CHCANYS DEFINING NEW DIRECTIONS
Community Health Care Association of New York State www.chcanys.org

COMMUNITY HEALTH CENTER FQHC QUALITY

October 27, 2015

Commander 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, (August 28, 2015)**

Dear Commander Pedley:

We are pleased to respond to the above-referenced proposed guidance published by the Health Resources and Services Administration (HRSA) on August 28, 2015 (80 FR 52300)("Guidance"). The Community Health Care Association of New York State (CHCANYS) is the nation's oldest Primary Care Association and serves as the voice of community health centers as leading providers of primary care throughout the state. We work closely with the more than 60 Federally Qualified Health Centers (FQHCs) that operate over 600 sites across New York State.

We write to you today to share our support for comments from the National Association of Community Health Centers, our national organization that represents health centers around the country, which are available at http://www.nachc.com/340Bmega.cfm. We would like to take this opportunity to highlight those issues of utmost importance to our health centers.

A fundamental characteristic of FQHCs is their commitment to serve all individuals, regardless of their insurance status or ability to pay. Nationwide, over 70% of health center patients live below the poverty line; if these individuals are uninsured, they pay no more than a nominal fee to receive the full range of FQHC services. An additional 20% of FQHCs patients are between 100% and 200% of the poverty line; if uninsured, these patients are generally charged reduced fees based on a sliding scale. 47% of health center patients are on Medicaid, 28% are uninsured, although these percentages can vary enormously across individual states, due to local and state conditions (including, but not limited to, whether the state has expanded Medicaid). Some states report uninsured rates as high as 54%.

New York State FQHCs serve 1.7 million New Yorkers annually. In 2013, 86% of patients served in New York were below 200% of poverty and 52% received Medicaid. One quarter of New York's FQHC patients are best served in a language other than English and three-fourths are racial and/or ethnic minorities. In short, FQHCs are New York's primary care safety net providers.

As you know, FQHCs are the classic example of the type of safety net provider that the 340B program was intended to support, and their participation in 340B has bipartisan support. FQHCs are required by statute to use 340B savings to advance their charitable, safety-net mission. 340B savings are frequently more critical to an FQHC's ability to sustain on-going operations than their Section 330 (health center) grant. FQHCs are already struggling with reduced 340B savings due to new rules around Medicaid managed care.

We support HRSA's efforts to strengthen the integrity of the 340B program, as this will protect the program in the long run for providers who use it appropriately. However, the Guidance generally takes a one-size-fits-all approach, which often seems geared towards a hospital structure. This broad-brush approach is often detrimental to HRSA grantees and their patients, as it does not reflect each grantee's unique statutorily-mandated structures and goals. 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 FQHCs and all other types of "HRSA grantees" that are is eligible for the program.

In these comments, we first discuss what we view as the most significant issue that the proposed Guidance will create for Health Centers – the proposed one-size-fits-all "patient definition." We then offer a recommendation that will address these concerns. Finally, we list recommendations and areas of support related to other issues covered under the proposed Guidance.

## Revisions to definition of "eligible patient" will have significant negative impacts on Health Centers and our patients

Our primary concern demonstrates the issue raised above – i.e., HRSA/OPA has proposed a one-size-fits-all definition of an "eligible patient." While this definition may help curb abuses in some settings, it will have significant negative impacts in the Health Center setting – impacts that are in direct contradiction to the expressed intent of the 340B program.

The proposed definition will make it impossible for FQHCs to provide 340B drugs to their patients who are referred out to see a specialist or other provider, or who are discharged from the hospital – despite the fact that FQHCs are responsible for managing their patients' care, providing pharmacy services as appropriate, and serving as their patients' Primary Care Medical Home. If applied to Health Centers, the new definition:

- will have **potentially devastating effects on their patients' health and financial stability,** as evidence clearly shows that higher prices cause many low-income patients to not get their prescriptions filled.
- **will negatively impact FQHCs' clinical outcomes** due to their patients not taking their prescribed medications, and increase frustration for FQHC providers as they are unable to care for their patients appropriately:
- will have **potentially devastating effects on FQHCs' finances**, due to:
    - Reduced 340B revenues
    - Increased spending, as many Health Centers' community-run Boards will likely choose to discount their uninsured patients' specialist-prescribed and/or discharge prescriptions so their patients can afford them
    - Reduced reimbursement due to worse quality and outcome measures

