AAPCHO

ASSOCIATION OF ASIAN PACIFIC COMMUNITY HEALTH ORGANIZATIONS

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

Subject: 340B Drug Pricing Program Omnibus Guidance, Federal Register, Vol. 80, No. 167, 52300

Dear Captain Pedley:

AAPCHO is a national not-for-profit association of 35 community-based health care organizations, 29 of which are Federally Qualified Health Centers (FQHCs). AAPCHO members are dedicated to promoting advocacy, collaboration, and leadership to improve the health status and care access of medically underserved AA&NHOPIs in the U.S., its territories, and its freely associated states.

We write today to voice strong concern about the proposed "patient definition" in the proposed 340B guidance. If implemented, the new definition of patient will dramatically limit the ability of AAPCHO's health centers to participate in the 340B program.

AAPCHO members focus on providing services that are uniquely appropriate to their patient populations including: comprehensive primary medical care, culturally and linguistically appropriate health care services, and non-clinical enabling services such as interpretation and case management. On average, AAPCHO's health centers have a higher percentage of patients age 65+ than other health centers (10% vs. 7%). Our members also have a much higher rate of patients who are Limited English Proficient (LEP) (50% vs. 23%), with some health centers serving as many as 99% LEP individuals. AAPCHO members also provide a higher average number of enabling service encounters (9274 vs. 4953) than other health centers in response to the needs of our patients (HRSA Uniform Data System, 2013).

AAPCHO thanks HRSA for the opportunity to comment on the proposed 340B guidance. Our FQHCs are the target safety net providers that Congress intended to benefit when they established the 340B program, and we are required to use the savings to expand our mission. As good stewards of the 340B program, AAPCHO members have used the revenue from this program to further provide services and expand capacity to serve low-income AA&NHOPI populations.

The 340B program recognizes the critical role of pharmacies within the integrated community health center setting. Our clinics serve communities that are disproportionately impacted by chronic conditions, such as diabetes, heart disease, and hepatitis B, and many patients rely on pharmaceutical drugs to support effective treatment. Our clinics have found that integrating in-language and culturally competent pharmacy care is an essential element of effective care. Many clinics deliver in-house pharmaceutical services in-language and are able to reiterate or expand on the guidance of physicians, allowing the patient to better understand and navigate their treatment protocol. We have seen that integration of in-language and culturally competent pharmaceutical care leads to better adherence to treatment regimens, resulting in more effective care.

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340B plays a critical role in helping AAPCHO members meet their mission by providing needed revenue to stretch federal dollars. We serve all patients without regards to their ability to pay or their insurance status, and we offer services on a sliding fee scale. What's more, given the unique AA&NHOPI population our clinics serve, we provide a wide range of culturally and linguistically appropriate care that improves health outcomes but is often underpaid or not reimbursed by external payors.

340B has helped to fill in the gaps by providing additional resources to serve our vulnerable patients and allowing our members to expand their services and support other activities that are included under their Section 330 scope of services. While every health center may use their 340B savings differently, these funds are commonly used to support sliding fee discounts, clinical pharmacy programs, and provider salaries, ultimately increasing patient access to care. And when they receive their medications in partnership with a AAPCHO center, our patients also receive in-language assistance and other culturally appropriate care which is critical for medication adherence.

AAPCHO's primary specific concern with the proposed guidance concerns revisions to the definition of "eligible patient" which prescribes a cookie cutter definition of who can be a 340B patient. The proposed definition ignores the specific organizational structures, program requirements, federal oversight, and statutory goals that apply to FQHCs and all other types of "HRSA grantees" that are eligible for the program. This definition also ignores the many complex relationships that FQHCs have with their partners, including the need to refer out some complex patients to specialists. We strongly recommend that HRSA not apply the new patient definition to FQHCs or the other original HRSA grantees.

AAPCHO recommends that HRSA instead adopt the Bureau of Primary Health Care's long-standing definition of a "Health Center patient" which is used by all Health Centers in its annual reporting under the Uniform Data System (UDS). This approach is consistent with HRSA/OPA's long-standing policy of applying a unique patient definition to the AIDS Drug Assistance Programs (ADAPs) in recognition of their unique structure.

In addition, AAPCHO formally supports the comments submitted by the National Association of Community Health Centers (NACHC). In particular, we support their comments on specific sections (in order of guidance):

Part A – 340B Program Eligibility and Registration
NACHC recommends that HRSA/OPA

- Streamline and accelerate the site registration process to avoid multi-month delays in 340B access for FQHCs and their patients.
- Simplify or eliminate the site registration requirement for in-scope, non-traditional sites.
- Permit 340B sites to replenish drugs provided to eligible patients prior to their termination.
- Increase flexibility in site registration rules in cases of Public Health Emergencies.

Part B - Drugs eligible for purchase under the 340B Program
NACHC recommends that HRSA/OPA make the Guidance consistent with the Summary by adding language to the Guidance that:

Reflects both statutory criteria for drugs excluded under Section 1927(k).

