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October 27, 2015

Commander Krista Pedley
Director, Office of Pharmacy Affairs
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:

Bi-State Primary Care Association is 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”).

Established in 1986, Bi-State is a nonpartisan, nonprofit 501(c)(3) charitable organization that promotes access to effective and affordable primary care and preventive services for all, with special emphasis on underserved populations in Vermont and New Hampshire. Bi-State works with federal, state and regional health policy organizations, foundations and payers to develop strategies, policies and programs that provide and support community-based primary health care services in medically-underserved areas. Our members include Community Health Centers, which include Federally Qualified Health Centers (hereafter interchangeably referred to as Health Centers or FQHCs); Rural Health Clinics; private and hospital-supported primary care practices; Community Action Programs; Health Care for the Homeless programs; Area Health Education Centers; Clinics for the Uninsured, and social service agencies.

A fundamental characteristic of FQHCs is their commitment to serve all individuals, regardless of their insurance status or ability to pay. Nationally, 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 FQHC 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 to the 0-133% FPL population). Some states report uninsured rates as high as 54%.

In Vermont and New Hampshire, FQHCs are part of the essential primary care fabric and health care ecosystem. Collectively, our Health Centers serve over 236,000 patients in underserved communities across our two states. The 340B program is essential to the Vermont and New Hampshire FQHCs; allowing them to provide affordable pharmacy services to their patients.

Bi-State is focusing its comments primarily on issues that are of particular importance to Health Centers and the patients they serve. Bi-State’s comments begin with a summary of our key points. We then provide general background on Health Centers and the 340B program to provide context for our specific comments and requests. We then offer a few cross-cutting comments, before commenting on each section of the proposed Guidance. In addition to our comments, we fully endorse the National Association of Community Health Center’s (NACHC) letter that will be submitted before the deadline. With NACHC’s permission, our letter parallels their comments and concerns.

SUMMARY OF BACKGROUND INFORMATION AND COMMENTS:

FQHCs and the 340B program

- 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 in Congress.
- FQHCs are required by statute to reinvest all 340B revenues into activities that are approved under their HRSA/Bureau of Primary Health Care (BPHC) Scope of Project and advance their charitable mission. HRSA/BPHC's continuous oversight of Health Centers ensures that they comply with this requirement.
- Savings from 340B are a fundamental portion of FQHCs' budgets and are critical to their ability to sustain ongoing operations.
- FQHCs are already struggling with reduced 340B savings due to new rules around Medicaid managed care.

Overarching comment

Bi-State supports 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 toward 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. Therefore, we 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 grantee" that are eligible for the program.

Primary concern: revisions to definition of "eligible patient"

Bi-State's primary concern demonstrates the issue raised above; i.e., HRSA/Office of Pharmacy Affairs (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 ongoing 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 longstanding 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 Health and Human Services (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; and 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.*

For all of these reasons, Bi-State urges 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 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, Bi-State strongly recommends 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 (UDS).

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.”
- It will 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.

Other 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.

Comments on specific sections (in order of Guidance)

Part A: 340B Program Eligibility and Registration

- Bi-State 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.
 - 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

- Bi-State recommends 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, Bi-State offers the following comments on individual provisions of Part C.

- Bi-State strongly supports HRSA/OPA's proposals to:
 - Continue to recognize the unique structure and purpose of AIDS Drug Assistance Programs (ADAP) 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
- Bi-State recommends 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 for 120 days or less 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

- Bi-State supports 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) and use discretion in determining consequences for minor violations, such as non-systemic failure to produce records.
- With regard to avoiding duplicate discounts, Bi-State recommends 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.
- 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 regard to audits of covered entities, Bi-State 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

- Bi-State supports HRSA/OPA's proposals to: not limit the number of pharmacies with which an FQHC can contract and to instruct covered entities to ensure their contract pharmacy arrangements are consistent with the intent of the 340B program.
- Bi-State recommends that HRSA/OPA make it easier for covered entities to add contract pharmacies in response to public health emergencies.

Part F: Manufacturer Responsibilities

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

Part H: Program Integrity

- Bi-State 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 impacts Health Centers and other types of covered entities in order to avoid any unintended but detrimental outcomes.
- Bi-State supports HRSA's proposals to ensure that covered entities are subject to no more than one audit at a time and to place reasonable parameters around manufacturers' audit practices.
- Bi-State recommends 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; and 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.
 - 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.

INTRODUCTION

As will be discussed further, 340B plays a critical role in enabling Health Centers to achieve their Congressionally-mandated mission of providing comprehensive primary and preventive care and case management to underserved patients. In addition, Health Centers are broadly recognized as using the program in a manner that is consistent with Congressional intent and HRSA requirements, and are often struggling to absorb significant 340B losses associated with Medicaid Managed Care patients.

Bi-State supports efforts to strengthen the integrity of the 340B program, as they will protect the program for providers who use it appropriately. However, it is critical that specific proposals recognize the unique circumstances of each type of covered entity, to avoid damaging parts of the program that are already working well. This can occur in two ways: 1) by prohibiting Health Centers (and other types of covered entities) from engaging in long-standing practices that have never raised compliance concerns; and 2) by creating administrative barriers that are so burdensome that they effectively prohibit Health Center and other compliant providers from using the program as intended.

Unfortunately, Bi-State is concerned that many of the policies proposed in the draft Guidance would have one or both of these unintentional, but highly detrimental, impacts on FQHCs and their patients.

We begin our comments with general background on Health Centers and the 340B program, to provide context for our specific comments and requests. We then offer several cross-cutting comments, before commenting on each section of the proposed Guidance in order.

BACKGROUND ON FQHCs AND THE 340B PROGRAM

- FQHCs are the classic example of the type of safety net provider that the 340B program was intended to support. We make care affordable, charging persons below the poverty level no more than a nominal fee, and charging those between 100-200% of the FPL based on a sliding fee scale. We serve only those areas and populations that HRSA has designated as being highest need. We develop long-term relationships with our patients, providing a stable source of care as many of them churn between periods of Medicaid, private coverage, and being uninsured. We coordinate their care, serving as a Primary Care Medical Home which manages their overall care even when patients need to seek care elsewhere, such as from a specialist or hospital. As discussed below, every penny of 340B savings is – by law – reinvested in our HRSA-approved safety net project. Given all these factors, it is not surprising that at a Congressional hearing held this spring by the House Energy and Commerce Subcommittee on Health to focus on the 340B program, the majority of the speakers (both witnesses and members of Congress) expressed support for Health Centers as examples of the type of safety net providers that the 340B program was designed to support.
- FQHCs are required by statute to reinvest all 340B revenues into activities that are approved under their HRSA/BPHC Scope of Project and advance their charitable mission. HRSA/BPHC’s continuous oversight of Health Centers ensures that they comply with this requirement. Section 330 of the Public Health Service Act (PHSA, also referred to as the “Section 330 statute” or “Section 330”), which created the Health Center program, states in Section (e)(5)(D) that any savings that the Health Center receives as a result of being a Section 330 Health Center must be used for a purpose that promotes the Section 330 project. All FQHCs are either Section 330 grantees or “look-alikes” (which means that they meet all of the Section 330 requirements but are not receiving a grant). In other words, since Health Centers are eligible for 340B as a result of being approved as a Section 330 Health Center, they are required to use any 340B proceeds to support other activities that are included under their Section 330 scope. 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. In addition, HRSA/OPA can be confident that all Health Centers comply with this requirement, given that (as will be discussed below) HRSA/BPHC conducts detailed, intense oversight of Health Center activities on a continuous basis.

- 340B savings are a fundamental portion of FQHCs' budgets and are critical to their ability to sustain on-going operations. While Section 330 grants are often critical to our Health Centers' ability to fulfill our safety net mission, Health Centers frequently report that 340B savings are even more important to their ability to keep their doors open. In other words, among FQHCs, 340B is serving its Congressionally-intended purpose of assisting covered entities "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Therefore, new limitations on FQHCs' ability to access 340B savings will not only impact their patients' ability to access affordable pharmaceuticals, they will also undermine Health Centers' ability to support many of their core services and activities.
- FQHCs are already struggling with reduced 340B savings due to new rules around Medicaid managed care. As you are aware, for close to two decades, FQHCs and other 340B covered entities have used 340B drugs for patients covered by Medicaid MCOs. However, since the passage of the ACA, states have also been eligible to seek rebates for drugs provided to MCO patients. The statutory language requires states to establish methods for identifying 340B claims for exclusion from other Medicaid managed care rebate requests to manufacturers. In practice, states are making the process for identifying 340B claims so burdensome that it effectively prohibits FQHCs from using 340B drugs for MCO patients. It is our hope that this Guidance and the forthcoming CMS Medicaid regulation on managed care will clarify that covered entities are absolutely entitled to dispense 340B medication to their Medicaid MCO patients, and that neither explicit policies nor administrative processes may prohibit them from doing so while continuing to realize 340B-related savings. Nonetheless, while we are awaiting these critical clarifications, many FQHCs are already facing the loss of 340B-related savings for Medicaid MCO patients who often can comprise close to half of their entire patient population. If additional limitations on FQHCs' access to 340B savings are imposed on top of the loss of part or all of the savings from Medicaid MCO patients, the results could be potentially devastating for many FQHCs.

CROSS-CUTTING COMMENTS

- **Our overarching concern is the proposed revisions to the "patient definition."** 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. While this approach may be appropriate in a hospital environment – in which a provider may see a patient once, refer them to other outside providers, and never see them again – it is inappropriate in an FQHC environment, where statute and federal oversight require us to manage the patient's overall care (including providing appropriate pharmacy services) and be held publicly accountable for the quality of care provided.
- **The proposed one-size-fits-all approach to managing covered entities is often detrimental to HRSA grantees¹ and their patients and does not reflect each grantee's unique statutorily-mandated structures and goals.** Bi-State recognizes that hospitals account for the large 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, Bi-State has serious concerns about applying this one-size-fits-all approach to managing covered entities. We recognize that from an administrative standpoint, a one-size-fits-all approach is easier than having different standards for different types of covered entities. However, Bi-State urges HRSA/OPA to remember that each grantee program was established individually by Congress to operate in unique ways and serve unique

¹ References to "HRSA grantees" and "grantee programs" are intended to include both Health Center grantees and Health Center look-alikes. We are using the term "grantee" for simplicity, as all other non-hospital covered entities are grantees.

goals. Thus, proposals that may be appropriate in a hospital setting are often counterproductive in an FQHC setting and in many other grantee settings. As will be discussed at length below, this proposed 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."

