

Chapter 1: Definition of Scope of Project and Overview

Section A: Definition of Scope of Project

Comment 1: NACHC appreciates HRSA's commitment to compliance with the Health Center Program requirements. However, NACHC requests clarification that HRSA will follow the current Progressive Action Process set forth in the Health Center Program Compliance Manual to correct a health center's scope of project, rather than taking unilateral action.

NACHC supports HRSA's role in monitoring health centers' compliance with the essential requirements that form the core of the Health Center Program. Further, NACHC welcomes HRSA's support in maintaining overall compliance as well as an accurate scope of project. To that end, Section A indicates that "[I]f HRSA identifies non-compliance, HRSA may address this through legally available actions, with notice to the health center." Such actions may include correction or modification to a health center's approved scope of project, when sites, services, or other activities are deemed inconsistent with the scope of project policy. NACHC acknowledges the importance of maintaining an accurate scope of project. However, as drafted, it is unclear whether HRSA intends to (i) take such corrective action on a unilateral basis with only retrospective notification to the health center or (ii) communicate the alleged non-compliance to the health center and follow the Progressive Action Process set forth the Health Center Program Compliance Manual.

If HRSA acts unilaterally, such action could be substantially detrimental to a health center's operation, ultimately resulting in potential harm to the patients served by the health center. We are seeking clarity that HRSA would provide advance written notice before removing from a health center's scope a service or site that was previously approved by HRSA. Health centers deserve their due process, and we are concerned that unilateral action could result in an additional administrative burden and unanticipated costs to work through an appeals process. HRSA should keep in mind that in terms of modifications to Form 5B sites, it has been previously adjudicated that any decision to remove such site from a health center's scope of project must meet requirements of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A). While HRSA can reverse course on an agency decision, it is required to provide a reasoned explanation for the change. If it does not provide a certain level of analysis associated with a change, the removal of a site would be arbitrary and/or capricious and would not be permitted to carry the force of law. Furthermore, HRSA will have to contend with the Supreme Court's recent decision in *Loper Bright Enters. v. Raimondo*, 603 U.S. —, 144 S.Ct. 2244 (U.S. June 28, 2024) and the end of Chevron deference towards the decisions it makes in administering the Health Center Program.

NACHC strongly recommends that HRSA modify this section to indicate that if it determines that a health center's scope requires modification or correction, HRSA will follow the process set forth in the "Progressive Action Overview" Section of Chapter 2 of the Health Center Program Compliance Manual, which provides for the placement of a condition that describes the nature of and reason for the condition, the action needed to remove the condition and the time allowed to take corrective action.

Section B: Governing Board Role and Authorities Related to Scope of Project:

Comment 1: NACHC recognizes that Section B generally reiterates the board's authorities, as set forth in Section 330, the implementing regulations, and the Compliance Manual. Notwithstanding, NACHC requests revision to the language in the 5th bullet to reflect the current requirement in Chapter 19 of the Compliance Manual.

The 5th bullet in Section B appears to expand the board's authority to approve certain contractual arrangements beyond what is currently required, overstepping into and disregarding what is traditionally the role of management. Chapter 19, Element C of the Health Center Program Compliance Manual requires the board to approve "the Health Center Program project's sites, hours of operation and services, including *decisions* to subaward or contract for a substantial portion of the health center's services." The latter is defined in Chapter 12 as a contract with a single entity for the majority of health care providers. On the other hand, the 5th bullet appears to expand board approval to include all "decisions to subaward or contract for the operation of sites and the delivery of services."

NACHC agrees that the board should approve decisions to subaward funds insofar as such decisions may have significant compliance implications. However, we are seeking additional clarity on the board's role in approval of decisions to contract for "the operation of sites and the delivery of services". As drafted, this language can be interpreted as an expansion of the board's authority into management's role by requiring approval of any management decisions to utilize contracts in the operation of the health center. For example, it is not uncommon for health centers to maintain multiple contractual relationships for diagnostic laboratory and/or radiology services. Typically, the board delegates authority to the CEO to make decisions regarding which diagnostic providers the health center should maintain contractual relationships. Requiring the board to approve new contracting decisions that don't require a change in scope would be overly burdensome and unworkable from a practical standpoint, because of the volume of management decisions that occur on a daily basis. Additionally, this change would be inconsistent with the current requirement in Chapter 19 of the Health Center Program Compliance Manual. Further, requiring board approval in such circumstances would be an egregious overstep of the board's oversight role into management's role. HRSA itself recognizes that the board's role should not be "confused" with that of management, stating in Chapter 19 that "The governing board of a health center is generally responsible for establishing and/or approving policies that govern health center operations, while the health center's staff is generally responsible for implementing and ensuring adherence to these policies (including through operating procedures)."

NACHC recommends that HRSA strike "[T]his includes decisions to subaward or contract for the operation of sites and the delivery of services" from the Fifth (5th) Bullet and replace it with "This includes decisions to subaward or contract for a substantial portion of the health center's services," for consistency with the current requirement in Chapter 19 of the Compliance Manual. While the board may determine whether it prefers to conduct a more detailed review than what is required under its proscribed authorities (such as a review of specific service contracts above a certain dollar threshold), such a decision should be left to the discretion of the board, not HRSA. The requirement in the draft Scope Manual should be consistent with and reflect only those authorities required under Section 330, the implementing regulations, and the Compliance Manual.

Section C: General Criteria for Including Activities within the HRSA-Approved Scope of Project:

Comment 1: NACHC generally agrees that to include services, sites, and activities within a health center's scope of project, the services delivered, sites operated, and activities conducted should occur "on behalf of" the particular health center's project. Notwithstanding, NACHC has concerns and recommendations regarding a few of the criteria for demonstrating that activities occur "on behalf of" the health center. Please see our comments under Chapter 3 for additional concerns regarding the application of similar criteria to services and activities provided by contractors, subrecipients, and cooperative arrangements.

Criterion b: The health center provides services under the authority and direction of the health center's governing board and in accordance with the health center's policies and procedures. NACHC agrees that services provided directly by a health center should be provided under the board's direction and "in accordance with the health center's policies and procedures." However, this general reference without more specific details may not accurately apply in situations where the health center utilizes contractors, subrecipients, or cooperative arrangements to provide in-scope services.

Contractor: Under a typical contractor arrangement, the contractor provides services "on behalf of" the health center insofar as it is acting as a representative or agent of the health center and providing services under the health center's direction. Nevertheless, it may be inappropriate to require a contractor providing in-scope services to comply with *all* health center policies and procedures, such as personnel policies. Further, the health center may not maintain applicable clinical policies and procedures for contracted services not provided by the health center directly, such as diagnostic laboratory services.

Subrecipient: As described in Chapter 12 of the Compliance Manual, subrecipients perform a "specific portion of the HRSA-approved scope of project." Services provided under subawards are recorded on the health center's Form 5A and the sites at which they are provided are recorded on the health center's Form 5B. Further, the services provided are reported as part of the health center's UDS reports. However, in performing a "portion of the HRSA-approved scope of project," the subrecipient does not render services as an agent or representative of the prime grantee. Rather, a subrecipient is a separate, independent entity, that maintains its own medical records for the patients served, bills third party payors and patients directly for the services rendered under its own billing numbers and in accordance with its own HRSA-compliant billing/collections policies and procedures, establishes and complies with its own board-approved HRSA-compliant policies and otherwise retains clinical responsibility for and control over the services it provides. For example, policy and procedures of both the prime grantee and the subrecipient will comply with Health Center Program requirements for the sliding fee discount schedules they may differ in substance. This operational independence is consistent with federal regulations, 45 CFR § 75.351.

Cooperative Arrangements: Services provided under cooperative arrangements are *coordinated* by the health center. However, the health center board does not *direct* the provision of services via the

cooperative arrangement, nor are the services provided in accordance with the health center's policies and procedures.

NACHC recommends that HRSA revise this criterion to read “The health center provides services under the authority and direction of the health center’s governing board and, for purposes of services provided directly, in accordance with the health center’s policies and procedures.” We further recommend explicitly exempting subrecipients and cooperative arrangements from this criterion insofar as the prime grantee’s board does not “direct” the provision of services via a subrecipient or under a cooperative arrangement, and both of those providers maintain their own policies and procedures.