  - Hundreds of thousands of dollars in upfront and on-going costs for FQHCs with in-house pharmacies, as they will be forced to maintain a second, non-340B inventory.
- will have impacts that are **contrary to the purpose of the Health Center program**, as expressed in long-standing statutory language and recently reaffirmed by HRSA/BPHC (e.g., requirements to provide case management, to offer pharmaceutical services as appropriate, and to serve as a Primary Care Medical Home.)
- will have impacts that **directly conflict with numerous Affordable Care Act (ACA) and HHS-wide goals,** including:
  - decreasing preventable hospital readmissions
  - increasing Health Center funding in order to increase their capacity
  - better integration of behavioral and primary health care
  - all three elements of the Triple Aim
- are **not justified under the statute**, as this proposal defines eligibility on a script-by-script basis, while the statute defines eligibility on a person-by-person basis
- **is inconsistent with the intent of the 340B program**, as explicitly stated by Congress, to enable entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." This proposal will have the exact opposite effect on Health Centers, reducing resources available to them, and forcing them to spend more of their existing resources to fund discounts that were formerly available through 340B. ***These costs will generally need to be financed using Section 330 grant funds, and given that most FQHCs operate on a margin of less than 1%, this will force FQHCs to cut other services.***

## HRSA/OPA should define "Health Center patient" for 340B purposes in the same way that HRSA/BPHC defines "Health Center patient" for purposes of overseeing the Health Center program

For all these reasons, we urge HRSA/OPA in the strongest possible terms not to apply these proposed revisions to Health Centers. Instead, we recommend that HRSA/OPA recognize the characteristics that distinguish Health Centers from all other types of covered entities:

- Unlike hospitals, Health Centers have long-term relationships with patients and are statutorily-required to coordinate their patients' care
- Unlike other grantee types, Health Centers do not focus on a specific diagnosis or type of service; rather, they provide a full range of primary and preventive services and are expected to coordinate all of their patients' care and serve as their Primary Care Medical Home.
- Health Centers are required by statute to provide their patients with appropriate pharmaceutical services.
- Federal oversight of Health Centers is more detailed, continuous and intense than that of any other type of grantee, and is performed by HRSA/OPA's sister Bureau, the Bureau of Primary Health Care (HRSA/BPHC.)
- Health Centers are required by statute and HRSA/BPHC to reinvest all revenues, including 340B, into activities that are approved under their HRSA/BPHC Scope of Project and advance their charitable mission

Because the Health Centers' statutorily-mandated roles and responsibilities are significantly different from all other types of covered entities, they should have a distinct definition of "eligible patient." We therefore urge HRSA/OPA to develop a unique patient definition for Health Centers.

Specifically, we strongly recommend that HRSA/OPA define "Health Center patient" for 340B purposes in the same way that HRSA/BPHC defines "Health Center patient" for purposes of overseeing the Health Center program – namely, by using the long-standing definition used under the Uniform Data System.

The UDS definition of Health Center patient is appropriate for use in the 340B program for several reasons:

- It is an established, clearly-defined definition.
- HRSA/BPHC provides continuous oversight to ensure that Health Centers apply the definition properly.
- The UDS definition ensures that individuals who have only a limited relationship with a Health Center do not qualify as "Health Center patients."
- Under the statute, every person who qualifies as a "Health Center patient" is entitled to access a full range of primary and preventive care through the Health Center, as well as case management services and appropriate pharmaceuticals, regardless of their ability to pay.
- It ensure that individuals who meet the definition of "Health Center patient" can access 340B drugs for all their outpatient prescriptions, even if they are written by non-FQHC providers:
- Each Health Center is held publicly accountable for the quality of care provided to every person who meets the UDS definition of a Health Center patient.

## Additional Comments:

Please see the comments submitted by NACHC, available at http://www.nachc.com/340Bmega.cfm , for more information on each of the issues below.

**Cross-cutting comments**

- The Guidance should not create large administrative burdens in an attempt to rectify small issues of non-compliance.
- The official Guidance language should reflect all important provisions addressed in the Summary.

### Part A – 340B Program Eligibility and Registration

- We recommend 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, and
  - Revise the description of the Annual Recertification process to require reporting of only material instances of non-compliance.

### Part B - Drugs eligible for purchase under the 340B Program.

- We recommend incorporating Summary language prohibiting manufacturers from denying 340B sales based on perceived compliance with the bundled payment restriction into the official Guidance.

**Part C - Individuals Eligible to Receive 340B Drugs.**

In addition to the overarching comments offered above about the impact of the proposed patient definition on FQHCs and their patients, we offer the following comments on individual provisions of Part C.