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 eligible for the program.*

- **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 Bi-State contends that HRSA/OPA lacks statutory authority (e.g., failure to produce certain records requested during HRSA/OPA audits).

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. Bi-State is 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, Bi-State recommends 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.

- **The Guidance should reflect all important provisions addressed in the Summary:** We have noted several instances where the Summary makes important points, but these points are not specifically addressed in the Guidance. Given that this Guidance may function as a stand-alone document in the future, we strongly recommend that all key points from the Summary be included in the Guidance, particularly in situations where the issue is not immediately self-evident based on the Guidance language (for example, as discussed below, Part C(s) of the Summary states that residency, internships, locum tenens, etc., programs meet the employment/independent contractor requirement; however, the Guidance language at Part C(a)(2) does not make this clear if it is read independently).

COMMENTS ON SPECIFIC SECTIONS (in order of Guidance)

Part A: 340B Program Eligibility and Registration

A1. Streamline and accelerate the site registration process to avoid multi-month delays in 340B access for FQHCs and their patients:

Issue: Bi-State supports HRSA maintenance of 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 ensure that covered entities have met all eligibility requirements and attested to (or otherwise demonstrated their compliance with) all 340B requirements prior to listing them in the system.

However, the current enrollment timelines require a new or relocated FQHC 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 Health Center must wait until the next quarterly enrollment period to register, and then wait an additional 3 months for the approval to become effective. For other provider types, these timeframes may be necessary to provide HRSA/OPA staff time to ensure that the covered entity meets the eligibility requirements. However, a Health Center has already been approved by *another HRSA Bureau* as meeting all 340B eligibility requirements prior to starting the registration process. Thus, HRSA/OPA has no need to conduct additional oversight for FQHCs prior to listing them as eligible, meaning that ***the 3-6 month delay is unnecessary from a program integrity standpoint; yet, has significant negative impacts on FQHCs and their patients.***

As you are aware, Carolina Health Centers in Greenwood, SC, recently sent a letter to HRSA Acting Administrator Jim Macrae about two sites that are being significantly impacted by this issue. We appreciate both BPHC's and OPA's responses to this letter, and the specific efforts that were made to reduce how long existing patients in both sites will be unable to access 340B drugs. However, we remain concerned that these "fixes" were limited to the two Carolina sites and did not resolve the underlying issue, so similar situations will continue to occur.

Given HRSA/BPHC's extensive oversight of FQHCs, Bi-State feels strongly that this multi-month delay is unnecessary from a program integrity standpoint and is harmful to patients and Health Centers. The delay might be understandable if HRSA/OPA needed time to do its "due diligence" to ensure that the new site met all 340B eligibility requirements. However, FQHC eligibility for 340B is based entirely on their compliance with Section 330 requirements (including Scope of Project), which are overseen by HRSA/BPHC. As you are aware, HRSA/BPHC has an extensive, detailed process for determining which sites are approved for inclusion under a Section 330 Scope of Project. HRSA/OPA is not required to provide any additional oversight or verification to determine that an FQHC site meets the eligibility requirements, beyond the *de minimis* task of ensuring that a site is listed in the HRSA Electronic Handbook (EHB) as approved in a Health Center's Scope of Project.

In conclusion, ***we see no need – from either an administrative or oversight perspective – for the 3-6 month delay in eligibility which results in enormous harm to both new and established Health Centers and their patients.***

Recommendation: The most logical and straightforward solution to this situation – from both the HRSA/OPA and the Health Center perspective – is for **HRSA/OPA to accept the extensive due diligence performed in HRSA/BPHC's inclusion of a new or relocated site under a Section 330 Scope of Project as sufficient to approve a Health Center site for 340B eligibility effective on the day that it becomes operational.** The Health Center site could initiate the approval process by contacting HRSA/OPA in advance and providing proof that it has been approved under a Section 330 Scope of Project. It would also provide an attestation of 340B compliance at the same time. HRSA/OPA would simply need to verify the attestation by the Health Center site status as approved and operational in the EHB prior to adding them to the list.

This approach would require HRSA/OPA to **accept applications from FQHCs on a rolling basis** as opposed to a quarterly basis. We emphasize that approving FQHC sites is a very quick and straightforward process for HRSA/OPA as no oversight is needed beyond checking EHB and the attestation. We believe that this important change will remedy the enormous harm that the current timeframes are causing Health Center and, more importantly, their patients.

If HRSA/OPA is unable or unwilling to accept FQHCs applications on a rolling basis, we offer two alternatives:

- Accept and review registrations on a monthly basis (as opposed to quarterly) and approve eligible applicants to participate in 340B starting on the first day of the next month. In addition to the significant benefits for patients and covered entities, this approach would enable HRSA/OPA to spread the workload associated with registering new sites more evenly throughout the year.
- Maintain the quarterly registration periods and have HRSA/OPA verify Health Centers' eligibility within 10 days following the end of the registration period. Health Centers will then be eligible by the 25th of the month in which they registered.

A.2. Streamline and accelerate the site registration process for contract pharmacies, particularly when ownership changes but operations are not interrupted:

Issue: Along with the delays that Health Centers face when registering their own sites on the OPA database, they also encounter significant delays when registering their contract pharmacies. For example, Health Centers often build a pharmacy space in their building and lease it to a contract pharmacy. The Health Center will face the same 3-6 month delay in gaining eligibility for these sites as they do for their own sites. Furthermore, if the pharmacy operator ever leaves, changes ownership or causes any change to its DEA registration, the relationship terminates, resulting in another 3-6 months gap in eligibility.

Recommendation: HRSA/OPA should streamline and accelerate the registration process for contract pharmacies, such as by accepting registrations on a rolling basis or adopting a monthly registration window.

A.3. Simplify or eliminate the site registration requirement for in-scope, non-traditional sites: *(Please see related comments on first prong of proposed patient definition and flexibility in the event of public health emergencies):*

Background: The first prong of the six-part patient definition states that a “(t)he individual receives a health care service at a covered entity site which is registered for the 340B Program and listed on the public 340B database.” Bi-State has numerous concerns about this proposed requirement. This section will address concerns about the potential administrative difficulties for FQHCs to register all their BPHC-approved non-traditional sites on the 340B database.

By definition, FQHCs are required to be responsive to the unique needs of their communities and to serve individuals whom traditional providers often overlook. We are also expected to respond to emerging community needs in a timely manner, providing care where it is needed, even if these needs could not have been predicted well in advance. In addition, we are asked to coordinate care for our patients whose needs go beyond primary care and ensure that our patients have access to the full range of services required under Section 330, even while facing enormous challenges in recruiting and retaining providers.

In fact, certain Health Centers are statutorily required to provide care to certain medically underserved populations, commonly referred to as “special populations,” which necessitates that these Health Centers maintain non-traditional sites. Sections 330 (g), (h), and (i) of the PHSA designate funds for services to special populations which include seasonal and migratory agricultural workers, individuals and families experiencing homelessness, and residents of public housing. Health Centers are required under HRSA’s implementing guidance to go out into the community and meet these populations where they are—in public housing, on farms, or even the street. For all these reasons, Health Centers often (under their Scope of Project, and with HRSA/BPHC approval): provide care in temporary sites, such as homeless shelters, migrant camps and in response to local emergencies (both “officially-declared” and others); contract with outside providers to care for our patients, including for services that are required under Section 330; and “make rounds” on our patients when they are in a hospital or long-term care facility.

Thus, as written, this proposal will significantly increase the number of BPHC-approved non-traditional sites that Health Centers will need to register on the 340B database.

Bi-State is 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 HRSA/BPHC has approved under a Health Center's Scope of Project. The current system works well for a traditional "four walled" entity who 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 FQHCs operate. Specifically:

Issue: Sites that are under the Scope of Project of, but not legally "part of" a Health Center: The Guidance defines an "associated site" as "a health care delivery site which is not located at the same physical address as a non-hospital covered entity, but is *part of* and delivers outpatient services for the non-hospital covered entity." (*emphasis added.*) Due to well-documented provider shortages, many Health Centers must contract with outside providers to provide care for their patients, including for services that they are required to provide under Section 330. These arrangements are approved by HRSA/BPHC, but do not meet HRA/OPA's definition of an "associated site."

Recommendation: Revise 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.*"

Please note that it is important to use the term "Scope of *Project*" as opposed to "Scope of *Grant*" as Section 330 Health Center look-alikes do not receive a grant; however, they adhere to all the same requirements around their Scope of Project as do Health Center grantees.

Issue: Need for, and process to, list non-traditional sites on the 340B database: As discussed above, while all Health Centers have at least one traditional four-walled site, many also have "non-traditional" sites included under their HRSA/BPHC approved Scope of Project. These non-traditional sites can take many forms, including but not limited to mobile vans, homeless shelters, migrant encampments, and sites that pop up to respond to urgent, unforeseen community needs. (See A.5, below, for recent examples.) The proposal to register each of these sites individually on the 340B website raises concerns on two levels:

- First, there are literally thousands of these "non-traditional" sites across the national Health Center network, and while registering a single site is an easy process (as described above), multiplying this effort by thousands of new sites turns registration into a much larger issue.
- Second, if the requirement to register non-traditional sites is not lifted, how will OPA allow flexibility for Health Center to fulfill statutory mandates related to serving special populations (such as homeless individuals and migrant workers), and other general outreach obligations?
 - Will the registration system accept sites that do not have a fixed address (e.g., migrant encampments) or will application be rejected if the address field is left blank?
 - What about sites that "pop-up" to address unpredictable, emergent issues that don't rise to the level of a "nationally-declared emergency"?
 - FQHCs are required to have providers on-call 24 hours a day, 7 days a week. What about when a doctor prescribes a medication over the phone in an urgent situation? Prescriptions issued over the telephone from a provider's house, car, restaurant or other location should be eligible when working within the scope of the employment or contract of the FQHC.

Recommendation: As in the general registration process, Bi-State encourages HRSA/OPA to not duplicate federal oversight and rely on the extensive monitoring and due diligence performed by its sister Bureau, HRSA/BPHC. If HRSA/BPHC has approved a non-traditional (e.g., *Hundreds of thousands* non-four-walled) site as being in a Section 330 Health Center's approved Scope of Project, Bi-State recommends that HRSA/OPA consider that site to have met eligibility requirements without requiring them to register separately. This will save both HRSA/OPA and Health Centers the burden of registering literally thousands of new sites.