Criterion d: Health center employees, individual contractors, and volunteers deliver in-scope services at the service site or other location at which health center services may be provided. By explicitly using the term “individual contractors” HRSA appears to leave out organizational contractors, which is an allowed service delivery method under Chapter 3 of the draft Scope Manual. **NACHC recommends that HRSA revise the language in criterion d for consistency with the defined contractors in Chapter 3. Accordingly, it should read “health center employees, individual contractors, organizational contractors, and volunteers.”**

Criterion e: If the health center provides services to its patients through subawards, contracts or cooperative arrangements with other organizations, the health center’s governing board approves such subawards, contracts, or cooperative arrangements. As noted in our comments for Section B of this Chapter 1, Chapter 19, element c of the Health Center Program Compliance Manual requires the health center to demonstrate that the board approves “the Health Center Program project’s sites, hours of operation and services, including *decisions* to subaward or contract for a substantial portion of the health center’s services.” By proposing that the board approve all subawards, contracts, and cooperative arrangements, HRSA is expanding the board’s authority beyond what is currently required (i.e., approval of decisions to subaward or contract), inconsistent with the requirement in Chapter 19 of the Compliance Manual and crossing the line into management’s role. Further, this criterion indicates that the board should approve the actual agreements and not simply management’s decisions to enter into the agreements, which is inconsistent with both the Compliance Manual and Section B of Chapter 1. As discussed under Section B, requiring the approvals contemplated under this criterion would also be overly burdensome and unworkable from a practical standpoint, as well as an egregious overstep of the board’s oversight role into management’s role. Effectively, this requirement could result in the board having to approve each contract and cooperative arrangement. **NACHC recommends that HRSA strike criterion e as drafted and replace it with “If the health center provides services to its patients through subawards or contracts for a substantial portion of the services, the health center’s governing board approves decisions to enter into such subawards and contracts” for consistency with the current requirement in Chapter 19 of the Compliance Manual. While the board may determine whether it prefers to conduct a more detailed review than what is required under its proscribed authorities (such as a review of specific service contracts above a certain dollar threshold), such a decision should be left to the discretion of the board, not HRSA. The requirement in the draft Scope Manual should be consistent with and reflect only those authorities required under Section 330, the implementing regulations, and the Compliance Manual.**

Criterion g: The health center establishes and maintains health records for all individuals served. NACHC agrees that health centers should establish and maintain health records for patients served either directly by the health center or through contractual means. However, for the reasons discussed in our comments on Section C, Criterion b, subrecipients would establish and maintain their *own* set of medical records. Further, the health center would not establish medical records pertaining to services provided under cooperative arrangements. Rather, the other provider would establish such records and provide the health center with the information necessary to provide follow-up care (such as diagnosis and treatment notes). **NACHC recommends that HRSA revise this criterion to read “The health center establishes and maintains health records for all individuals served by the health center directly or through contracts.” We further recommend explicitly exempting subrecipients and cooperative arrangements from this criterion.**

Section D: Limitations on Health Center Program Scope of Project and Other Lines of Business

Comment 1: NACHC agrees that the HRSA-approved scope of project should be limited to services, sites, and activities that are operated or conducted on behalf of the health center, that are compliant with the Health Center Program requirements and that are consistent with the purposes of the Health Center Program as defined in statute and regulations. However, NACHC requests clarification regarding the examples of out-of-scope activities provided.

Paragraph 2 of this Section D indicates that “HRSA considers activities that are not consistent with the purposes of the Health Center Program (for example, when a health center operates a thrift store) or that a health center performs on behalf of another entity (for example, contracting to manage or staff an employer-operated health clinic or a hospital department) to be other lines of business outside of the health center’s scope of project.” It appears that that the latter example precludes situations under which another party (such as an employer or a PACE organization) provides payment to the health center as a “payor” in order for the health center to furnish services to a limited population associated with such other party (such as employees or PACE beneficiaries), even when other criteria indicating that the services are provided “on behalf of” the health center are present. For example, under such payor arrangements, typically:

- The health center maintains full responsibility for the clinical care it provides.
- The individuals served are registered as health center patients and except for billing the other party for the services, the individuals served are treated as health center patients (for example, they have access to all the health center’s in-scope services).
- The services are provided under the authority and control of the health center board and in accordance with the health center’s policies and procedures.
- The health center establishes and maintains a medical record for each patient; and
- All other criteria indicating that the health center is providing services on its own behalf are present in the arrangement.

Such situations are common among health centers, especially those looking to create innovative models of care, as well as expand and diversify their health center projects and establish themselves

as the provider of choice within their communities. Further, such arrangements may be prime approaches to stabilize revenues and funding streams. **NACHC recommends that HRSA revise this paragraph to distinguish between (1) situations under which the health center is the provider of the services, the individuals treated are considered health center patients and all other criteria to demonstrate that the health center is providing services on its own behalf are present, despite the fact that the other party provides payment to the health center, albeit merely as a third party payor and (2) situations under which the health center is truly acting on behalf of the other entity.**

Comment 2: NACHC agrees with the limitations on the use of grant funds and program income consistent with Section 330. However, NACHC requests clarification that the limitations in the draft Scope Manual are not intended to preclude the use of Excess Program Income for out-of-scope activities that otherwise meet the criteria for the use of program income.

Paragraph 4 of this Section D establishes that “a health center must not use Health Center Program award funds to support other lines of business or program income/non-grant funds to support other lines of business that do not further the objectives of the Health Center Program project.” This requirement is consistent with Section 330 and Chapter 15 of the Compliance Manual.

It has long been held that Excess Program Income (EPI) can be used to support out-of-scope activities, including other lines of business, provided that the use meets the standards set forth in Section 330 and Chapter 15 of the Compliance Manual – it must further the objectives of the project and cannot be specifically prohibited by the Health Center Program, as set forth in 42 U.S.C. 254b(e)(5)(D). **NACHC recommends that, for purposes of addressing the expenditure of “nongrant funds,” as such term is defined in Section 330, HRSA ensures that HRSA’s scope policy aligns with the Section 330 statute. NACHC also requests explicit confirmation that HRSA policy will not restrict health centers from using EPI to support such other lines of business as long as such activities are not specifically prohibited under Section 330 if such use furthers the objectives.** Accordingly, we recommend that HRSA revise paragraph 4 to include the following: “This limitation does not preclude a health center from utilizing Excess Program Income to support other lines of business that further the objectives of the Health Center Program project and are not specifically prohibited by the Health Center Program, as set forth in 42 U.S.C. 254b(e)(5)(D).”

Chapter 2: Medically Underserved Populations, Special Medically Underserved Populations, and Service Areas

B: Service Area

Comment 1: NACHC acknowledges and supports that the description of “service area” under Section B is consistent with the Section 330 statute, its implementing regulations, and the Compliance Manual. In particular, NACHC supports that a health center’s service area would continue to include, at a minimum, those ZCTAs where at least 75% of the current health center patients reside. This framework to define a service area reflects that health centers, such as NACHC, serve all who present for care, regardless of their residency. In fact, addressing the acute needs of *all individuals* who present for care, regardless of their residency, is set forth as a requirement under Section B. Given the significant lack of access to critical primary care across

the country, especially in rural, frontier, and island populations, it is not uncommon for individuals to seek care from health centers despite residing outside of the service area. Although health centers serve such individuals, as mandated by HRSA, a health center does not include a ZCTA in its Form 5B unless there are enough patients residing in such ZCTA to warrant inclusion in the defined service area. **Preserving the policy that up to 25% of the patient population may reside outside of the service area is in line with the realities of health center operations. This approach is also consistent with the health center mission to address unmet need and serve those who seek care, particularly individuals who are low income and encounter significant access barriers.**

Comment 2: NACHC requests a minor revision for consistency and clarity. The second paragraph of Section B states that “[a] health center funded or designated by HRSA to provide services under section 330(e) must provide services to all residents of its defined service area.” The Compliance Manual uses terminology that incorporates the concept of “access.” For example, Chapter 4, element a, states the following: “The health center provides access to all services included in its HRSA-approved scope of project (Form 5A: Services Provided) through one or more service delivery methods.” **NACHC requests that HRSA modify the first sentence of the third paragraph to “[a] health center funded or designated by HRSA to provide services under section 330(e) must provide access to services to all residents of its defined service area.” This minor revision, incorporating the word “access,” is consistent with the Compliance Manual.**

Chapter 3: Required Primary and Additional Health Services

Section A: Services Within the Scope of Project

Comment 1: NACHC supports HRSA’s decision to preserve the three service delivery methods (with the understanding that “formal referral arrangements” have been replaced with “cooperative arrangements”), and requests that HRSA clarify certain text in the second paragraph. NACHC agrees that it is the responsibility of the health center to make all in-scope services available in accordance with the applicable Health Center Program requirements. However, NACHC requests that such a requirement be applied in a manner that is clear and does not impose unnecessary administrative burdens. This request is specifically relevant to the second sentence of the second paragraph of Section A, which requires each health center to ensure it “has policies and procedures in place or that contracts and cooperative arrangements include provisions” for the following: quality improvement/assurance, provider credentialing and privileging, sliding fee discount program, and access for patients with limited English proficiency. NACHC’s specific comments and recommendations/requests are described below.

