Title X grantees subcontract with other providers for the provision of services. Those providers are referred to as sub-recipients. In many instances, Title X grantees do not deliver any services, and all of the services supported by the grant are delivered by sub-recipients or service sites. NFPRHA requests clarity on when it is appropriate for sub-recipients to be registered as independent covered entities, and when the grantee should register its sub-recipients as child sites. In addition, NFPRHA seeks clarity on which entity has the power to decide whether sites will be registered as child sites or independent covered entities.

In the past couple of years, HRSA and Apexus have both encouraged covered entities to decentralize the registration and recertification responsibilities and to select an authorizing official at the health center level. NFPRHA supports this policy, as it ensures that the covered entity providing the health care services is responsible for its own compliance and updating

registration information and recertification attestations. NFPRHA would oppose any effort by HRSA to reverse this current interpretation of policy by requiring that Title X grantees register as parent sites and/or for Title X sub-recipients to be registered as child sites.

NFPRHA urges HRSA to adopt a registration process which limits waiting time

The registration process currently leaves a three- to six-month gap between when an entity receives a grant award conferring 340B eligibility and when they are able to begin purchasing drugs at a 340B price. The Office of Population Affairs is moving all Title X grants to be awarded with either an April 1 or July 1 start date. If all goes as planned, all of the sub-recipients and service sites under a newly awarded grant will be able to register within the April 1-15 or July 1-15 registration periods. Even in this ideal situation, these providers have a three month gap between becoming eligible to be a 340B covered entity and being able to purchase 340B drugs. This time gap affects patient access, and is unnecessary. Given the negative impact of these delays on Title X-funded health centers and their patients, we recommend that HRSA:

- Accept applications from grantee sites on a rolling basis, as opposed to a quarterly basis;
- Process applications as quickly as possible, as opposed to requiring a three-month delay for all applications, and;
- To the extent possible, accept the “due diligence” performed by other HHS agencies (including other parts of HRSA) which have independently verified that the grantee or sub-recipient meets all eligibility requirements for 340B. Those applications where other HHS agencies (or HRSA) have already verified eligibility should receive a much faster “turn-around” than those where HRSA must make an independent assessment of eligibility.

PART B – DRUGS ELIGIBLE FOR PURCHASE UNDER THE 340B PROGRAM

NFPRHA requests that HRSA not apply the limiting definition to the 340B program

In the Medicaid rebate program, the limiting definition precludes rebates for drugs that are included in a bundled Medicaid payment by excluding those drugs from the definition of covered outpatient drug. However, the limiting definition was only ever intended to apply to the Medicaid rebate program, not to 340B. Applying the limiting definition (and excluding drugs paid for by Medicaid in a bundled manner) is inconsistent with the intent of the 340B program and would be extremely difficult to implement. In effect, this would mean that each state and each of its Medicaid managed care plans could determine which drugs are eligible for 340B based on its own reimbursement methodologies, and the payer could effectively exclude drugs from 340B by choosing to reimburse in a bundled manner.

NFPRHA believes this is contrary to congressional intent. If implemented, this proposed interpretation would result in tremendous variability across the states as to which drugs can be purchased under the 340B program, and would deny otherwise eligible Medicaid patients access to discounted drugs simply because of where they live or in which Medicaid managed care plan they are enrolled.

The Obama administration has made its commitment to payment reform plain. Bundled payment has been one of the more prominent options being explored by the Centers for Medicare & Medicaid Services (CMS) and others to decrease cost and improve quality and health outcomes. NFPRHA believes that applying the limiting definition related to bundled payments to the 340B program is short-sighted and does not take the future of health care payment into account.

PART D – COVERED ENTITY RESPONSIBILITIES

NFPRHA urges HRSA to provide more guidance to states regarding the development of a process to avoid duplicate discounts in the Medicaid managed care context

Early on in the implementation of the 340B Program, HRSA recognized that covered entities needed leverage when negotiating reimbursement rates with state Medicaid programs. To that end, HRSA acknowledged in guidance that covered entities have the right to decide whether or not to use 340B products with Medicaid beneficiaries—referred to as carving-in when using 340B products with Medicaid beneficiaries or carving-out when using non-340B products with Medicaid beneficiaries.¹ Because states have the potential to realize more savings through the 340B Program rather than through collecting rebates, the idea was to incentivize states to offer higher dispensing fees or other shared savings arrangements to encourage providers to carve-in.

HRSA has noted that the covered entity is in the best position to determine the appropriateness of its drug purchasing practices,² which would include the financial implications of a state's reimbursement methodology and the impact it may have on patient access to health care services. For example, if a state is reimbursing only at cost or at cost with an inadequate dispensing fee, the covered entity's best option to fulfill the intent of the 340B Program—to enable it to stretch scarce resources to provide more comprehensive care to more patients—may be to forgo using 340B products with Medicaid beneficiaries.

¹ Notice Regarding the Section 340B Drug Pricing Program—Program Guidance Clarification, 65 Fed. Reg. 13983 (March 15, 2000).

² *Notice Regarding HRSA Grant Requirement— Participation in the 340B Drug Pricing Program*, 65 Fed. Reg. 6383 (Feb. 9, 2000) (HRSA withdraws a proposal which would have required grantees listed in the 340B statute to participate in the 340B Program or provide good-cause for non-participation).

The ability to decide whether to use 340B products with Medicaid beneficiaries is an important federal protection and a significant leverage point for 340B providers that must be preserved.³ Unfortunately, many states are taking this protection away from providers, requiring them to use 340B products with Medicaid beneficiaries while at the same time subjecting them to woefully inadequate reimbursement rates. Other states, mostly with respect to Medicaid managed care, are considering not allowing providers to use 340B products because they do not have a system in place to identify claims that utilize these products for purposes of exempting them from rebates.

NFPRHA applauds HRSA's assertion that 340B covered entities "may make differing selections by covered entity site and managed care organization." It is, however, evident that the states need more direction regarding avoiding duplicate discounts in Medicaid managed care. The requirement to determine such a process was made necessary by the Affordable Care Act, which became law over five years ago. Yet, many states have still not made any moves to develop this process, and Title X-funded health centers and other safety-net providers are paying the price. NFPRHA strongly urges HRSA to take a stronger position on what this process should look like to assist states in moving forward with the requirement.

PART H – PROGRAM INTEGRITY

NFPRHA requests that HRSA auditors adhere to the Generally Accepted Government Auditing Standards

Federal grantees and sub-recipients 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), also known as the "Yellow Book." However, 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. 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. 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.

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 should be triggered by the date the audit

³ *Id.*

findings are received by the covered entity, not from the date they were issued by HRSA. The difficulties associated with such a short period of time for responding are further exacerbated if there was not a full and complete disclosure of the auditor's concerns during the Exit Conference. NFPRHA requests that, at a minimum, the auditor should provide 45 - 60 days' response time that begins upon the covered entities receipt of the report, not the date of the report.

NFPRHA appreciates the opportunity to comment on this proposed guidance. If you require additional information about the issues raised in this letter, please contact Mindy McGrath at 202-293-3114 ext. 206 or at mmcgrath@nfprha.org.

Sincerely,

A handwritten signature in cursive script that reads "Clare M. Coleman".

Clare Coleman
President & CEO