If HRSA/OPA is unable or unwilling to accept HRSA/ BPHC's approval of non-traditional Health Center sites, we recommend that HRSA/OPA ensure that:

- As discussed above, Health Centers are allowed to enroll sites on a rolling basis, so that sites that "pop-up" to address emergent issues may become 340B eligible as soon as HRSA/BPHC approves them.
- Sites that lack a fixed address are not prevented from enrolling.
- Health Centers and HRSA/OPA have an extended time period to enroll non-traditional sites, as there literally thousands of sites will need to be added.

A.4. 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. Bi-State thinks this prohibition is entirely consistent with program integrity, with one small exception. As you are aware, many Health Centers 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 purchases 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.

Bi-State is concerned Health Centers (and other 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 Health Center will be required to pay full price for them.

Recommendation: To address this concern, Bi-State recommends 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 (suggested new language is in italics and underlined):

- *(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 the covered entity 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 drugs 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”

A.5. Increase flexibility in site registration rules in cases of public health emergencies: *(Related comments are included at C.4. and E.3.)*

Issue: Bi-State appreciates HRSA/OPA’s recognition that 340B program requirements, such as those around site registration, may need to be adjusted in the case of public health emergencies. However, we are concerned that the proposed flexibilities are not broad enough to reflect the full range of emergencies to which Health Centers are called and expected to respond. Here are two examples from the past 6 months:

- During the April 2015 riots in Baltimore, MD, some FQHCs’ pharmacies were looted or otherwise damaged. Neighboring FQHCs sought to assist by providing care to the patients of the damaged FQHCs. However, they were unable to provide 340B medications to these patients, as these patients were not associated with their sites, and no exceptions process was in place. Also, while Baltimore was under an official “State of Emergency” during this period, it was not classified as a “Public Health Emergency.”
- During the October 2015 flooding in South Carolina, a number of FQHC sites and pharmacies were inaccessible due to high waters, washed-out roads, and/or power losses. Health Centers are still feeling the effects of these floods and determining the impact on their patients, but this provides another example of the need for increased flexibility in these situations.

To address these concerns, we recommend that the flexibility around public health emergencies be expanded to allow HRSA/OPA to use it as follows:

- ***Broaden the definition of public health emergencies to include those declared by a state or local authority:*** Many man-made and natural emergencies can be devastating to individual communities, but not be broad enough to be declared a public health emergency by the Secretary of Health and Human Services. For example, a large fire affecting numerous residences could result in large number of displaced individuals who are in need of care; however, this impact would be limited to the specific community and would not rise to the level of the Secretary declaring a public health emergency. Nonetheless, Health Centers are required – by statute, by HRSA/BPHC, and by their mission – to provide care to these individuals in response to the emergency, regardless of their ability to pay, etc. Therefore, in recognition of the role that Health Centers and other safety net providers play in assisting their communities to respond to local emergencies, Bi-State requests that HRSA/OPA broaden this language to include public health emergencies declared by the federal, state, or local government.
- ***Permit FQHCs and other covered entities to petition HRSA to approve specific situations as a public health emergency:*** Some public health emergencies may never be officially “declared” by governmental entities. In these situations, Bi-State recommends that FQHCs and other covered entities be permitted to petition HRSA/OPA for flexibilities in the registration and eligibility rules, and that HRSA will review and potentially approve these requests on a case-by-case basis.
- ***Provide flexibility for retroactive registrations in the case of public health emergencies:*** In the event of a public health emergency, Health Centers’ first priority is to treat patients in need, not to focus on administrative requirements. In recognition of these priorities, Bi-State recommends that HRSA/OPA allow Health Centers (and other covered entities) to meet registration and related requirements on a retroactive basis when services were provided in response to an emergency. To ensure program integrity, it would be reasonable and appropriate to place time limits on how soon the Health Center must meet the requirements after the emergency is addressed (e.g., 30 days.).

Recommendation: To address these recommendations, Bi-State recommends that HRSA/OPA add the following language (*in italics and underlined*) to the Guidance:

Part A, Registration and Termination, (a): “HHS may provide a special registration opportunity for entities during a public health emergency declared by the Secretary *or other State and local governmental authorities*. The geographic scope and time period limitations of the Secretary’s public health emergency notice will govern limits for this special registration. *Special registrations may, at HRSA’s discretion, be made retroactive. Covered entities may petition HRSA for special registration periods in response to other events which HRSA determines, on a case-by-case basis, qualify as public health emergencies.*”

A.6. Revise the description of the Annual Recertification process to require reporting of only material instances of non-compliance: (*See related discussion under Cross-Cutting comments, above.*)

Issue: As discussed above, the Guidance currently requires covered entities to report *every* instance of non-compliance to HRSA/OPA, no matter how insignificant or quickly fixed. This will result in a massive administrative burden for both HRSA/OPA and covered entities without providing any significant improvement in program integrity. We are optimistic that HRSA/OPA will revise the Guidance to require reporting only of those violations that rise to the level of being “material,” and wish to point out that language on the Annual Recertification process will need to be adjusted to reflect this policy.

Recommendation: To ensure that HRSA/OPA and covered entities are not overburdened with reports of immaterial violations, the Summary language should be revised as follows (*new language in italics and underlined*):

“By certifying compliance with all 340B Program requirements, a covered entity attests that it... notifies HHS in the event the entity...has *materially* violated any 340B Program requirement, subject to HHS audit.”

Part B: Drugs Eligible for Purchase Under the 340B Program

B1. Expand Guidance to incorporate prohibition on manufacturers denying 340B sales based on their perception that a covered entity is not complying 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.”

Bi-State supports and appreciates this provision, as it clarifies that the authority for determining compliance with this provision lies with HRSA/OPA rather than manufacturers. However, we are concerned that this language is not included in the actual text of the Guidance.

Recommendation: Bi-State recommends 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: Individuals Eligible to Receive 340B Drugs

Bi-State has very serious concerns about the proposed revisions to the criteria for determining which patients are eligible to receive drugs purchased under the 340B program. These revisions:

- Will have potentially devastating effects on patients' health and financial stability.
- Will have potentially devastating effects on FQHCs' ability to achieve high-quality outcomes, financial stability, provider satisfaction, and capacity to maintain current level of services.
- 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.
- Will have impacts that are in direct contrast to numerous ACA and HHS-wide goals.
- Are not justified under the statute.
- Are inconsistent with the intent of the 340B program, as explicitly stated by Congress.

In short, we urge HRSA/OPA in the strongest possible terms not to apply these proposed revisions to Health Centers. Instead, as discussed below, we recommend that HRSA/OPA recognize the characteristics that distinguish Health Centers from all other types of covered entities, and establish a patient definition for Health Centers that reflects these characteristics.

We have organized our comments on Part C as follows:

- C1. Overall impact of the proposed revisions on FQHCs and their patients
- C2. Comments on the individual criteria in the proposed definition
- C3. Recommendation for HRSA/OPA to 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
- C4. Comments on other Part C provisions

C.1. Overall impact of the proposed revisions to "patient definition" on FQHCs and their patients

As currently drafted, the "clarified" patient definition would prohibit FQHCs from using 340B drugs to fill prescriptions written for their patients by any non-FQHC provider. This definition would prohibit all prescriptions written: by specialists, even if the FQHC referred the patient to the specialist and/or has a formal referral agreement with the specialist; when the patient is being discharged from an inpatient hospital stay; and by non-FQHC providers who provide required FQHC services under a formal agreement with the FQHC. For example, HRSA/BPHC policy permits FQHCs to provide required primary care services² to patients through referral arrangements that meet BPHC standards and are listed on the FQHC's Form 5A column III. The proposed Guidance would exclude such individuals from 340B eligibility for the referred services, even though BPHC holds the FQHC generally responsible for the referrals and the patient receives other services directly from the FQHC.

While the proposed revisions may be appropriate for many hospital settings, in the FQHC environment, the changes will potentially have devastating impacts on multiple levels, as follows:

- ***Negatively impacts FQHC patients' health outcomes and economic stability:*** Without the benefit of 340B pricing, the cost of drugs prescribed for FQHC patients by non-FQHC providers will rise significantly, with increases running between 33% and 100%, depending on the specific medication.³ To the extent that these higher costs are passed onto FQHC patients, it will become increasingly difficult for many people to afford their medication. This will lead to FQHC patients taking less – or none – of the medication they have been prescribed, which in turn ultimately leads to poorer health outcomes.

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

² Those services specified in Section 330 of the PHS Act (42 USC 254(b))(1).

³ These estimates are based on HRSA/OPA's statements that 340B prices are typically 25%-50% below traditional prices; drugs currently available under "penny pricing" would incur a much larger percentage increase.

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. The study’s specific findings included:

- Participants reporting both cost-related medication underuse and food insecurity were more likely to be Hispanic, black, and have more chronic medical conditions than were patients reporting neither.
- Those not experiencing food insecurity but not meeting medication needs were more likely to have dependent children in the house, to lack insurance or have insurance that didn’t include drug coverage, and to have more chronic medical conditions.

Thus, those populations which are at greatest risk for medication underuse mirror those heavily served by FQHCs. Specifically, almost 60% of FQHC patients are either Hispanic or and black; 28% are uninsured; and 31% are children under 18. Therefore, the proposed revisions will exacerbate an already significant issue of medication underuse among patients whom the program was intended to assist.

Also note that the FQHC patients most likely to be affected by these revisions are those with the greatest health needs, as they are the ones most likely to see specialists, be hospitalized and need multiple medications prescribed by specialists. These individuals are also likely to be disproportionately lower-income as their health issues make it harder for them to work and increase their expenses. Therefore, these proposals will disproportionately affect the sickest and poorest of FQHC patients.

Finally, some individuals have argued the FQHC patients who are in need of 340B-priced medications prescribed by a specialist can simply seek care from a specialist who is 340B-eligible. While this may seem reasonable in theory, it is unrealistic in practice. By definition, FQHCs serve areas and/or populations that are experiencing a shortage of providers. Typically, there are even fewer specialists in these areas than primary care providers. In order for the office visit to be affordable for a low-income uninsured patient, the specialist must offer a sliding fee scale – which further reduces the pool of eligible specialists. Also, the specialist must be eligible for 340B, reducing the pool even more. Finally, the specialist must be in a location that is reasonably accessible to the patient (because, unlike FQHCs, specialists do not provide transportation). Given all of these limitations, it is unrealistic to think that low-income, uninsured, and chronically ill patients can easily access 340B discounts for drugs prescribed by specialists simply by going to “the right” specialist.