Enabling Services: The second paragraph is specific to “all in-scope services.” Quality improvement/assurance, provider credentialing and privileging, and sliding fee discount program are inapplicable to enabling services. The absence of carving out enabling services from these requirements is inconsistent with existing practice set forth in the Site Visit Protocol. Specifically, the Site Visit Protocol includes an explicit exception for enabling services from certain requirements that apply solely to clinical services. **NACHC requests that the Scope of Project Policy Manual includes footnotes recognizing that certain requirements do not pertain to enabling services. For example, NACHC recommends that HRSA insert the following**

footnote, which is consistent with text from page 14 of the Site Visit Protocol: “For purposes of contracts and cooperative arrangements for enabling services (for example, transportation, translation, outreach) provided via Column II or III, compliance is demonstrated even if the contracts or cooperative arrangements do not address all of the provisions required for clinical services (for example, general primary medical care, preventive dental).” This revision would provide clarity and avoid inconsistencies between the Scope of Project Policy Manual and the Compliance Manual (including the Site Visit Protocol).

Alignment with Site Visit Protocol: With respect to services provided by contract or cooperative arrangement, it appears that compliance with the elements set forth in the second paragraph can only be demonstrated by including specific provisions in the applicable agreements. This is inconsistent with existing practice set forth in the Site Visit Protocol. Specifically, with respect to contracts and formal referral arrangements (*i.e.*, cooperative arrangements), the Site Visit Protocol includes flexibility to demonstrate compliance with certain requirements (such as sliding fee discount program and credentialing and privileging) through “other documentation.” For example, under the Site Visit Protocol, compliance with provider credentialing and privileging for Column III arrangements can be satisfied through documentation of Joint Commission accreditation. These flexibilities have reduced administrative burdens and eliminating them would be a step backward. **NACHC requests that, for purposes of contracts and cooperative arrangements, HRSA clarify that compliance with certain requirements (for example, provider credentialing and privileging, sliding fee discount program, and access for patients with limited English proficiency) may be demonstrated through documentation other than written provisions in the underlying agreement, consistent with the Site Visit Protocol. This revision would preserve existing flexibilities, avoid the imposition of unnecessary administrative burdens, and preserve consistency between the Scope of Project Policy Manual and the Compliance Manual (including the Site Visit Protocol).**

Quality Improvement/Assurance: It is unclear how “quality improvement/assurance” (QI/A) must be addressed in contracts and cooperative arrangements, as QI/A may be irrelevant. For example, a contracted lab company would not participate in a health center’s QI/A program. As another example, a rural health center may have a cooperative arrangement with a small private dental practice that does not maintain a formal QI/A program, notwithstanding the fact that it provides exceptionally high-quality care. This dental practice would likely terminate its cooperative arrangement with the health center if it were required to represent that it maintains a QI/A program or will participate in the health center’s QI/A program. The loss of such relationships would be incredibly harmful to health center patients and would hinder the ability to provide access to all in-scope services through one or more of the three service delivery methods. **NACHC requests that HRSA clarify the relevance of QI/A requirements to contracts and cooperative arrangements, with consideration of the concerns described above. Insofar as HRSA indicates that QI/A is a required element for contracts and cooperative arrangements, we request that HRSA (1) insert the term “as applicable” following the reference to QI/A, and (2) establish that compliance may be achieved through documentation other than provisions in the written contract and cooperative arrangement, such as through health center policies and procedures.**

Access for Patients with LEP: NACHC agrees that it is responsible for ensuring that contracts and cooperative arrangements comply with the HRSA requirement regarding access for patients with limited English proficiency. (The cited statute, Section 330(k)(3)(K), is specific to “a center which serves a population including a *substantial proportion* of individuals of limited English-speaking ability” (emphasis added).) NACHC is, however, concerned by the proposed new mandate that such requirements be explicitly addressed in the body of contracts and cooperative arrangements. Contractors typically render services within the health center’s service sites and utilize the health center’s existing interpretation and translation services; this is rarely (if ever) specifically addressed in the body of the contract. Off-site contractors who provide services at their own facilities often can access the health center’s language line, if necessary. In addition, for purposes of cooperative arrangements, providers who accept Medicare or Medicaid payments are *already required* to provide access for individuals with limited English proficiency under federal law, such as Title VI of the Civil Rights Act of 1964 and Section 1557 of the Affordable Care Act, as well as related regulations. Consequently, exceptionally few contracts and cooperative arrangements address the issue of access for patients with limited English proficiency. Mandating such provisions in the body of contracts and cooperative arrangements would require amending most, if not all, of these agreements, which would be a tremendous administrative burden. This is also a deviation from the Site Visit Protocol which, for many requirements (for example, sliding fee discount program and provider credentialing and privileging), establishes that compliance may be demonstrated through other documentation. **NACHC requests that HRSA clarify that compliance may be achieved through provisions in contracts and cooperative arrangements or through health center policies and procedures.**

Consolidate with C.2 and C.3.1. Insofar as this paragraph sets forth provisions that must be included in contracts and cooperative arrangements, it appears to supplement the list of required contract and cooperative arrangement provisions, per Sections C.2 and C.3.1. **For clarity and consistency, NACHC recommends that the required provisions for contracts and cooperative arrangements are set forth exclusively in Sections C.2 and C.3.1 and are not included in the second paragraph of Section A. Alternatively, Section A should closely align with, but not supplement, Sections C.2 and C.3.1.**

Section B: Criteria Required for In-Scope Services

Comment 1: NACHC agrees with the criteria for in-scope services yet has concerns and recommendations regarding the applicability of the “on behalf of” standard to cooperative arrangements and subrecipients. Section B.b indicates that, for a service to be considered “in-scope,” the service must be provided “on behalf of” the health center, regardless of the service delivery model. As noted in the comments to Chapter 1, the term “on behalf of” generally implies that one entity is acting as a representative or agent of another entity, providing services under their direction. For the reasons set forth below, NACHC believes that it is inaccurate to characterize subrecipients and cooperative arrangements as rendering services “on behalf of” the health center; suggesting otherwise will result in confusion and the unintended consequence of exposure to liabilities.

Subrecipients: As described in Chapter 12 of the Compliance Manual, subrecipients perform a “specific portion of the HRSA-approved scope of project.” Services provided under subawards are recorded on the health center’s Form 5A and included in the health center’s UDS reports. However, in performing a “portion of the HRSA-approved scope of project,” the subrecipient does not render

services as an agent or representative of the prime grantee. Rather, a subrecipient maintains its own medical records for the patients served, bills third-party payors and patients directly for the services rendered under its own billing numbers and in accordance with its own HRSA-compliant billing/collections policies and procedures, and otherwise retain clinical responsibility for and control over the services it provides. This operational independence is consistent with federal regulations, 45 CFR § 75.351, which recognize that contractors and subrecipients are distinct and substantively different. For example, 45 CFR § 75.351 sets forth that a subrecipient is “[i]s responsible for adherence to applicable Federal program requirements specified in the Federal award,” while a contractor “[i]s not subject to compliance requirements of the Federal program as a result of the agreement, though similar requirements may apply for other reasons.” In addition, 45 CFR § 75.351 establishes that a subrecipient, unlike a contractor, determines who is eligible to receive what Federal assistance, and has responsibility for programmatic decision making. The description of a subrecipient, per 45 CFR § 75.351, is inconsistent with several of the “on behalf of” elements under Chapter 1, Section C, including that services are rendered in accordance with the health center’s policies and procedures, and the health center establishes and maintains health records for all individuals served. It is critical that the Scope of Project Policy Manual not blur this critical distinction between contractors and subrecipients.

Cooperative Arrangements: Services provided under cooperative arrangements are *coordinated* by the health center. However, the health center board does not *direct* the provision of services via the cooperative arrangement, nor are the services provided in accordance with the health center’s policies and procedures, as is required under Chapter 1, Section C.b. Further, Section C.3 of this Chapter 3 indicates that while the activities conducted by the health center that are related to the establishment of a cooperative arrangement are considered “in-scope,” the services provided under the arrangement are not.