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- Incorporates the prohibition on manufacturers denying 340B sales based on perceived compliance with the bundled payment restriction.

Part C - Individuals Eligible to Receive 340B Drugs
NACHC strongly supports HRSA/OPA's proposals to:

- Continue to recognize the unique structure and purpose of ADAP programs by establishing a unique patient definition for them.
- Require the covered entity to have a provider-to-patient relationship with the patient and to be responsible for the patient's overall care in order for the patient to be 340B-eligible.

NACHC recommends that HRSA/OPA:

- Add language to the Guidance explicitly recognizing the role of telemedicine.
- Expand Guidance to incorporate the broad definition of employed or contracted providers provided in the Summary.
- Clarify that prescriptions which are clinically-appropriate to be written for an eligible patient's partner or family member can be filled under 340B.
- State that a drug's "outpatient" status will be determined based on where and when the drug is intended to be taken, not where and when the prescription was written, making discharge prescriptions eligible for 340B.
- Clarify that a covered entity is responsible for services that its patients receive via telemedicine.
- Increase flexibility in determining "eligible patients" in the event of Public Health Emergencies.
- Incorporate into Guidance language giving manufacturers discretion in whether to request repayment from covered entities for small amounts.

Part D – Covered Entity Responsibilities
NACHC supports HRSA/OPA's proposals to:

- Permit Health Centers and other covered entities to vary carve-in/ carve-out decisions based on site and MCO.
- Use discretion in determining consequences for minor violations, such as non-systemic failure to produce records.

NACHC recommends that HRSA/OPA:

- Correct language mischaracterizing Medicaid Managed Care duplicate discounts.
- Clarify that the Medicaid Exclusion File (MEF) currently applies only to Fee-for-Service.
- Minimize the requirements and approval timeframes associated with agreements to prevent duplicate discounts at contract pharmacies.
- Revise Guidance language on covered entities' liability for repayment to reflect statutory provisions and their limited ability to ensure that states and MCOs use information properly prioritize the development of detailed guidance on methodologies for Health Centers and other covered entities to identify 340B drugs to States/ MCOs.
- Encourage or require States to develop a single mechanism for Health Centers and covered entities to identify 340B drugs to States/ MCOs.
- Implement requirement to maintain auditable records for 5 years on prospective basis.
- Publish detailed guidance defining "auditable records."
- Ensure that all auditors adhere to the same standards with regards to auditable records" and other provisions.

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Part E - Contract pharmacy arrangements.
NACHC supports HRSA/OPA's proposals to:

- Not limit number of contract pharmacies.
- Instruct covered entities to ensure their contract pharmacy arrangements are consistent with the intent of the 340B program.

NACHC recommends that HRSA/OPA make it easier for covered entities to add contract pharmacies in response to Public Health Emergencies.

Part F – Manufacturer Responsibilities
NACHC supports HRSA/OPA's proposal to require manufacturers to ensure that limited distribution networks do not discriminate against 340B covered entities.

NACHC recommends that HRSA/OPA state explicitly in the Guidance that 340B prices apply to drugs sold via Limited Distribution Networks.

Part H – Program Integrity
NACHC generally supports efforts to strengthen the integrity of the 340B program, as they will protect the program in the long run for providers who use it appropriately. However, it is critical to examine the specific ways in which a general proposal impact Health Centers and other types of covered entities, in order to avoid any unintended but detrimental outcomes.

NACHC supports HRSA's proposals to:

- Ensure that covered entities are subject to no more than one audit at a time.
- Place reasonable parameters around manufacturers' audit practices.

NACHC recommends that HRSA/OPA:

- Ensure that consequences for non-compliance are commensurate with the scope, intention, and impact of the violation.
- Clarify and strengthen the HHS audit process by:
    - Publishing HRSA/OPA's audit protocol, to assist covered entities in knowing how compliance will be evaluated, and increase consistency across auditors;
    - Conducting audits in accordance with the Government Accountability Office (GAO) published standards for government performance audits ("GAGAS" or the "Yellow Book");
    - Permitting auditors to discuss preliminary findings with the covered entity; and
    - Establishing a robust, independent appeals process.
- Incorporate the current requirement for manufacturers to follow GAGAS ("Yellow Book") standards into the Guidance language around manufacturer audits.
- 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.

The 340B program provides important revenue for AAPCHO members and allows our clinics to expand services to vulnerable AA&NHOPI populations. It is critically important that HRSA ensure that FQHCs and other HRSA grantees and the patients they serve are eligible to participate in the program and use the revenue to stretch scarce federal resources, as Congress intended. The changes outlined in this

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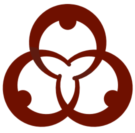

comment letter will allow FQHCs to fully participate in the program and remain stewards of the program. We urge HRSA to adopt these changes as soon as possible.

If you have any questions or need further information about AAPCHO or our members' participation in 340B, please contact Isha Weerasinghe, Director of Policy and Advocacy, at isha@aapcho.org.

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