- ***Negatively impacts FQHCs’ ability to achieve high-quality outcomes, financial stability, provider satisfaction, and maintain current level of services:*** While the most immediate negative impacts of the proposed patient definition will be among FQHC patients, the proposal will also have significant negative impacts on the operational and financial stability of the FQHCs themselves. These negative impacts will include:
 - ***Reduced reimbursement due to worse quality and outcome measures:*** Increasingly, third-party payers (including Medicaid, Medicare and private insurance) are basing reimbursement on a provider’s ability to meet quality and outcome measures. Many private insurers are also using these measures to determine which providers to include in their network. As discussed above, patients’ lack of access to affordable medications will lead to poorer performance on quality and clinical measures for the FQHC overall, which will in turn lead to lower reimbursement, thereby exacerbating the impact of the proposed change. Further, reduced reimbursement will impact the FQHC’s capacity to provide access to healthcare services to persons that are already at risk of having less access to these services.
 - ***Increased frustration for FQHC providers as they are unable to care for their patients appropriately:*** For FQHC providers, it is highly frustrating and discouraging to know that a patient needs a drug but is unable to access it. Not only are they expected to watch their patients go without appropriate care, but they are also expected to “pick up the pieces” that result when a condition is left untreated. At a time when FQHCs are struggling to fill provider slots, being unable to ensure appropriate care for their patients is a strong disincentive for providers to choose to work at a FQHC.

- ***Hundreds of thousands of dollars in upfront and ongoing costs for FQHCs with in-house pharmacies to maintain a second, non-340B inventory:*** Many FQHCs with in-house pharmacies (particularly those in rural areas) will be forced to maintain two separate inventories for the same patients – one for 340B drugs and another for regularly-priced drugs. This will create an upfront cost of hundreds of thousands of dollars for FQHCs to purchase the second inventory; it will also raise on-going costs due to the needs to store and administer the separate inventories as well as bill claims from multiple inventories using varied billing methods. FQHCs with in-house pharmacies who have a contract pharmacy nearby may choose to send all non-340B prescriptions to the contract pharmacy; however, this will be very inconvenient for patients, as they will need to go to two different pharmacies to get their scripts filled and creates safety concerns as neither pharmacy will be able to run drug utilization review (DUR) on the complete medication profile.
- ***Reduced ability to provide a comprehensive range of services:*** As intended by Congress, savings achieved through the 340B program enable Health Centers to “stretch their scarce federal resources as far as possible, reaching more eligible patients and ***providing more comprehensive services.***” (*emphasis added.*) And, as stated above, Health Centers invest every penny of 340B savings into their federally-approved projects, often to provide services which they would otherwise be unable to support. Examples include, but are not limited to, clinical pharmacy services, medication therapy management programs, and provider salaries. Thus, new policies that restrict Health Center access to 340B savings will result in a decrease in the range of comprehensive services they can provide for their patients.

Finally, note that patient access and well-being is the core of every FQHC’s mission. By law, FQHCs must be governed by a Board on which the majority of members are not only members of the community, but actual patients of the health center. Given this focus, and the myriad of issues described above, Bi-State predicts that FQHCs will choose to discount their uninsured patients’ specialist-prescribed and/or discharge prescriptions so that their patients can afford them. These discounts are likely to be significant, mirroring the discounts offered under the sliding fee scale used for provider services. This will lead to large, increased costs for FQHCs. ***Given that most FQHCs operate on a margin of less than 1%, financing these discounts will require reducing spending on other needed FQHC services, and will often need to be financed using Section 330 grant funds.***

- ***Contrary to the purpose of the Health Center program, as expressed in long-standing statutory language and regularly reaffirmed by HRSA/BPHC:***
 - ***Referrals:*** The Section 330 statute explicitly requires Health Centers to provide “referrals to providers of medical services (including specialty referral when medically indicated) and other health-related services (including substance abuse and mental health services).” It is inconsistent with good clinical practice to require Health Centers to refer their patients out for specialty and other services, but then to force the Health Center or patient to absorb higher costs for the drugs prescribed as a result of the referral because the patient would not be able to fill the prescription using 340B under the proposed Guidance.
 - ***Case management:*** Section 330 also explicitly requires Health Centers to provide “patient case management services (including counseling, referral, and follow-up services).” Again, it is inconsistent with good clinical practice to require Health Centers to provide case management and follow-up services but to make it much harder for them to do so by restricting patient access to affordable medication.
 - ***Pharmacy is a required services:*** Section 330 also explicitly requires Health Centers to provide “pharmaceutical services as may be appropriate for particular centers” as a required primary care service.
 - ***Patient Centered Medical Home (PCMH) model:*** A key BPHC/HRSA goal has been to increase the number of Health Center sites that are certified as PCMHs (in fact, this has been the only HRSA metric reported to the White House on a monthly basis). As you are aware, the central purpose of a PCMH is to ensure that patients receive appropriate, coordinated care and achieve the highest possible health outcomes. However, as discussed above, the proposed “patient definition” is in direct contrast to these goals, as it will make it much harder for uninsured patients to access affordable medications, and/or will

force FQHCs to divert funding from other activities under their Health Center Scope of Project to fund the needed discounts.

- ***In direct contrast to numerous ACA and HHS-wide goals:*** If the proposed changes to “patient definition” are implemented as proposed in FQHCs, it will result in outcomes that are in direct contrast to multiple goals being pursued by BPHC, HRSA, and the entire federal HHS:
 - ***Will increase preventable hospital readmissions:*** A key ACA goal is to reduce preventable hospital readmissions. Yet numerous studies – including [one released last month by Harvard Medical School](#) – have found that readmission rates are strongly influenced by a patient’s education and income, with more disadvantaged patients being at a much higher risk of readmission. By making it harder for FQHCs’ insured patients to access 340B drugs for prescriptions written upon hospital discharge or by specialists, HRSA would be directly contributing to a rise in preventable hospitalizations, in direct contrast to an ACA/HHS goal.
 - ***Will decrease the impact of ACA funding expand the reach of FQHCs:*** Another central ACA goal was to expand the reach of the Health Center program. The ACA appropriated \$11 billion over 5 years for this purpose, and Medicare Access and CHIP Reauthorization Act (MACRA) – which Congress passed this spring with overwhelming bipartisan support – extended Health Center funding for an additional two years. However, HRSA/OPA’s proposed “patient definition” will have the complete opposite impact on FQHCs, by forcing them to use funds that were intended to expand their reach into their communities to instead “backfill” costs that used to be covered under the 340B program.
 - ***Will discourage integration of primary and behavioral health care:*** FQHCs are regularly encouraged – by HRSA, SAMHSA, and CMS – to integrate behavioral health into primary care. However, the proposed patient definition will make these integration efforts much more difficult and less likely to succeed. For example, if psychiatry services are provided through referral (and psychiatric medications are prescribed by the psychiatrist), the patient would not be eligible for 340B discounted drugs. Given the high cost of many mental health drugs, the patient may choose not to fill the prescription; thereby, undermining the efforts of the primary care provider.
 - ***Violates all three elements of the Triple Aim:*** Since the passage of the ACA, both CMS and HHS Secretary have structured their policy goals around the “Triple Aim,” defined as: 1) improving the patient experience of care (including quality and satisfaction); 2) improving the health of populations; and 3) reducing the per capita cost of health care. Unfortunately, as discussed above, the proposed patient definition clearly violates the first and second element. Also, when higher costs prevent patients from taking their prescribed medications, the result is often higher costs elsewhere in the health care system (e.g., increases in complications and preventable hospital readmissions).
- ***In violation of the language and the intent of the 340B statute:***
 - ***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 that are not eligible for 340B 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.
 - ***Contrary to Congressional intent, as it will reduce the “stretch” of “scarce federal resources”:*** As HRSA/OPA states in the Guidance’s opening paragraph, Congress stated that the purpose of the 340B program is to permit covered entities “to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” As discussed above, many FQHCs – and their patient-led Boards – could seek to minimize the negative health and financial impacts that this

proposed policy will have on their patients by using their own funds to provide discounts that were formerly available through 340B. *These discounts 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. In addition, as previously discussed, 340B savings enable Health Centers to provide clinical services for which no other funding source is available (e.g., clinical pharmacy programs) and these programs will need to be significantly reduced or eliminated if FQHCs are no longer able to access these savings.*

- *Discounts for patients' medications would then have to be financed using other sources of health center revenue (e.g., Section 330 grant funds, donations, etc.). Given that most FQHCs operate on a margin of less than 1%, this will force FQHCs to cut other preventive and primary health care services. Additionally, as previously discussed, 340B savings enable Health Centers to provide other clinical services for which no other funding source is available (e.g., clinical pharmacy programs). The effect of significantly reducing or eliminating either of these types of service, because FQHCs are no longer able to access these 340B saving, would be detrimental to patient health outcomes.*

C.2. Comments on the individual criteria in the proposed definition

1. Site:

Please see our comments in Section A1 and A2 about the process and timeline for registering sites. In brief:

- HRSA/OPA's current registration timeline and system imposes a 3-6 month delay between when an FQHC site meets all eligibility requirements to participate in 340B, and when they become eligible to participate.
- As written, this language will require literally thousands of new sites to be registered on the database, many of which have no permanent address; it will also prohibit other sites (e.g., contractor sites) from registering.

Bi-State, therefore, recommends that HRSA/OPA:

- **Accept FQHC site applications on a rolling basis.**
- **Accept the extensive due diligence performed in HRSA/BPHC's inclusion of a new or relocated site under a Section 330 Scope of Project as sufficient to approve a Health Center site for 340B eligibility effective on the day that it becomes operational.**
- **Not require the enrollment of thousands of non-traditional sites.**

As detailed in our remarks on public health emergencies (see A.5), we are concerned that the delays currently imposed by the registration timelines will make it impossible for FQHCs to enroll sites that they may need to establish in response to public health emergencies (other than those officially declared by the HHS Secretary). We, therefore, recommend that HRSA/OPA **grant flexibility to the site registration requirements on a case-by-case basis in the event of public health emergencies that are not officially declared by the HHS Secretary.**

Add language to the Guidance explicitly recognizing the role of telemedicine.

Issue: Bi-State appreciates HRSA/OPA's explicit recognition of the growing importance of telemedicine. The Summary states:

“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.”

Recommendation: Bi-State requests that this reference to telemedicine be incorporated into the Guidance. To limit potential abuses, HRSA/OPA could restrict eligibility to arrangements where the patient (rather than the provider) is located at the covered entity site. We suggest the adding the following language to the end of this section:

“Registered site may provide eligible services via telemedicine to their patients who are physically located at the site.”