While there is close coordination for purposes of subawards and cooperative arrangements, with the health center ensuring compliance with applicable HRSA programmatic requirements, neither the subrecipient nor the cooperative arrangement provider is rendering services “on behalf of” the health center. The health center is responsible for ensuring compliance with the applicable HRSA programmatic requirements, which is substantively different from *directing* the provision of services. Suggesting otherwise may have the unintended consequence of imposing liability on the health center for the other provider's actions and omissions in delivering services. In addition, for purposes of subrecipients, this “on behalf of” standard would be inconsistent with 45 CFR § 75.351. **NACHC recommends that HRSA qualify Section B.b to indicate that, for the reasons described above, the “on-behalf of” requirement would not apply to subrecipient arrangements and cooperative arrangements. In addition, NACHC requests that the Scope of Project Policy Manual not characterize subrecipients as a type of contractor due to their distinct legal standards. Specifically, to enhance clarity and to promote consistency with 45 CFR § 75.351 and Chapter 12 of the Compliance Manual, NACHC requests that the Scope of Project Policy Manual includes a description of subrecipients that are separate from contractors.**

Section C: Service Delivery Method

Comment 1: NACHC is aligned with HRSA’s desire for health centers to directly provide in-scope required primary and additional health care services that reduce barriers to accessible, patient-centered care. However, we encourage HRSA to take into consideration that health

centers expand their capacity and reach in their communities through contracted services and cooperative agreements. There are a lot of local considerations that determine whether a contract or cooperative arrangement is the best (and perhaps necessary) means to make certain required and additional services available to its patient population. For example, providing certain services, such as preventive dental, cancer screening, and obstetrics, is often cost-prohibitive due to the high expense of specialized equipment and/or provider shortages. In addition, existing community providers are often highly qualified to provide the applicable required or additional service, with sufficient capacity and relevant experience and expertise. **NACHC urges HRSA to ensure health centers can continue to enhance access to quality care through contracts and cooperative agreements that directly benefit patients.**

Section C.1: Direct (Form 5A, Column I)

Comment 1: NACHC requests a minor revision to footnote 30 to reflect that many health centers do not maintain provider employment agreements. Footnote 30 indicates that employee status for purposes of the provision of direct services is “generally documented by a Form W-2 that identifies the health center as the employer and an associated employment contract with the health center.” Many health center employees are “at-will” without employment agreements. This is particularly true for non-clinical employees. **To ensure that HRSA is not requiring health centers to execute employment agreements with all employed health center providers, NACHC recommends that HRSA add the phrase “as applicable” before “an associated employment contract ...”**

Section C.2: Contracts including Subawards (Form 5A, Column II)

Comment 1: NACHC requests a minor revision to reflect that contractors may be individuals. The first sentence of this Section C.2 indicates that a contract is a “formal written agreement between the health center and another entity” Later in the paragraph, HRSA indicates that contractors can be individuals or entities. **NACHC recommends that HRSA revise the first sentence to indicate that a contract is a “formal written agreement between the health center and another entity or individual ...”**

Comment 2: NACHC requests that HRSA set forth scope requirements applicable to subrecipients in a separate section. As described in NACHC’s comments to Section B of Chapter 3, NACHC requests that the Scope of Project Policy Manual does not characterize subrecipients as a type of contractor due to their distinct legal standards. In addition, many of the mandated provisions set forth in Section C.2 would be inapplicable to subrecipient relationships. For example, there is no exchange of medical records for treatment purposes between the prime grantee and the subrecipient, as is contemplated in sub-section (c). Unlike a contractor, a subrecipient is required to comply with all of the HRSA programmatic requirements. **NACHC requests that the Scope of Project Policy Manual include a description of subrecipients that are separate from contractors, including a separate description of the mandated provisions, drafted in alignment with 45 CFR § 75.351 and Chapter 12 of the Compliance Manual.**

Comment 3: NACHC requests that HRSA verify that “evergreen” contracts satisfy the “current” requirement. The fifth paragraph in Section C.2 establishes that contracts for in-scope services must, among other things, be “current.” NACHC requests that HRSA verify that an evergreen provision is consistent with this concept of a “current” contract. Evergreen provisions allow contracts to automatically renew under specified conditions and are standard and widely accepted

in contract law. Courts have consistently upheld evergreen clauses, recognizing them as legitimate mechanisms for ensuring continuity in contractual relationships. Evergreen provisions minimize the administrative burden of unnecessarily renegotiating and re-executing contracts. **NACHC requests that HRSA include the following footnote within the Scope of Project Policy Manual (or within the Site Visit Protocol, when amended): “To demonstrate that a contract is current, the contract must be in effect and unexpired. Contracts that periodically and automatically renew are consistent with such standard.”**

Comment 4: NACHC requests clarification regarding four of the required contractual provisions, per Section C.2. The fifth paragraph in Section C.2 establishes that contracts for in-scope services must include several provisions, some of which align with the Compliance Manual, while others reflect new requirements. NACHC has comments regarding (b), (d), (f), and (g), as described below. NACHC strongly encourages HRSA to provide health centers with a phased implementation timeline to minimize administrative burdens related to amending existing contracts and potential disruptions to patient care.

b. How health center patients will access services provided by the contractor. This reflects a new requirement for Column II contracts. Unlike cooperative arrangements, patients seen under contractual arrangements are typically treated at the health center site. For contracts that require the patient to present at the contractor’s facility, the health center typically addresses such access through internal processes (e.g., the health center’s established scheduling platform) since it does not require the agreement of the other entity. As such, this provision is unnecessary to include in the contract. **NACHC recommends that HRSA delete this requirement or at a minimum, acknowledge that a health center procedure in lieu of a contractual provision will suffice.**

d. How provider credentialing and privileging will be accomplished. Existing HRSA policy requires that contracted providers are credentialed and privileged, per Chapter 5 of the Compliance Manual. However, compliance with this requirement can be documented through either contractual provisions or “other means,” such as a review of the contractor’s credentialing and privileging policies or documentation of the contractor’s accreditation from a nationally recognized accreditation organization. **NACHC recommends that HRSA revise this requirement to include the existing flexibilities set forth in the Site Visit Protocol.**

f. If the contractor bills and collects for services, the billing and collections process, including the requirement that the health center reviews and approves the contractor’s compliant sliding fee discount schedule. Commonly, services provided via contract are billed by the health center in accordance with the health center’s sliding fee discount program and its billing/collections policies. Notwithstanding, in those rare instances under which the contractor bills for the services, requiring that the health center review and approve the billing and collection process in its entirety is overly broad. Insofar as a significant portion of the billing and collection procedures address third-party reimbursement (some of which may be confidential pursuant to the contractor’s health plan agreements), review and approval of the contractor’s billing and collection processes should be limited to the sliding fee discount schedule and billing and collection processes related to the sliding fee-eligible patients only. **NACHC recommends that HRSA revise this requirement to reflect the review and approval of billing and collection processes (including the sliding fee discount schedule) that apply solely to the sliding fee patients. NACHC further recommends clarification that this criterion is applicable only if the health center is not billing and**

collecting for the contracted services in accordance with its sliding fee discount schedule and its related policies and procedures. Further, NACHC requests that HRSA indicate that such review should be conducted consistent with Chapter 9, element i and Chapter 16, elements g and h of the Health Center Program Compliance Manual.

g. The applicability of federal and state laws, including those related to patient privacy, HHS grant regulations, and civil rights. The parties to a contract are bound by applicable federal and state laws (for example, patient privacy civil rights), regardless of whether such laws are expressly referenced in the body of the contract. While it is preferable that contracts include explicit provisions acknowledging such compliance, the absence of such terms does not exempt either party from their legal obligations under applicable law. In addition, contracts often include a “catch all” requirement to comply with applicable federal and state laws. It would be burdensome, with no substantive legal effect, to require that health centers modify their Column II contracts to include the above. Further, the requirements in the HHS grant regulations would not apply to non-federally funded contracts, other than the requirements explicitly incorporated into the required contract provisions set forth in Chapter 12, element f of the Compliance Manual (which are already addressed in (i) of this Section). **To avoid confusion, NACHC recommends that HRSA strike this requirement in its entirety.**

Section C.3: Cooperative Arrangements (Form 5A, Column III)

Comment 1: NACHC requests a minor revision to reflect that cooperative arrangements may be entered into with individuals. The first sentence of this Section C.3 indicates that a cooperative arrangement is a “formal written arrangement between the health center and another entity” However, the list of potential cooperative arrangement partners set forth in the third paragraph includes both individuals and entities. **NACHC recommends that HRSA revise the first sentence to indicate that a cooperative arrangement is a “formal written arrangement between the health center and another entity or individual ...”**

Comment 2: For consistency with the Compliance Manual, NACHC requests that HRSA revise the text establishing that the health center is responsible for “oversight” of the cooperative arrangement. The first sentence of the third paragraph of Section C.3 states that the health center “maintains responsibility for oversight of the cooperative arrangement.” While there is close coordination for purposes of cooperative arrangements, the health center does not have broad oversight authority over the cooperative arrangement provider’s provision of in-scope services. Suggesting otherwise may have the unintended consequence of imposing liability on the health center for the other provider's actions and omissions in delivering services. Further, insofar as the health center is not providing payment to its cooperative arrangement partner(s), it is highly doubtful that such partners would execute a written arrangement that includes “oversight” by the health center, thus disrupting and delaying care for patients. **NACHC recommends that HRSA revise the first sentence of the third paragraph to read, as follows: “The health center maintains responsibility for overseeing the coordination of the cooperative arrangement, which includes responsibility for making and managing the patient’s access to the services provided under the cooperative arrangement.”** This approach is consistent with the last paragraph of Section C.3, which sets forth that the “oversight” is specifically with regards to ensuring that the services provided comply with all applicable Health Center Program requirements. It is also consistent with Chapter 4 of the Compliance Manual, which

establishes that “the health center is responsible for the act of referral for health center patients.”