- We strongly support 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
- We recommend that HRSA/OPA:
  - Add language to the Guidance explicitly recognizing the role of telemedicine and clarify that a covered entity is responsible for the services its patients receive via telemedicine
  - Clarify that eligibility should be based on the date a prescription is filled, not written
  - Expand the 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.
  - Increase flexibility in determining "eligible patients" in the event of Public Health Emergencies
  - Modify the Summary to indicate that accumulator errors that do not result in diversion are not considered violations, and that covered entities may maintain small positive "virtual" inventories without being considered a violation.
  - Incorporate into the Guidance language giving manufacturers discretion in whether to request repayment from covered entities for small amounts.

**Part D – Covered Entity Responsibilities**

- We support HRSA/OPA's proposals to:
  - permit Health Centers and other covered entities to vary carve-in/carve-out decisions based on site and Managed Care Organization (MCO). This issue is of particular interest to CHCANYS, as New York State recently announced that covered entities who choose to enroll in the 340b program must use 340b drugs in both Fee for Service (FFS) and Managed Care Medicaid. Many New York State health centers do not currently participate in the 340b program in FFS Medicaid and to require them to do so in order to receive discounts in managed care would be a large administrative burden and contradict the intent of the 340b program. We emphatically support HRSA's flexibility in permitting covered entities to make their own carve-in/carve-out decisions.
  - use discretion in determining consequences for minor violations, such as non-systemic failure to produce records:
- With regards to avoiding duplicate discounts, we recommend that HRSA/OPA:
  - publish detailed guidance on methodologies for covered entities to identify 340B drugs to States/ MCOs as soon as possible
  - encourage or require States to develop a single, standardized mechanism for Health Centers and covered entities to identify 340B drugs to States/MCOs

  - permit Health Centers to vary carve-in/carve-out decisions based on individual drug
  - ensure consistency with CMS policy by referencing CMS regulatory language stating that MCOs are responsible to prevent duplicate discounts and correct the language mischaracterizing Medicaid Managed Care duplicate discounts
  - clarify that the Medicaid Exclusion File (MEF) currently applies only to Fee-for-Service. We strongly recommend that HRSA clarify this issue. In July 2015, New York State announced that covered entities must provide indicator codes for all 340b drugs- in both FFS and Managed Care- for inclusion the MEF, contradicting earlier federal guidance that the MEF is intended to help 340B covered entities, states, and manufacturers avoid duplicate discounts specific to FFS. Clarification from HSRA would resolve this confusion for New York State health centers.
  - provide a template and expedited review times for agreements to prevent duplicate discounts at contract pharmacies
  - revise the Guidance language on covered entities' repayment liability to accurately reflect the statute and ensure that Health Centers are not held responsible for States' or MCOs' actions.
- With regards to audits of covered entities, we recommends that HRSA/OPA:
  - implement the requirement to maintain auditable records for 5 years on prospective basis
  - publish guidance explaining what specific records, and in what form, a covered entity must maintain in order to meet the "auditable records" standard
  - ensure that all auditors adhere to the same standards with regards to "auditable records" and other provisions.

**Part E - Contract pharmacy arrangements.**

- We support HRSA/OPA's proposals to:
  - not limit the number of pharmacies with which an FQHC can contract
  - instruct covered entities to ensure their contract pharmacy arrangements are consistent with the intent of the 340B program.
- We recommend that HRSA/OPA make it easier for covered entities to add contract pharmacies in response to Public Health Emergencies.

**Part F – Manufacturer Responsibilities**

- We support HRSA/OPA's proposal to require manufacturers to ensure that limited distribution networks do not discriminate against 340B covered entities.
- We recommend that HRSA/OPA state explicitly in the Guidance that 340B prices apply to drugs sold via Limited Distribution Networks.

**Part H – Program Integrity**

- We generally support 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 impacts Health Centers and other types of covered entities, in order to avoid any unintended but detrimental outcomes.
- We support 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.
- We recommend that HRSA/OPA:

- Ensure that consequences for non-compliance are commensurate with the scope, intention, and impact of the violation
- Provide covered entities with at least 60 days to respond to a written notice of audit findings.
- 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.

Thank you for your consideration of these comments. Should you have any questions about any of the issues outlined above, please do not hesitate to contact me at bgrossman@chcanys.org or (518) 434-1112

Sincerely,

Beverly Grossman
Senior Policy Director