We note that an exception would need to be made for Hemophilia Treatment Centers and other grantee types who serve a small, specific population that is spread across the country. For these providers, it is appropriate for their providers to be located at the grantee site and their patients to be located throughout the country.

Clarify that a site’s eligibility should be based on the date a prescription is to be filled and not when it was issued.

2. Provider:

- Our **significant concerns** with prohibiting FQHC patients to access 340B drugs for prescriptions written by non-FQHC providers (most commonly specialist-written and discharge prescriptions) has been **addressed at length earlier** in these comments.
- **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 *italics and underlined*):

“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.*”

3. Service:

- Our **significant concerns** with prohibiting FQHC patients to access 340B drugs for prescriptions written by non-FQHC providers (most commonly specialist-written and discharge prescriptions) has been **addressed at length earlier** in these comments.
- **Clarify that prescriptions which are clinically appropriate to be written for an eligible patient’s partner or family member can be filled using the 340B program.**

Issue: FQHC providers encounter at least 3 situations in which standard medical guidelines support writing prescriptions for a patient’s partner(s) or family members, even if the provider has not personally examined the partner(s)/family member. These situations are:

- **Expedited Partner Therapy (EPT):** EPT is the practice of providing antibiotics or a prescription for antibiotics to a patient who tests positive for a Sexually Transmitted Disease (STD), again for the patient to give to his or her partner(s). 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.

- **Emergency contraception prescribed to males:** CDC treatment guidelines also support prescribing emergency contraception for a man to give to his partner.
- **Naloxone:** This medication can reverse the effects of an opioid overdose. It is legal in some states for individuals to carry naloxone for the purpose of providing it to friends, family members, etc., in the event of a possible overdose.

These are just 3 examples where Bi-State is concerned that certain statements in the guidance could be interpreted to not permit the use of 340B drugs in these circumstances. Should other circumstances arise in the future where this type of prescription is deemed appropriate, we would appreciate OPA's flexibility to address those instances when they arise.

Recommendation: We suggest the inclusion of the following language in the final guidance to ensure that covered entities are permitted to use 340B drugs in the situations outlined above:

“Pursuant to CDC treatment guidelines, HRSA recognizes as 340B-eligible the prescriptions written for partners of 340B-eligible patients which are prescribed as emergency contraception for the partner, or to treat or prevent re-infection of the partner with a sexually-transmitted disease carried by the patient. HRSA also recognizes as 340B-eligible prescriptions written to 340B-eligible patients to help them respond to a potential opioid overdose by a partner, family member, or other person with whom they have close contact.”

4. Consistent with Scope of Grant

- **Drugs provided or managed as a result of the requirement for Health Centers to provide referrals and case management should be eligible under this criteria:** As previously discussed, Health Centers are required under the Section 330 statute and their Scope of Grant (or Scope of Project for look-alikes) to provide referrals to specialists, case management services, and pharmacy services as appropriate. Most Health Centers also receive Section 330 funding to serve as Primary Care Medical Homes. Given this Scope, Bi-State thinks that all prescriptions which the Health Center views “as appropriate” – including those written as a result of referrals and those managed as part of case management services – should be eligible for 340B.

5. Outpatient Classification

- **A drug's “outpatient” status should 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.**

Issue: 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.” Bi-State supports 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, this statement is overly broad in one important area: it 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.

Bi-State believes that defining discharge prescriptions as inpatient care is inappropriate and illogical. Long-standing medical 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.

Recommendation: To address these concerns, Bi-State recommends that HRSA/OPA expand the Guidance as follows (new language in *italics and underlined*):

“The individual is classified as an outpatient when the drug is ordered or prescribed, *or the drug is ordered or prescribed during discharge from an inpatient stay.*”

6. Responsibility for Care:

- **Strong support for requiring the covered entity to have a provider-to-patient relationship with the patient and to be responsible for the patient's overall care.** Bi-State strongly supports this proposed language, as it is consistent with the Health Center model of care, which emphasizes care coordination, case management, and serving as a medical home. It is also consistent with HRSA/BPHC's oversight of the Health Center program, which holds Health Centers publicly accountable for the quality of care provided to all their patients.
- **Clarify that a covered entity is responsible for services that its patients receive via telemedicine.**

Issue: As stated previously, Bi-State appreciates HRSA/OPA's recognition of the growing importance of telemedicine and related technologies in providing high-quality, easily-accessible care. However, we are concerned that questions could be raised in the future about whether services provided or received via telemedicine meet this criteria.

Recommendation: To avoid any potential confusion, Bi-State recommends that HRSA/OPA explicitly state that covered entities are responsible for services provided or received via telemedicine or related technologies as long as all other requirements are met.

- Please see our related comments in section D.10 regarding “**auditable records.**”

C3. Recommendation for HRSA/OPA to 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

We believe that HRSA/OPA has largely adopted a one-size-fits-all approach to establishing Guidance for the 340B program despite major differences in the structure, requirements, and statutory purpose of the various types of covered entities. Nowhere is this approach more apparent – or detrimental – than in the approach to “patient definition.” In this section, Bi-State outlines some key elements that differentiate Health Centers from all other categories of covered entities, and then proposes a “patient definition” that is specific to Health Centers and consistent with how HRSA/BPHC oversees the Health Center program.

- **Health Centers differ significantly from all other types of 340B covered entities:** The HRSA/OPA website lists 4 categories of covered entities: Health Centers; hospitals; Ryan White AIDS Program grantees; and specialized clinics. Health Centers have critical differences from all these other types of covered entities.
 - *Unlike hospitals, Health Centers have long-term relationships with patients that include coordinating all their care.* Due to their focus on inpatient and specialty care, hospitals often care for patients for a brief period during an acute episode and then discharge them back to their primary care provider for long-term monitoring and care coordination. In contrast, Health Centers develop and maintain long-term relationships with their patients, coordinating their care and serving as the Primary Care Medical Home on an ongoing basis.
 - *Unlike other grantee types, Health Centers do not focus on specific diagnosis or type of service:* Health Centers also differ significantly from other grantee types. As indicated on the HRSA/OPA webpage, all

other grantee types focus on a specific diagnosis or type of service (e.g., AIDS, hemophilia, family planning, Black Lung, STDs). As a result, they provide only those services which are directly linked to the disease or type of service for which they receive their grant funding. In contrast, as discussed above, Health Centers have long been responsible for providing their patients with a full range of primary and preventive services, pharmaceutical services, referrals to specialists and other appropriate providers, care coordination, and case management and in recent years they are increasingly expected to serve as their patients' Primary Care Medical Home.

- *Federal oversight of Health Centers is intense and continuous:* Finally, Health Centers differ from hospitals and other grantees in the degree to which HRSA subjects them to continuous, detailed oversight of every aspect of operations included under their Scope of Project. As discussed previously, HRSA/BPHC has extremely detailed policies around 19 Program Requirements which Health Centers must comply with in order to remain in the program; it also has over 200 full-time staff whose primary purpose is to ensure that each Health Center complies with every requirement. In addition, any changes to a Health Center's Scope of Project (such as adding or moving a site⁴) are subject to lengthy and intensive reviews to ensure that they will not lessen the Health Center's ability to remain fully compliant with all HRSA/BPHC requirements. To the best of our knowledge, no other type of covered entity is subject to a similarly intense degree of federal oversight over all aspects of their Scope of Project.
 - *Health Centers invest all 340B savings into activities that are approved under their HRSA/BPHC Scope of Project and advance their charitable mission.* As discussed above, every penny of savings that Health Centers receive as a result of the 340B program is reinvested in services provided to their community and approved under their HRSA/BPHC Scope of Project.
- **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:"** Given how distinct Health Centers are from all other categories of covered entities, Bi-State strongly encourages HRSA/OPA not force us into the one-size-fits-all "patient definition," but rather establish a patient definition that is distinct to Health Centers.

We note that HRSA/OPA has already adopted a distinct patient definition for another type of grantee – AIDS Drug Assistance Programs. In the same way that HRSA/OPA has recognized ADAPs' unique characteristics and created a unique patient definition to reflect them, we encourage HRSA/OPA to create a unique patient definition to reflect Health Centers' unique roles and responsibilities.

- **HRSA/OPA should adopt HRSA/BPHC's definition of a "Health Center patient," as detailed in the UDS:** As previously stated, HRSA/BPHC has a detailed list of Program Requirements for Health Centers, and their compliance with the requirements is monitored on an ongoing basis. One of these Program Requirements is to report detailed patient, financial and clinical data to HRSA/BPHC on an annual basis. This reporting system is called the UDS and it generally defines a Health Center patients as individuals who had at least one reportable visit during the reporting year. For a visit to be considered "reportable", the interaction must be a documented, face-to-face contact between a patient and a licensed or otherwise credentialed provider who exercises independent, professional judgment in the provision of services to the patient.

As will be discussed below, this general definition is subject to numerous caveats and clarifications to ensure that individuals who have only a limited or tangential connection with a Health Center do not qualify as patients.

⁴ A Health Center must submit a Change in Scope (CIS) request for any activities that impact the Health Center's Scope of Project. A Health Center's Scope of Project is continually reviewed by HRSA and must be consistent with statutory and regulatory requirements and the mission of the Health Center. Health Centers must submit the CIS at least 60 days before implementation of a change that would add a new service or service delivery site, terminate an existing service or service delivery site, or add a new target population. HRSA must approve any CIS requests before the change is implemented.