Comment 3: For consistency with the Compliance Manual, NACHC requests that HRSA revise the text establishing that the health center is responsible for “the patient’s treatment plan and any follow-up care.” The second sentence of the third paragraph states that the “health center maintains responsibility for the patient’s treatment plan and any follow-up care, based on the care and follow-up instructions provided by [the cooperative arrangement partner].” While current policy in the Compliance Manual requires the health center to retain responsibility for the provision of follow-up care, the presumption is that such care will be limited to services included within the health center’s existing scope of project. Often, there may be instances where the services rendered via cooperative arrangements are not pursuant to an underlying health center “treatment plan.” For example, if a health center patient, who customarily receives preventive dental services from the health center, becomes pregnant and is provided access to obstetrical services via a cooperative arrangement, the licensed obstetrical provider would oversee such pregnancy; it is inaccurate to suggest that the health center provider “maintains responsibility for the patient’s treatment plan.” **NACHC recommends that HRSA revise this sentence by deleting the reference to “the patient’s treatment plan,” while maintaining and clarifying the existing requirement that the health center maintain responsibility for “appropriate” follow-up care. This approach is consistent with Chapter 4 of the Compliance Manual, which establishes that column III agreements must set forth “the process for tracking and referring patients back to the health center for appropriate follow-up care (for example, exchange of patient record information, receipt of lab results).”**

Comment 4: For consistency with the Compliance Manual, NACHC requests that HRSA modify text regarding the requirement that health centers assist patients make appointments to receive services via cooperative arrangements. The last sentence of the fourth paragraph of Section C.3 provides an example of the activities that the health center may carry out to establish the cooperative arrangement, stating that in the context of an arrangement for laboratory services, the health center “would assist the patient in making an appointment for the laboratory service and would ensure that it receives all follow up results and coordinates ongoing care for the patient as needed.” While this is provided solely as an example, it should be noted that assistance with making appointments and the exchange of patient health information from the cooperative arrangement provider to the health center can never be absolute. Rather, HRSA must consider the patient’s authority to decide whether and how to make their own appointments and share their health information. **We recommend that HRSA revise this paragraph for consistency with the existing requirements, per Chapter 4 of the Compliance Manual, and modify the last sentence to state that the health center “may” as opposed to “would” engage in the activities provided in the example.**

Section C.3.1: Provisions in Cooperative Arrangements

Comment 1: NACHC requests that HRSA verify that “evergreen” cooperative arrangements satisfy the “current” requirement. NACHC appreciates that a cooperative arrangement may be in various forms, such as an email that documents acceptance. This sentence further establishes that cooperative arrangements must, among other things, be “current.” NACHC requests that HRSA clarify that an evergreen provision is consistent with this concept of a “current” cooperative arrangement, as described above in our comments regarding Column II contracts. Evergreen

provisions minimize the administrative burden of unnecessarily renegotiating and re-executing cooperative arrangements. **NACHC requests that HRSA include the following footnote within the Scope of Project Policy Manual (or within the Site Visit Protocol, when amended): “To demonstrate that a cooperative arrangement is current, the cooperative arrangement must be in effect and unexpired. Cooperative arrangements that periodically and automatically renew are consistent with such standard.”**

Comment 2: NACHC requests clarification regarding three of the required cooperative arrangement provisions, per Section C.3.1. Section C.3.1 establishes that cooperative arrangements must be in writing and include several provisions. Some of these provisions align with the Compliance Manual, while others reflect new requirements that are inapplicable, inconsistent with existing requirements, or otherwise unnecessary to explicitly include in the body of the written arrangement. NACHC strongly encourages HRSA to provide health centers with a phased implementation timeline to minimize administrative burdens related to amending existing contracts and potential disruptions to patient care. NACHC has comments regarding (b), (c), and (e), as described below.

b. How the other entity will apply a sliding fee discount to its schedule of charges for services the other entity provides to health center patients. Existing guidance, via the Site Visit Guide, sets forth that a health center may provide “other documentation” to demonstrate the application of a sliding fee discount under a cooperative arrangement (such as the other entity’s charity care policy) in lieu of provisions in the written agreement. **NACHC recommends that HRSA revise this requirement to align with Chapter 9, Element j of the Compliance Manual, and include the existing flexibilities to demonstrate compliance through other documentation, as contemplated in the Site Visit Protocol.**

c. How health center patients will access services provided by the other entity. NACHC agrees that each individual health center is responsible for ensuring that its patients have access to in-scope services via cooperative arrangements. However, this is typically addressed through internal processes since it does not require the agreement of the other entity. As such, this provision is unnecessary to include it in the cooperative arrangement. **NACHC recommends that HRSA delete this requirement or, at a minimum, acknowledge that an internal procedure in lieu of a provision in the cooperative arrangement will suffice for purposes of demonstrating compliance.**

e. Any provisions required by federal and state laws including those related to patient privacy, HHS grant regulations, and civil rights. The parties to a cooperative arrangement are bound by applicable federal and state laws (for example, patient privacy civil rights), regardless of whether such laws are expressly referenced in the written agreement. Accordingly, while it is preferable that agreements include explicit provisions acknowledging such compliance, the absence of such terms does not exempt either party from their legal obligations under applicable law. It would be burdensome, with no substantive legal effect, to require health centers to modify their Column III cooperative arrangements to include the above. Further, the requirements in the HHS grant regulations apply solely in cases where funds are expended and, as such, would not apply to cooperative arrangements. **To avoid confusion, we recommend that HRSA strike this requirement in its entirety.**

Section D. Criteria Required for Additional Health Services

Comment 1: NACHC acknowledges and understands HRSA's desire to more closely align additional health services with Section 330. However, as the largest network of primary care providers, health centers are exposed to the growing unmet need in their communities for an extensive array of advanced additional and specialty services. When feasible, health centers provide additional health services based on the needs of their patients, and NACHC strongly encourages HRSA to reconsider its position and include in Section D a discussion of criteria for adding specialty services to scope.

Section D appears to include an abbreviated version of the general criteria in PIN 2009-02 for including additional and specialty services in a health center's scope of project. However, it neither explicitly references "specialty services," nor includes the language in PIN 2009-002 indicating that the proposed service should "function as a logical extension of the required primary care services already provided by the health center" and/or "complement the required primary health care services." Rather, the draft Scope of Project Policy Manual indicates that the proposed service should "support" the primary health services currently provided by the health center.

It is unclear whether some of the advanced additional and specialty services currently provided by health centers would fit within this "support" standard. For example, a health center that treats a large number of diabetic patients can consider that restorative dental services and vision care "support" comprehensive treatment for diabetes and other chronic conditions. It's imperative that HRSA implement language that preserves the health center's ability to provide advanced additional and specialty services within their scope of project that are critical to the health center's mission as a one stop shop for the most underserved and vulnerable patients. Elimination of such services could also have a concerning impact on operations, including but not limited to reduction of staff, deletion of sites, and financial de-stabilization. **To maintain consistency of existing operations and avoid disruption of vital services provided to patients, NACHC recommends that HRSA revise this section to include specialty services, and the criteria used to evaluate their inclusion on scope (i.e., function as a logical extension of and/or complement the required primary care services), consistent with current HRSA policy. At a minimum, HRSA should include a footnote indicating that the new criteria are not intended to preclude the inclusion of advanced additional services and specialty services necessary for the health and well-being of health centers' patient populations, along with a cross-reference to the "supplemental services" defined in the implementing regulations (42 CFR § 51c.102(j)), which provide a broader array of services than the statute, and examples of allowable specialty services from PIN 2009-02.**

Chapter 4: Services Provided by Telehealth

A. Considerations for Delivering Services via Telehealth

Comment 1: NACHC appreciates HRSA's proposed policy establishing that telehealth is a means to complement in-person services and that the provision of in-scope services by telehealth would not require HRSA approval. NACHC further supports HRSA's proposed policy that an individual may become an established health center patient through receiving an in-scope service

by telehealth. These flexibilities reflect that telehealth has transitioned from an emerging innovation to a mainstream and essential component of health care delivery.