- **Adopting the UDS patient definition for Health Centers is appropriate for many reasons:**
 - *It is an established, clearly-defined definition:* Health Centers have been required to collect and report UDS data for 20 years. The BPHC dictates in enormous detail how specific UDS terms are defined; including “patient.” For example, the manual describing how UDS data is to be defined, collected and analyzed for Calendar Year (CY) 2014 is 172 pages long⁵. In Appendix A, we have provided key excerpts from the UDS patient definition. For additional details, please see the CY2014 UDS Manual.
 - *HRSA/BPHC provides continuous oversight to ensure that Health Centers apply the definition properly:* As part of its continuing oversight, HRSA/BPHC receives, reviews and publishes UDS data from each Health Center. Thus, another part of HRSA (separate from OPA) ensures that patients are classified correctly.
 - *The UDS definition ensures that individuals who have only a limited relationship with a Health Center do not qualify as “Health Center patients.”* UDS has very clear rules around who does not qualify as a Health Center patient; namely, persons who have only a limited or tangential connection with the Health Center. The CY2014 UDS Manual states:

“Persons who only receive services from community based efforts such as immunization programs, medical or dental screening programs, dental varnishing programs, and health fairs are not counted as patients. Persons whose only service from the Health Center is a part of the WIC program or other programs are not counted as patients. During the course of addressing the health care needs of the community, Health Centers see many individuals who do not become patients as defined by and counted in the UDS process. **“Patients,” as defined for the UDS, never include individuals who have such limited contacts with the Health Center, whether or not documentation is done on an individual basis.**” (emphasis added)

The CY2014 manual then provides a detailed list of individuals who do not meet the criteria to be Health Center patients. These include (but are not limited to): “When the only services provided are lab tests, x-rays, sonography, mammography, retinography, immunizations or other injections, TB tests or readings, and/or filling or refilling a prescription.”For a longer list of individuals who do not qualify as Health Center patients under UDS, see Attachment A (or the full CY2014 UDS Manual). Note that – similar to long-standing 340B policy – the UDS definition explicitly states that individuals whose only connection to the Health Center is getting a prescription filled there do not qualify as Health Center patients.
 - *It will 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:* If HRSA/OPA adopts the UDS patient definition for Health Centers, then individuals who meet this definition will be eligible to receive 340B drugs for all their outpatient prescriptions. This will address the concerns that we raised in Section C.1, by ensuring patients’ access to 340B drugs for scripts written by specialists and other providers to whom an FQHC may refer its patients (e.g., if the FQHC refers a patient to an outside provider to receive a service required under the Section 330 statute). Also, if HRSA/OPA reclassifies hospital discharge prescriptions as “outpatient,” Health Center patients would be eligible to have these scripts filled with 340B drugs as well.
 - *Health Centers are required by statute to coordinate care and to provide case management and appropriate pharmacy services to all patients, regardless of ability to pay:* As previously stated, Health

⁵ The full manual is available at <http://bphc.hrsa.gov/datareporting/reporting/2014udsmanual.pdf>

Centers are required by statute to provide a full range of primary care, preventive and enabling services to all patients who present for care, regardless of their ability to pay. These services include case management, care coordination, and appropriate pharmacy services.

- *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:* As previously stated, Health Centers are required to report a broad range of data to HRSA/BPHC each calendar year. This data includes over a dozen measures of the quality of care provided, including measures around prenatal care, preventive care, and the management of chronic diseases (For a full list of required quality measures, see Appendix B). When calculating these measures, ***Health Centers must report on the care provided their entire patient population*** that meets the demographic qualifications (e.g, only women are counted in the pap smear measure). Whenever possible, Health Centers include data from every qualifying patient when calculating their results. For measures where it is not yet possible to easily compile data from the entire eligible population, Health Centers must pull a random sample of 70 charts from the entire population.

Upon reviewing each Health Center's UDS submission, HRSA/BPHC publishes each Center's quality measures on its website⁶. ***Thus, Health Centers are truly responsible for the overall care of all individuals who meet the UDS definition of a patient; not just because of statutory requirements, but also because they are each held publicly accountable for the care it provides to its patients.***

- *It ensures consistency with how HRSA manages Health Centers by using the same definition for activities overseen by HRSA/BPHC and HRSA/OPA:* Using the same definition of "Health Center patient" across HRSA will lead to consistency and efficiency, enabling HRSA/OPA to take advantage of the due diligence and extensive oversight that HRSA/BPHC provides for the Health Center program.
- *Recommendation:* For all the reasons listed above, Bi-State strongly recommends 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 UDS. This could be accomplished by adding the language below (*in italics and underlined*) immediately beneath the section on the patient definition for ADAPs (we are quoting the ADAP language here both to indicate where our proposed language should be placed, and how it mirrors the current ADAP language).

(1) AIDS Drug Assistance Program. An individual enrolled in a Ryan White HIV/AIDS Program AIDS Drug Assistance Program funded by Title XXVI of the PHSA will be considered a patient of the covered entity for purposes of this definition.

(2) Consolidated Health Centers Program. An individual considered a patient of a Health Center grantee or look-alike under the Uniform Data System of the Consolidated Health Centers Program will be considered a patient of the covered entity for purposes of this definition.

C4. Comments on other Part C Provisions

1. Unique Patient Definition for ADAPs

- **Strong support for unique patient definition recognizing the unique structure and purpose of ADAP programs:** Bi-State strongly encourages HRSA/OPA to establish policies that reflect the unique structure and purpose of each type of covered entity, as opposed to applying a "one-size-fits-all" approach. Bi-State strongly supports this provision, as it is appropriate to the unique character of ADAPs.

⁶ To see any Health Center's results, go to <http://bphc.hrsa.gov/uds/datacenter.aspx?q=d> and click on the appropriate state, and then the name of the individual Health Center. Alternatively, you can search go "2014 Health Center Profile."

2. Public health emergencies: (Please see detailed comments in A.5)

- Issue: As discussed in A.5, Bi-State is concerned that proposed flexibilities in the event of a public health emergency event are not broad enough to reflect the full range of emergencies to which Health Centers 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 FQHCs and other covered entities to petition HRSA to approve specific situations as a public health emergency.
 - Make flexibility in the case of public health emergencies retroactive.
- Recommendation: To address these recommendations, Bi-State recommends 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 it determines, on a case-by-case basis, qualify as public health emergencies. The ability to apply alternate patient eligibility criteria may, at HRSA” discretion, be retroactive to the date that the emergency began.*”

3. Replenishment:

- **As requested in A.4 above, permit covered entities to replenish drugs provided to eligible patients prior to their termination date.**

Issue: This section of the Guidance states that: “a covered entity that utilizes a drug replenishment model may only order 340B drugs based *on actual prior usage* for eligible patients of that covered entity as defined by this guidance.” [emphasis added]

Bi-State supports this provision, and would like to point out how it relates to the issue raised in Section A.4. This language states that under a replenishment model, 340B drugs may only be purchased to replace eligible drugs that have *already* been dispensed. Thus, covered entities or contract pharmacies who use the replenishment model and are exiting the program must wait until after their termination date to order 340B drugs to replenish the ones they dispense in their last days of eligibility.

Recommendation: As discussed above, Bi-State recommends 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.

- **Modify Summary to indicate that accumulator errors that do not result in inappropriate orders are not considered violations, and that covered entities may maintain small positive “virtual” inventories for 120 days or less without being considered a violation, if they result from errors being reversed.**

Issue: In the first paragraph of the Summary section on “Drug inventory/replenishment models,” we appreciate HRSA/OPA’s clear and accurate explanation of how replenishment models and accumulators work. However, we are concerned about the following statement from the second paragraph:

“If the covered entity **improperly accumulates** or tallies 340B drug inventory, **even if it is prior to placing an order**, the covered entity has **effectively sold or transferred drugs** to a person who is not a patient, in violation of section 340B(a)(5)(B) of the PHSA.”

We are concerned that this language will unfairly penalize FQHCs and other covered entities who perform appropriate oversight of their replenishment model, and potentially force them to stop using this model. This is because this language turns small, honest errors (and efforts to correct them) into official “violations” even when they exist only in an electronic recording system and have no impact on purchases. As with any program, there will be times when small errors occur unintentionally; for example, a provider ceases employment with a covered entity, and the Management Services Provider (MSP) who oversees the processing of the FQHC’s 340B claims may not update its system immediately, leading to a few ineligible scripts being filled with 340B drugs. When conducting its due diligence, the FQHC will identify the error and reverse the entries for the ineligible scripts on the accumulator. However, under the language above, the FQHC would be required to report this “violation” to the manufacturer and HRSA, despite the fact that it was immediately rectified with no impact on the quantity of 340B-priced drugs purchased.

In addition, consider a situation where a new supply of a specific drug is ordered prior to an error involving that drug being identified and reversed. In this case, if no additional units of the drug had been dispensed since the order was placed, then the accumulator would register a small, positive “virtual” inventory until a new 340B-eligible script was filled. Under the language quoted above, the FQHC would again be considered to have violated the rules against drug diversion and be required to report it; despite the fact that the positive inventory was small, temporary, and a result of the entity’s due diligence.

As a result, this language makes it practically impossible for covered entities to operate replenishment models. It turns small, honest errors which are quickly reversed and have no impact on purchasing into official violations; and it can have a similar effect when entities seek to correct these errors. The level of administrative effort that would be necessitated to ensure that no errors occur would be overwhelming, making it impractical for them to use the replenishment model.

Recommendation: Bi-State recommends that HRSA/OPA either delete the sentence quoted above, or else modify it as follows (additions are in italics and underlined):

“If the covered entity improperly accumulates or tallies 340B drug inventory and as a result the entity orders a new supply of the drug that exceeds the total quantity of eligible drugs dispensed, ~~even if it is prior to placing an order~~, the covered entity has effectively sold or transferred drugs to a person who is not a patient, in violation of section 340B(a)(5)(B) of the PHSA. Entities may maintain a small quantity of a 340B drug in excess of the quantity dispensed if this small quantity results from the documented reversal of an error. If these excess drugs are not dispensed to 340B eligible patients within 120 days, they must be reported to the manufacturer.”

These edits will ensure that FQHCs and covered entities are required to report to manufacturers only when incorrect accumulator figures result in an actual order of drugs that exceed the quantity dispensed to 340B eligible patients. In addition, they recognize that on rare occasions, the correction of errors will result in positive inventories that generally are used up rapidly. However, it also ensures that if these errors result in a positive inventory that remains for more than 120 days, the covered entity will notify the manufacturer of a violation.

4. Repayment:

- **Incorporate into Guidance language giving manufacturers discretion in whether to request repayment from covered entities for small amounts:**

Issue: We appreciate HRSA/OPA's statement in the summary that: "A manufacturer retains discretion as to whether to request repayment based on its own business considerations..." We have heard anecdotal evidence of FQHCs having great difficulty repaying manufacturers very small sums of money that are technically owed, but are so small, the manufacturer does not have a simple process for receipt. However we are concerned that this flexibility is not mentioned in the Guidance.

Recommendation: We recommend adding the language from the Summary verbatim into the Guidance as follows (*additions are in italics and underlined*):

Part C, (d): "*Repayment. If a 340B drug is found to have been diverted to an individual who is not a patient of the covered entity contrary to the statutory prohibition on diversion, the covered entity is responsible for offering repayment to all affected manufacturers. A manufacturer retains discretion as to whether to request repayment based on its own business considerations, provided that, when exercising its discretion, the manufacturer complies with applicable law, including the Federal anti-kickback statute (42 U.S.C. 1320a-7b(B)).*"

Part D: Covered Entity Responsibilities

D.1. Correct language mischaracterizing Medicaid managed care duplicate discounts

As a preliminary matter, Bi-State notes that the introductory paragraph of this section of the draft guidance misstates the applicable law. Specifically, the proposed guidance provides:

"Section 340B(a)(5)(A)(i) of the PHSA prohibits duplicate discounts whereby a State obtains a rebate on a drug provided to a Medicaid fee-for-service or managed care organization patient when that same drug was discounted under the 340B Program."

While this may have been intended as an accurate restatement of the statutory language, it includes an important error that has significant negative consequences for FQHCs and other covered entities.

Section 340B(a)(5)(A)(i) provides, in pertinent part, that:

"[a] covered entity shall not request payment under [Medicaid] with respect to a drug [purchased at the 340B ceiling price] *if the drug is subject to the payment of a rebate to the State under section 1927 [of the Medicaid] statute.*" (emphasis added).

However, 340B drugs dispensed to Medicaid MCO beneficiaries are expressly exempt from a manufacture rebate. Per Section 1927(j)(1) of the Medicaid statute, 42 USC 1396r-8(j)(1): "(1) Covered outpatient drugs are not subject to the requirements of this section if such drugs are...(B) subject to discounts under section 340B of the PHSA."

Accordingly, a state is not legally entitled to claim a rebate on a 340B drug dispensed to a Medicaid MCO beneficiary and it is legally impossible for a covered entity to bill an MCO for a 340B drug in violation of Section 340B(a)(5)(A)(i).

This misstatement is consequential. It leads off Part D of the proposed Guidance entitled *Covered Entity Responsibilities, Prohibition on Duplicate Discounts*; thereby, suggesting that a covered entity is responsible even if a state inappropriately seeks a rebate on a MCO-covered 340B drug or any other 340B drug on which a rebate is not payable. In effect, HRSA is shifting responsibility for state actions to the covered entity.

Recommendation: Bi-State strongly recommends that HRSA/OPA quote the statutory language directly rather than paraphrasing it in a manner that introduces inaccuracies.

D.2. 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 MEF, all drugs billed under the Medicaid provider number or NPI are purchased outside of the 340B Program.”

Bi-State is 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 (particularly given the language mentioned earlier which incorrectly muddles Medicaid fee-for-service and Medicaid managed care requirements for duplicate discounts.) As HRSA/OPA is aware, there have already been issues with states and MCOs misinterpreting the MEF as applying to managed care.

Recommendation: Bi-State recommends 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.3. Support for permitting Health Centers and other covered entities to vary carve-in/carve-out decisions based on site and MCO

Bi-State supports 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.4. Permit Health Centers 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 Health Centers 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.5. Ensure consistency with CMS policy by referencing CMS regulatory language stating that managed care organizations are responsible to prevent duplicate discounts

Issue: In CMS’ Notice of Proposed Rulemaking published in May 2015 regarding Medicaid Managed Care, HRSA’s sister agency clearly stated in §438.3(s)(3) that 340B providers are not legally responsible for protecting manufacturers from being charged duplicate discounts on managed care claims. Rather, CMS stated that it is the

responsibility of the managed care entity (a term which jointly refers to MCOs, PIHPs, and PAHPs) to provide states with the data necessary to avoid duplicate discounts. Specifically, §438.3(s)(3) reads:

“The MCO, PIHP, or PAHP reports drug utilization data that is necessary for States to bill manufacturers for rebates in accordance with section 1927(b)(1)(A) of the Act no later than 45 calendar days after the end of each quarterly rebate period.”

Recommendation: To ensure consistency between HRSA and CMS policy, Bi-State strongly encourages HRSA/OPA to reference CMS’ language into the 340B Guidance. This language could be placed in Part D, at the end of the first paragraph under “Prohibition of Duplicate Discounts,” and could read as follows:

“In 42 CFR 438.3(s)(3), CMS has stated that Medicaid managed care entities must report drug utilization data that is necessary for States to bill manufacturers for rebates in accordance with section 1927(b)(1)(A) of the Act no later than 45 calendar days after the end of each quarterly rebate period.”

D.6. Prioritize the development of detailed guidance on methodologies for Health Centers and other covered entities to identify 340B drugs to states/MCOs

Issue: Section (d)(2)(B) of the 340B statute, as added by the ACA, instructed the Secretary to undertake numerous efforts to support covered entity compliance, including:

“The development of more detailed guidance describing methodologies and options available to covered entities for billing covered outpatient drugs to State Medicaid agencies in a manner that avoids duplicate discounts pursuant to subsection (a)(5)(A).”

At this time, the only guidance to date on this topic is the brief December 2014 Notice about the use of the MEF.

Recommendation: Bi-State requests that HRSA/OPA make the development and publication of this detailed guidance a high priority, as it will help increase compliance and reduce confusion among covered entities, states, and MCOs. We also request that:

- Compliance with the new Guidance be mandatory on a prospective basis (rather than a retrospective basis).
- All parties subject to the Guidance be given adequate time to come into compliance with any new policies before any penalties are imposed.
- HRSA/OPA work with NCPDP to develop methods that can be implemented by all industry stakeholders. Any such methods should be officially endorsed by HRSA and not require special authorization to use them.

D.7. Encourage or require States to develop a single, standardized mechanism for Health Centers and covered entities to identify 340B drugs to states/MCOs

Issue: FQHCs often contract with multiple Medicaid MCOs. If each MCO establishes its own methodology for how FQHCs are to identify 340B drugs, the FQHC 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 single, uniform system for all covered entities to identify drugs purchased under 340B to the state or MCOs. This will reduce administrative burden on covered entities, and also on states.

D.8. Provide a template and expedited review for agreements to prevent duplicate discounts at contract pharmacies

Issue: Section D.c. (under Prohibition of Duplicate Discounts) states that:

“If a covered entity wishes to purchase 340B drugs for its Medicaid FFS or MCO patients and dispense 340B drugs utilizing a contract pharmacy, the covered entity will provide *a written agreement for HHS approval* with its contract pharmacy and State Medicaid agency or MCO that describes a system to prevent duplicate discounts.” *[emphasis added]*

While Bi-State recognizes the importance of ensuring that protections to prevent duplicate discounts are in place, particularly at contract pharmacies, we are concerned that this requirement will create yet another barrier that effectively prohibits Health Centers from using 340B drugs for its Medicaid patients.

As we discussed at length in NACHC’s [comments on the Medicaid managed care NPRM](#)⁷ and briefly summarized above, Bi-State agrees with NACHC’s view that 42 USC §256b(a)(5)(A)(i) is clear that states and MCOs are eligible to seek Medicaid rebates only for those drugs which the covered entity has chosen not to fill using 340B. Unfortunately, in the five years since the ACA was enacted, no regulations have been published to enforce this provision, and given this void, some states and MCOs have imposed requirements that prevent covered entities from using 340B drugs for their Medicaid MCO patients.

Until such time that the ACA language is enforced, this proposed provision is yet another tool that states or MCOs could use to prevent Health Centers (and other covered entities) from using 340B drugs for Medicaid MCO patients. A state or MCO could simply refuse to sign an agreement; thereby, prohibiting carve-in at contract pharmacies. In addition, if HRSA/OPA imposes detailed requirements on these agreements, or takes extended periods of time to review them, this would also have a “freezing” effect on the use of carve-in at contract pharmacies.

Recommendation: To ensure that this provision does not restrict Health Centers’ ability to operate compliant carve-in programs via contract pharmacies, Bi-State recommends that:

- HRSA/OPA publish a standard contract template, based on the detailed Guidance and standardized methods discussed in D.6. and D.7.
- HRSA/OPA implement an expedited review and approval process for these agreements.
- Approval of the agreements be retroactive to the date a completed agreement was submitted to HRSA.

D.9. Revise Guidance language on liability for repayment to accurately reflect the statute and ensure that Health Centers are not held responsible for states’ or MCOs’ actions

Issue: Subsection D(2)(e) states:

“*Repayment.* In accordance with section 340B(a)(5)(D) of the PHSA, if the information provided to HHS does not reflect the covered entity’s actual billing practices the covered entity may be found in violation of the duplicate discount prohibition and would be required to repay rebate amounts to manufacturers if duplicate discounts have occurred due to the inaccurate information.”

This misstates the law in several respects:

- The term “actual billing practices” is overly broad, as it encompasses much more than the carve-in/out status which is reported in the MEF. According to longstanding HRSA policy, specific billing practices are a matter between the state Medicaid agency and the covered entity. See 65 Fed Reg. 13984 (March 15, 2000).
- If a covered entity that complies with state or MCO-mandated billing practices, such as by identifying 340B drugs when it submits claims, then it will have done all that it can reasonably do to avoid duplicate discounts.

⁷ Available at <http://www.nachc.com/client/NHCHC-comments-CMS-MCO-regs-July2015.pdf>

If the state or MCO fails to report this information appropriately to a manufacturer, resulting in duplicate discounts, the covered entity should not be held responsible. In other words, as long as the covered entity accurately advises the state or MCO of its utilization of 340B drugs, it should not be liable for any repayment.

- Section 340B(a)(5)(D) does not, as suggested here, create any obligation for a covered entity to provide information to HHS. That obligation, to the extent it exists, is established under 340B(a)(5)(A)(ii). Rather, Section 340B(A)(5)(D) provides covered entities with the right to notice and hearing before HHS can order repayment. It also should be noted that the repayment obligation, if ordered, extends to the amount of the reduction in price of the drug, not to rebate amounts as referenced in proposed D(2)(e).

Recommendation: Accordingly, Bi-State recommends that this section be revised to provide as follows:

“After notice and hearing as provided in 340B(a)(5)(D) of the PHSA, a covered entity that has been found to utilize 340B drugs in a manner that is not consistent with information that it has provided to a state Medicaid agency or MCO, as applicable, may be liable for repayment to manufacturers.”

D.10. Requirement to maintain auditable records for 5 years

- **Implement requirement to maintain auditable records for 5 years on prospective basis:**

Issue: Bi-State appreciates HRSA/OPA’s establishment of an explicit standard for how long Health Centers and other 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 Health Centers may not be able to comply immediately, as in the absence of a standard, some Health Centers currently keep records for fewer than 5 years. In addition, some auditors currently request records for more than a 5-year period.