Comment 2: NACHC requests a minor revision to Section A.b, which indicates that the health center must maintain policies and operating procedures that address “patients’ ability to opt out of receiving services by telehealth.” In light of varying state telehealth laws governing informed consent, NACHC recommends striking “including patients’ ability to opt out of receiving services by telehealth” from Section A.b. Accordingly, a health center may not be subject to informed consent laws. HRSA policy regarding telehealth should not extend into legal matters that are otherwise dictated by state law, as this may result in confusion. State law will control how a patient consents to care and, by extension, opts out of receiving care by a certain modality (*i.e.*, telehealth). **NACHC further requests that HRSA clarify that the examples set forth in Section A.b are not required, as some health centers may not be subject to telehealth informed consent laws.**

Comment 3: NACHC requests that the Scope of Project Policy Manual supersedes PAL 2020-01. It appears that HRSA intends to preserve PAL 2020-01: *Telehealth and Health Center Scope of Project*. Such PAL includes text inconsistent with the proposed Scope of Project Policy Manual. For example, the definition of a “service site” in PAL 2020-01 aligns with PIN 2008-01: *Defining Scope of Project and Policy for Requesting Changes*. In addition, PAL 2020-01 includes text that is redundant with Chapter 4 of the draft Scope of Project Policy Manual (for example, the need to comply with applicable laws). Having two separate guidance documents regarding telehealth with different requirements is likely to result in confusion. **NACHC urges HRSA to consolidate PAL 2020-01 into the draft Scope of Project Policy Manual or modify PAL 2020-01 so it exclusively addresses telehealth considerations that are not addressed in Chapter 4, notably the chart on page 4 of PAL 2020-01.**

B. Criteria for Delivering Services via Telehealth

Comment 1: NACHC urges HRSA to modify the geographic restriction applicable to the provision of in-scope services by telehealth, as the proposed approach would have the unintended consequence of limiting access in a manner that would harm health center ability to provide high quality, convenient, and accessible care for the most vulnerable and underserved individuals who seek care. The first paragraph of Section B sets forth that “a health center can provide services via telehealth to new or established patients who are physically located within a health center’s service area or within areas adjacent.” Section B.d focuses on the patient’s residency, establishing that “[n]ew or established patients receiving services via telehealth [must] reside within the health center’s service area or within areas adjacent to the health center’s service area.” In other words, there appear to be two distinct requirements for the purposes of providing in-scope services by telehealth: the patient’s physical location at the time of the visit and the patient’s residency, each of which is addressed below. For purposes of both standards, “adjacent” is defined in a footnote as the neighboring ZCTAs.

Physical Location at the Time of the Visit: NACHC has concerns that the proposed policy requiring the patient’s physical presence within the service area or an adjacent area at the time of a telehealth visit will create unnecessary access barriers, disruptions to patient care, and significant challenges from an operational perspective. Patients often are unaware of the ZCTA where they are located at

the time of a telehealth visit. Moreover, this approach would require that the health center check the patient's ZCTA location against the list of service area ZCTAs (including bordering ZCTAs), which is an exceptional administrative burden that would interfere with patient care. In addition, there are many reasonable reasons why an individual may be at a location that isn't within the service area or a bordering ZCTA. For example, under the proposed policy, if a patient with a scheduled telehealth appointment is at their job, which isn't within or adjacent to the service area, the health center would be unable to proceed with the visit. We urge HRSA to not limit health center patients' access that would be permitted under applicable state telehealth laws.

Residency. We strongly recommend that HRSA align telehealth with the patient's residency to more closely follow the statutory requirement to serve a defined service area. However, the narrow restriction to the service area and the adjacent area is inconsistent with current HRSA policy and guidance and limits the ability of a health center to see its patients. For example, HRSA defines service area in PIN 2008-01 as the "area in which the *majority* of the health center's patients reside ..." (emphasis added). In addition, current HRSA policy, per Chapter 3 of the Compliance Manual, establishes that the ZCTA codes reported on a health center's Form 5B: Service Sites should include the ZCTA codes in which *at least 75%* of current health center patients reside, as identified in the most recent UDS report. This provides flexibility to have up to 25% of patients residing outside of the service area; a health center does not include a ZCTA in its Form 5B unless there are enough patients residing in such ZCTA to warrant inclusion in the defined service area. It is also important to note that Chapter 2, Section B of the draft Scope of Project Policy Manual *requires* that health centers "address the acute needs of all individuals who present in-person at the health center for care, regardless of their residence." This stark distinction for patients who reside outside of the service area, with services *required* if in-person, and *prohibited* if remote, seems arbitrary and inconsistent with the purpose of the Health Center Program.

NACHC is concerned that the proposed geographic limitations, as described above, would have unintended consequences of hindering access to essential clinical care for individuals who would otherwise be considered health center patients. As an example, health centers would be required to provide in-person primary care services for an individual with diabetes who presents at a service site for care, notwithstanding the fact that such individual resides outside of the service area (and the adjacent area). Under the proposed telehealth policy, health centers would be unable to monitor and manage such patients' care by telehealth from their home between in-person appointments, which would significantly undermine their ability to provide timely and high-quality care.

This geographic limitation would particularly limit health centers' ability to serve individuals who fall within one of the special medically underserved populations (homeless, migratory or seasonal agricultural worker, and/or public housing patient population), as such individuals often do not have an established residence and/or are transient. HRSA policy should not hinder health centers' ability to serve these particularly vulnerable and high-need communities.

As HRSA considers the significant legal implications of its telehealth geographic limitation, it is important to note if health centers are off by a single ZCTA, either related to the patient's residency or their location at the time of the visit, and such location is outside of the service area (or an adjacent area), such visit would be deemed out of scope. In addition to the Section 330-related consequences of a visit being deemed out of scope, there are also FTCA consequences. Consider the following example: a health center provides care to an established patient at their place of

employment via telehealth and, even though the place of employment is in an adjacent county to the health center's service area, the ZCTA is not considered to be permissible, and the health center provider fails to diagnose cancer. The patient files an FTCA claim and the Office of General Counsel refuses to cover the claim because the care is deemed to be "out of scope" despite the health center and the health center provider doing everything in their power to provide the care within the confines of the FTCA program. In order to protect themselves against claims like these, health centers would have to purchase gap insurance for care that squarely fits within the purpose and intent of the health center program.

NACHC acknowledges that HRSA policy regarding telehealth must align with the premise that health centers must focus on providing in-scope services within their defined service area. **However, NACHC recommends modifications to the geographic limitation to avoid the unintended consequences of hindering access and negatively impacting the quality of health center care and the resulting health outcomes in affected communities. Specifically, NACHC recommends addressing the geographic restriction in sub-section d, with the following four requests:**

1. NACHC requests that the Scope Manual adopt the following definition of "adjacent," for consistency with PIN 2024-05: *Health Center Program Policy Guidance Regarding Services to Support Transitions in Care for Justice-Involved Individuals Reentering the Community*, footnote 25.

For the purposes of this policy, areas adjacent to a health center's service area are:

1) The local jurisdiction (county, township, borough, parish, city, or equivalent type of minor civil division) adjacent to the area covered in whole or in part by the Zip Code Tabulation Areas (ZCTAs), for each approved service site, as identified by the health center on its Form 5B: Service Sites, and

2) Any ZCTAs not identified on Form 5B, but that are within such local jurisdictions covered in part by the service area ZCTAs.

2. NACHC requests that the Scope of Project Policy Manual establish that, for purposes of telehealth, the patient must be in the service area (or an adjacent area) at the time of the visit, or the patient must reside in the services area (or an adjacent area). In addition, NACHC requests that HRSA policy establish that up to 25% of the telehealth visits may fall outside of this geographic limitation. Such standard is consistent with existing HRSA policy and would not undermine health center commitment to serving their HRSA-approved service area, while acknowledging that there may be periodic exceptions (for example, the patient moves outside of the service area and needs to receive services until they find a new medical home, as is contemplated in the draft Scope of Project Policy Manual). This limited flexibility would allow health centers to care for a subset of patients who do not fit neatly into the prescribed geographic limitations without the risk of being outside of the federal scope of services. As stated above, this is not only important for Section 330 compliance but also for protection under the FTCA program.
3. NACHC requests that HRSA acknowledge that part-time residency in the service area (or an adjacent area) would suffice for purposes of establishing an individual's "residency" applicable to the receipt of in-scope services by telehealth.

4. NACHC recommends that the telehealth geographic restriction does not extend to patients who fall within one of the statutorily defined special medically underserved populations. As described above, such individuals are often transient; if housed, it is often challenging to track their location at the time of the visit.

Chapter 5: Sites

Section B: Criteria Required for Service Sites

Comment 1: NACHC agrees generally with the criteria in Section B for defining a health center service site. Notwithstanding, NACHC has concerns and recommendations regarding criteria d and e, as described below.

Criterion d: The health center governing board: has approved the addition of the service site, the hours of operation, and services to be provided at the service site, and retains control and authority over the provision of all services provided by the health center at the service site.

NACHC acknowledges and agrees that the board should approve the addition of new sites, including the hours of operation and services provided at the sites, consistent with the board's long-standing authority under Section 330, the implementing regulations, and HRSA's current Scope of Project policy. NACHC recommends that HRSA consider that the implementing regulations (42 CFR 51c.304(d)) do not require the board to approve services on an individual site basis. Rather, the regulations require that the board adopt the "scope and availability of services, location and hours of services" HRSA recognizes that services are defined, approved, and recorded on Form 5A on an organizational basis, explicitly stating in Chapter 3, Section A of the draft Scope Manual that "[H]ealth centers record such services on Form 5A at an organizational level and not for each individual site." Insofar as the board approves the full scope of services provided by the health center, requiring board approval of services on an individual site basis would impose a significant burden with limited benefit to the health center and/or the patients served. Further, tracking services at a service site level and requiring the governing board to approve operational adjustments at individual service sites would create inefficiencies and divert the board's focus from their other critical duties. Health centers must retain the flexibility to make quick operational decisions required to meet the ever-changing needs of their patients and/or for business purposes. **NACHC requests that HRSA revise this criterion to state that the board "has approved the addition of the service site and its hours of operation, as well as the health center's overall scope of services."**

Criterion e: Health center visits are generated at the service site through the delivery of required primary or additional health services to health center patients and are documented in patient health records maintained by or accessible to the health center.

NACHC agrees that patient records should be maintained by or, at a minimum, *accessible* to the health center for patients served either directly by the health center or through contractual means. However, as noted in our previous comments under Chapter 1, Section C and Chapter 3, Section

B, subrecipients are separate legal entities that, among other things, establish and maintain their own medical records. Unless the health center prime grantee is involved with the provision of care to the subrecipient's patients, it would not have the authority to access the patient medical records maintained by the subrecipient. Any such access must be coordinated in compliance with the Health Insurance Portability and Accountability Act ("HIPAA"), as well as any applicable state law. Further, access to medical records creates significant legal exposure, as privacy and cyber breaches are taking place more frequently for health care organizations. **NACHC recommends that HRSA revise this criterion to read "Health center visits are generated at the service site through the delivery of required primary or additional health services to health center patients and, for services provided at sites operated directly by the health center or by a contractor on behalf of the health center, are documented in patient health records maintained by or accessible to the health center."** NACHC further recommends replacing the term "accessible" with "retrievable" for consistency with the Compliance Manual, and requests that HRSA include a footnote specifying that, to be "retrievable," the health center must have reasonable access to such records, but it does not need to be the custodian.

Section D: Service Site Types

Comment 1: NACHC requests a minor revision to the definition of "mobile service sites," as described below.

NACHC appreciates HRSA's clarification that "mobile service sites" include various types of large vehicles that are "equipped and licensed" to render in-scope services on behalf of the health center. However, licensure of service sites, including mobile units, is a matter of state law, and not all states require such licensure for mobile service units. **NACHC recommends that HRSA insert the term "as applicable" following the statement that a mobile service site must be "licensed to render in-scope services on behalf of the health center."**

Section E: Requirements for Documenting Other Sites

Comment 1: NACHC requests confirmation from HRSA that the current Scope Adjustment process will be used for adding or deleting "other" non-service sites identified in Chapter 5, Section E, consistent with current policy.

NACHC agrees that all sites should be documented on Form 5B, including "other sites" that do not meet the service site definition but where important activities that support the health center project are carried out, such as administrative sites and stand-alone pharmacy and other sites at which patient visits are not generated. Section A of Chapter 5 indicates that such other sites must be approved by HRSA. Currently, HRSA allows health centers to utilize a streamlined "Scope Adjustment" process (rather than submission of a full Change in Scope) to add or delete such other sites. To minimize administrative burden, it is important to maintain the ability to utilize this streamlined process. **NACHC requests that HRSA explicitly confirm that it will continue to utilize the current scope adjustment process or a similar streamlined process when approving the addition and deletion of such other non-service sites.**

Chapter 6: Additional Considerations When Adding a Service Site to Scope of Project

Section A: Service Area Overlap

Comment 1: NACHC appreciates HRSA's commitment to minimizing service area overlaps that do not present sufficient justification. Unnecessary overlap strains limited funding and resources, potentially duplicating services at a time when many areas remain underserved. Upfront assessment of potential service area overlap assists in avoiding preventable replication of services while allocating scarce resources to areas most in need. Given the importance of this assessment, NACHC requests that HRSA provide a clear and concise process with well-defined criteria that can be used by health centers when planning their expansions and will be used by HRSA when reviewing proposals.

NACHC supports HRSA's commitment to review funding and look-alike applications and change in scope requests for service area overlap based on (i) the extent to which unmet need in the proposed area exceeds the capacity of the existing health center service site(s) or other safety net providers; and (ii) the degree to which the proposed site will complement and not duplicate existing services in the area. However, the draft Scope Manual lacks information on the specific process and criteria that HRSA will use for either of these determinations. Section B of Chapter 6, which sets forth factors that *may* result in a request from HRSA for additional information, appears to address HRSA's determination of unmet need under criterion (a) and criterion (b). Similarly, criterion (g) appears to address whether the proposed site will complement rather than duplicate existing services by assessing the extent to which the health center demonstrates coordination and collaboration with other health centers serving the same service area. Nevertheless, Section A neither references these criteria nor provides separate assessment standards or factors that health centers can use when developing their expansion plans.

NACHC recommends that HRSA revise Section A to include information on the specific process and criteria that HRSA will utilize when assessing service area overlap based on the two factors listed in this Section. At a minimum, HRSA should include explicit references to Section B, criterion (a), criterion (b), and criterion (g), as they pertain to the assessment of unmet need and coordination with other resources. Please note that any comments we may have regarding the substance of those sub-sections are included under Section B for this Chapter 6.

Section B: Additional Factors for Adding a Service Site

NACHC supports HRSA in providing specific factors it may consider when assessing requests to add additional sites through either applications or change in scope requests. Many of these factors reflect and align with existing policy and/or practice, for which we do not have additional substantive comments. NACHC also recognizes that the factors listed in Section B are neither exhaustive nor dispositive in HRSA's decision to approve or disapprove

a site addition request. Notwithstanding, NACHC has an overall comment as well as some concerns and recommendations regarding a few of the criteria, as noted below.

Overall Comment: As noted above, NACHC recognizes that the additional factors listed in Section B are not dispositive in HRSA's decision to approve or disapprove a site addition request. Further, we understand that the examples provided in several of the criteria are provided solely for explanatory purposes and do not reflect requirements. However, to avoid potential confusion in the field as well as among individuals conducting compliance reviews, NACHC requests that HRSA revise the first paragraph of this Section to include the following statement, before the discussion of the specific factors: "Please note that none of the factors listed below will be dispositive in HRSA's decision to approve or disapprove a site addition request, nor will the responses to the factors result in automatic rejections. All facts and circumstances of the proposed site addition will be considered. Further, all examples provided within the factors are provided for illustrative purposes only and do not reflect required standards by which the factor will be evaluated."

Comment 1: Criterion b: The proposed service site is outside the health center's existing service area, and there is significant unmet need inside the existing service area as determined by HRSA. This factor could hinder a health center's expansion plans. Health centers expand for a variety of reasons, including, but not limited to: (i) diversification and/or enhancement of revenue streams that will support not only the proposed new site but also the health center's existing project, thus providing a degree of financial stability, and (ii) meeting the needs of existing patients who already reside outside of the service area by providing a more accessible location. **NACHC requests that HRSA qualify this factor by adding the following at the end of the first sentence: "absent justification for proposing a site outside of the health center's existing service area."**

Comment 2: Criterion c: The proposed service site is located within the same building or is close (for example, within 1 mile in an urban area or within 5 miles in a rural area) to a service site operated by another health center. There is an existing precedent for health centers currently operating in such close proximity, in particular within urban areas (such as New York City, Chicago, etc.), where there may be health centers located only blocks from one another. Close proximity may also be required in the context of limited service sites (such as dental only sites) and/or limited population sites (such as SBHCs), under which there would need to be a full service site nearby to ensure that the full complement of services is available to the patients served at the limited service site and/or the portion of the population not served by the limited service population site. **NACHC requests that HRSA qualify this factor by adding the following at the end of the first sentence: "absent justification for proposing a site in close proximity to a site operated by another health center."**

Comment 3: Criterion d: The location of the proposed service site is significantly distant from the health center's nearest service site (for example, greater than 15 miles in an urban area or greater than 30 miles in a rural area). There is an existing precedent for health centers currently operating within geographically dispersed areas, in particular within rural areas where there may be wide swaths of "open space" between towns, requiring centers to establish sites that could be greater than (and in some cases, much greater than) 30 miles apart. Significant distance between sites may also be required in the context of limited service sites and/or limited population sites, for the same reasons addressed in the comment under criterion c above. **NACHC requests that HRSA**

qualify this factor by adding the following at the end of the first sentence: “absent justification for proposing a site in distant from the health center’s existing site(s).”