Recommendation: Bi-State recommends that the 5-year requirement be made effective on a prospective basis, as of 5 years from the date the final Guidance is published. We also request that auditors be instructed that they may not penalize a Health Center or other covered entity for failure to keep records for time periods that are not required under the final Guidance.

- **Support for HRSA/OPA discretion in situations of non-systemic failure to produce records:** Bi-State appreciates and supports the following recommendation:

“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 elsewhere in these 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.

- **Need for clarity and consistent interpretation among auditors of what constitutes “auditable records.”**

Issue: As a general matter, Bi-State agrees that it is the responsibility of a covered entity 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.

Bi-State also agrees that covered entities should maintain records demonstrating that compliance, and be able to produce these records for inspection and oversight purposes. However, Bi-State is 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. Bi-State recognizes 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 Bi-State 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 ACA 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 official 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. Health Centers that have undergone HRSA audits report widely divergent findings on what is considered to be an "auditable record." Health Centers 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.

Recommendation: For all these reasons, ***Bi-State strongly encourages 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 H.4., below.)

Part E: Contract Pharmacy Arrangements

E1. Support for proposal to not limit number of contract pharmacies

Bi-State appreciates that the proposed Guidance does not limit the number of pharmacies that a Health Center can contract with to dispense 340B drugs to its eligible patients. Each Health Center has unique operational needs and its patients face unique challenges in getting to pharmacies, so we commend HRSA/OPA for maintaining Health Centers' ability to rely on contract pharmacies as most appropriate for their community.

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.”

Bi-State strongly supports 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, Bi-State encourages HRSA/OPA to include this language in the Guidance.

E3. Increase flexibility in using contract pharmacies in response to public health emergencies (Please see related comments in A.5. and C.4.)

Issue: As discussed in A.5, Bi-State is concerned that proposed flexibilities in the event of a public health emergency event are not broad enough to reflect the full range of emergencies to which Health Centers 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 FQHCs and other covered entities to petition HRSA to approve specific situations as a public health emergency.
- Provide flexibility for retroactive registrations in the case of public health emergencies.

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

Part E, (a): “A covered entity may request additional contract pharmacy locations under a public health emergency declared by ~~the Secretary~~ *a governmental body* for the geographic area and time period specified in the declaration, provided all other 340B Program requirements are met. *These contract pharmacies may be determined to be eligible for 340B participation retroactive to the date that the emergency started. HRSA may also permit a covered entity to establish temporary contract pharmacy locations in response to other events which it determines, on a case-by-case basis, qualify as public health emergencies.*”

Part F: Manufacturer Responsibilities – Limited Distribution Networks

F1. Support for requiring manufacturers to ensure that limited distribution networks do not discriminate against 340B covered entities

Bi-State supports 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 proposals 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 on-line posting of such plans.

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

Issue: Bi-State has heard anecdotal reports from Health Centers 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.42). However, this statement is not included in the Guidance.

Recommendation: Given the confusion that already exists around this issue, Bi-State recommends 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 H: Program Integrity

H.1. Ensure that consequences for non-compliance are commensurate with the scope, intention, and impact of the violation

Issue: 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 Bi-State contends that HRSA/OPA lacks statutory authority (e.g., failure to maintain records that meet HRSA/OPA definition of “auditable”).

Recommendation: Bi-State strongly urges 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. Provide covered entities with at least 60 days to respond to a written notice of 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.

Proposal: We recommend covered entities be provided a minimum of 60 days to respond to a written notice of adverse audit finding. This response period should begin the day that the covered entity receives the report, not the date of the report.

H.3. Support for permitting only one audit at a time

Bi-State supports 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.” Bi-State appreciates this provision, as it indicates that HRSA/OPA recognizes the administrative demands that audits impose on FQHCs and other covered entities.

H.4. Clarify and strengthen the HHS audit process

Based on FQHCs' experience with HRSA 340B audits, we recommend the following additions to the Guidance which would improve the quality of audits and covered entity adherence to compliance requirements:

- **Publish HRSA/OPA's audit protocol to assist covered entities in knowing how compliance will be evaluated, and increase consistency across auditors:** At present, the HRSA/OPA audit process is a "black box" for FQHCs. Unlike the audit requirements for federal grants, or the Operational Site Visit process used by HRSA/BPHC, FQHCs (and other 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, FQHCs (and other 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 FQHCs who have already undergone audits, they cannot be confident that they will be held to the same standards. For all these reasons, Bi-State strongly urges HRSA/OPA to issue its audit protocol for FQHCs and other covered entities. Ideally, this protocol should be subject to a public review and comment process.
- **Conduct audits in accordance with the GAO published standards for government performance audits ("GAGAS" or the "Yellow Book"):** This would promote the quality and consistency of audits and, as a result, improve covered entity compliance. HRSA already requires manufacturers to follow Yellow Book standards when auditing 340B covered entities, and proposes (in the Summary) to continue to do so. It is, therefore, both appropriate and consistent for the same standards to apply to HRSA/OPA audits. Bi-State recognizes that a Yellow Book audit of 340B covered entities is not required by the statute. However, GAO strongly recommend that all government agencies follow Yellow Book standards even when not required by law to do so.
- **Permit auditors to discuss preliminary findings with the covered entity:** HRSA auditors should be permitted to discuss primary findings with the covered entity prior to submit an official report to OPA (note that this is an explicit requirement under Yellow Book rules). Currently, HRSA auditors are explicitly instructed not to say anything to the auditee while on site. Health Centers report that matters that could easily have been cleared up on-site are left until the "final" audit report is received, sometimes months later, significantly increasing the administrative effort required to resolve it.
- **Establish a robust, independent appeals process:** While the Guidance does provide for a "notice and hearing" process for resolving audit findings, the final determination – including the potential decision to remove a covered entity from the program – is made by HRSA/OPA staff who have been involved with the audit from the start. Fundamental rules of due process indicate that an appeals process should include, at a minimum, a truly independent "finder of fact;" i.e., not someone who was involved in the initial finding and the opportunity to present collateral evidence and argument.

This due process protection is particularly important in situations where a finding could lead to the covered entity being required to repay substantial sums to a manufacturer, and/or being removed from the 340B program.

H4. Comments on manufacturer audit process

- **Support for reasonable parameters around manufacturers' audit practices:** Bi-State appreciates and supports HRSA/OPA's proposal 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 5 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 (page 54), 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 is 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.29.)

* * *

In closing, Bi-State recognizes this Guidance represents many years of hard work on the part of dozens of HRSA officials, and we thank you for the opportunity to comment on it. Please do not hesitate to contact me at (603) 228-2830 extension 112 or via e-mail at tkuenning@bistatepca.org if you require clarification on the comments presented above.

Sincerely,



Tess Stack Kuenning, CNS, MS, RN
President and Chief Executive Officer
Bi-State Primary Care Association

Attachment A

**Excerpts from the Definition of a Health Center Patient
According to HRSA/BPHC's Uniform Data System (UDS)**

Language is copied from the [2014 UDS Manual](http://bphc.hrsa.gov/datareporting/reporting/2014udsmanual.pdf), available at <http://bphc.hrsa.gov/datareporting/reporting/2014udsmanual.pdf>

PATIENT Patients are individuals who have at least one reportable visit during the reporting year, as defined [starting on page 8].

VISITS "Visits" are used both to determine who is counted as a patient (Tables 3A, 3B, 4, 5, 6A, 6B, and 7) and to report visits by type of provider staff (Table 5) and visits where selected diagnoses were made or where selected services were provided (Table 6A). To be counted as having met the visit criteria, the interaction must be:

- (1) Documented,
- (2) Face-to-face contact between a patient and a
- (3) Licensed or otherwise credentialed provider, who
- (4) Exercises independent, professional judgment in the provision of services to the patient.

Persons who only receive services from community based efforts such as immunization programs, medical or dental screening programs, dental varnishing programs, and health fairs are not counted as patients. Persons whose only service from the health center is a part of the WIC program or other programs are not counted as patients. During the course of addressing the health care needs of the community, health centers see many individuals who do not become patients as defined by and counted in the UDS process.

"Patients," as defined for the UDS, never include individuals who have such limited contacts with the health center, whether or not documentation is done on an individual basis. These other service users include, but are not limited to, persons whose only contact is:

- When a provider participates in a community meeting or group session that is not designed to provide clinical services; examples of such activities include information sessions for prospective patients, health presentations to community groups (high school classes, PTA, etc.), and information presentations about available health services at the center.
- When the only health service provided is part of a large-scale effort, such as an immunization program, medical or dental screening program, dental varnishing program, or community-wide service program (e.g., a health fair).
- When a provider is primarily conducting outreach and/or group education sessions, not providing direct services.
- When the only services provided are lab tests, x-rays, sonography, mammography, retinography, immunizations or other injections, TB tests or readings, and/or filling or refilling a prescription.
- When narcotic agonists or antagonists or mixes of these are dispensed to a patient on a regular basis such as daily or weekly.
- Services performed under the auspices of a WIC program or a WIC contract.

Attachment B

Quality of Care Measures which Health Centers Report Annually for all Patients (as defined by UDS) and Which are Posted On-Line

To see [annual results for individual Health Centers](http://bphc.hrsa.gov/uds/datacenter.aspx?q=d), go to the HRSA webpage at <http://bphc.hrsa.gov/uds/datacenter.aspx?q=d>

For **information on how each measure is calculated**, see the [2014 UDS Manual](http://bphc.hrsa.gov/datareporting/reporting/2014udsmanual.pdf), available at <http://bphc.hrsa.gov/datareporting/reporting/2014udsmanual.pdf>

Perinatal Health

- Access to Prenatal Care (First Prenatal Visit in 1st Trimester)
- Low Birth Weight

Preventive Health Screening & Services

- Cervical Cancer Screening
- Adolescent Weight Screening and Follow Up
- Adult Weight Screening and Follow Up
- Adults Screened for Tobacco Use and Receiving Cessation Intervention
- Colorectal Cancer Screening
- Childhood Immunization
- Depression Screening

Chronic Disease Management

- Asthma Treatment (Appropriate Treatment Plan)
- Cholesterol Treatment (Lipid Therapy for Coronary Artery Disease Patients)
- Heart Attack/Stroke Treatment (Aspirin Therapy for Ischemic Vascular Disease Patients)
- Blood Pressure Control (Hypertensive Patients with Blood Pressure < 140/90)
- Diabetes Control (diabetic patients with HbA1c <= 9%)
- HIV Linkage to Care