Comment 4: Criterion f: If the proposed site is located in a new service area, the degree to which meaningful community input from the new service area informed the proposed service site addition. Obtaining community input from a proposed new service area is both reasonable and consistent with the foundational requirement that health centers reflect the needs of the community. However, this criterion requires the health center to obtain “meaningful community input” through at least one of the specific examples provided in the draft Scope Manual, some of which may be impractical. First, a statement from a patient board member residing in the proposed new service area may not be practical (or even possible), since it would be highly unusual to have a patient board member from an area not included within the health center’s service area. Further, obtaining a petition signed by, or a statistically significant survey of, the residents of the proposed new service area could be administratively burdensome and, ultimately, untimely, hindering the health center from moving quickly to respond to documented need. Finally, insofar as “another similar mechanism” for obtaining community input appears to refer to the prior factors (i.e., “similar to the prior factors”), it too may suffer from the same deficiencies. **NACHC requests that HRSA revise this factor to allow greater flexibility in how a health center demonstrates community input. Specifically, NACHC recommends that HRSA revise this factor to state “[I]f the proposed site is located in a new service area, the degree to which meaningful community input from the new service area informed the proposed service site addition, through a methodology that may include but is not limited to: (i) ...; (ii) ...; and/or (iii)” (in lieu of the current language that requires the health center to utilize at least one of the examples provided by HRSA).**

Comment 5: Criterion i: Whether HRSA has previously disapproved of the request to add a service site at the same location. HRSA may disapprove a request to add a service site for a variety of reasons, including but not limited to: (i) a lack of necessary information in the initial request and the subsequent failure of the health center to submit such information on a timely basis; and (ii) circumstances that may have been accurate at the time of the initial submission but have since changed, resulting in a more favorable subsequent request. It is unclear why disapproval of an initial request to add a site should factor into the assessment of a subsequent request – each request should be evaluated on its own merits. **NACHC recommends that HRSA strike this factor in its entirety. Alternatively, NACHC requests that HRSA revise this factor to read as follows: “Whether HRSA has previously disapproved the request to add a service site at the same location more than twice within the past 12 months.”**

Section C: Service Sites Co-Located with Other Organizations:

NACHC welcomes and generally supports the considerations and criteria established by HRSA for approval of proposed co-located sites. Notwithstanding, NACHC has some concerns and recommendations regarding a few of the criteria, as noted below.

NACHC appreciates HRSA’s recognition of co-located sites. As providers of choice for over 30 million patients, the Health Center Program has expanded substantially since its inception. One of the innovative models used by health centers to foster growth is the “co-location” model, under which the health center co-locates a clinic in a facility in which another organization provides

health or other services. The reasons for proceeding with a co-location approach vary, including ensuring continuity of care, reaching new populations that would not otherwise have access to health center services, diversifying operations, stabilizing funding streams, and more. Regardless of the reason, the integrity, autonomy, and independence of the health center project must be maintained. In particular, NACHC agrees that the health center should ensure that (i) the services are provided on behalf of the health center and included within the health center's scope of project; (ii) the site meets the service site criteria in the Service Site Definition; and (iii) the co-located program meets applicable Health Center Program requirements.

Comment 1: Paragraph Three, Criterion a: The health center's governing board maintains full authority and control over the delivery of health services at the location and operates the service site in compliance with all Health Center Program requirements. NACHC supports a requirement mandating that co-located sites must be operated in compliance with the Health Center Program requirements. Compliance with the Health Center Program requirements is vital to maintaining the integrity of the Health Center Program. However, including this criterion without additional qualification may pose compliance concerns in situations where a health center co-locates in a facility (or with a program) that is licensed/regulated under other federal, state, and/or local laws and rules (e.g., a school-based site). While the health center site located within the facility would be operated by the health center in compliance with all applicable Health Center Program requirements, the health center may need to comply with other federal, state, and/or local requirements as well. For example, it is not uncommon for school-based health centers to provide services consistent with quality metrics dictated by the state regulatory agency, in addition to the health center's QI/QA program. Under such circumstances, the state-based metrics would supplement (not replace) the HRSA QI/QA requirements set forth in the Compliance Manual. Further, in many jurisdictions, the school-based health center is precluded under state law / local ordinance from operating during hours when the school is closed. In instances where the hours of operation of the school-based health center are required to be concurrent with those of the school in which it is located, the hours would be initially established by the school district and subsequently adopted by the health center board.

NACHC believes that a degree of flexibility is required when health centers co-locate within a facility (or with a program) that is licensed / regulated under other federal, state, and/or local laws and rules. Any indication that the health center cannot comply with other federal, state, and/or local requirements that supplement the Health Center Program requirements could result in termination of the arrangement. **For purposes of clarity and to minimize confusion among the health centers as well as HRSA staff and reviewers, NACHC requests that HRSA add the following qualification to this criterion: "Compliance with Health Center Program requirements is not intended to preclude the health center from complying with other federal, state and/or local legal requirements applicable to the particular co-location model, provided that such other requirements do not conflict with Health Center Program requirements."**

Comment 2: Paragraph Three, Criterion b: The health center demonstrates on an ongoing basis that the services delivered at the co-located service site meet all of the criteria outlined in Chapter 1: Definition of Scope of Project and Overview, including that services are delivered on behalf of the health center and the proposed site meets all service site criteria in the Service Site Definition (refer to Chapter 5, Section B. Criteria Required for Service Sites). NACHC does not object to this requirement *per se*. However, we noted in our comments for Chapters 1 and 5 several

concerns regarding the specific requirements included in those Chapters that may impact a co-location arrangement, whether such site is operated directly or through a contractual arrangement (including, but not limited to, the board's role in approving services provided at a new site, the board's role in approving contracts, and criteria for determining when activities are provided "on behalf of" the health center). **NACHC requests that HRSA incorporate and apply those prior comments to this criterion as well.**

In addition to our prior concerns addressed in Chapters 1 and 5, NACHC has additional concerns regarding the application of the following two requirements set forth in Chapter 1 in a co-location setting.

- Chapter 1, Section B includes a requirement that the board retain authority to approve sites, hours of operation, and services. As discussed above, in situations where a health center co-locates in a school facility, typically, the locations of the school-based sites and the hours of operation are consistent with those of the school facility, which are established by the school district. Further, the school district's agreement with the state or local jurisdiction often includes specific service requirements, which are passed down to the health center. While the health center's overall scope of services would be included in the health center's scope of project and managed and overseen by the health center and its board, the specific services offered at the school-based health center, in whole or in part, are often established by the school district.
- Chapter 1, Section C requires that services be provided "in accordance with the health center's policies and procedures" to be considered on behalf of the health center. As discussed in Comment 1 under Chapter 6, Section C, including this requirement without additional qualification may pose compliance concerns in situations where a health center co-locates in a facility (or with a program) that is licensed / regulated under other federal, state, and/or local laws and rules (e.g., a school-based site). While the health center site located within the facility would be operated by the health center in accordance with the health center's applicable policies and procedures, the health center may need to comply with other federal, state, and/or local requirements as well. For example, under a typical school-based health center program, the program is licensed or otherwise regulated by state law, which may require specific clinical standards related to the provision of services at the school-based health center site. These standards would supplement (not replace) the health center's policies and procedures.

For purposes of clarity and consistent oversight, NACHC requests that HRSA add the following footnote to *Paragraph Three, Criterion b*: "For school-based health center sites, HRSA recognizes that state or local rules regulating such sites as well as the agreement between the state / local jurisdiction and the school district may require the school district/school establish the locations and hours of operation of the school-based sites, the specific services offered at such sites, and specific standards related to the provision of services. Health centers are not precluded from complying with such requirements, provided that the health center and its board maintains compliance with applicable Health Center Program requirements, including the board's ultimate approval of the locations, hours of operation and services offered at school-based health center site and operation of the site consistent with the health center's policies and procedures."

Section D: Service Sites Operated by Contractors including Subrecipients

Comment 1: NACHC requests that HRSA revise the introductory paragraphs of Section D (the paragraphs through Section D.1) to distinguish and separate the requirements that are applicable to contractors from those applicable to subrecipients.

The introductory paragraphs of Section D (the paragraphs through Section D.1) do not distinguish between a subrecipient and a contractor. For example, paragraph 1 of Section D establishes that “[A] health center requesting to add a service site operated entirely by a contractor, including a subrecipient, must demonstrate that the contractor will operate the site on behalf of the health center” (emphasis added). As noted in our comments for Chapter 1, Section C and Chapter 3, Section B, contractors and subrecipients are distinct legal concepts per 45 C.F.R. § 75.351 (subrecipient and contractor determinations) and are substantively very different. While the services provided under subawards are recorded on the health center’s Form 5A and included in the health center’s UDS reports, and the sites at which the subrecipient provides services are recorded on the health center’s Form 5B, unlike a contractor, the subrecipient does not render services as an agent or representative of the prime grantee. As such, the subrecipient does not provide services “on behalf of” the health center. Rather, a subrecipient must independently comply with the Health Center Program requirements, including billing third-party payors and patients directly for the services rendered under its own billing numbers and in accordance with its own HRSA-compliant billing/collections policies and procedures, establishing and complying with its own board-approved HRSA-compliant policies, maintaining its own medical records for the patients served, and otherwise retaining clinical responsibility for and control over the services it provides.

Given the distinctions between a contractor and a subrecipient, NACHC strongly recommends that the Scope Manual distinguish and separate the requirements in the introductory paragraphs of Section D that are applicable to contractors from those applicable to subrecipients. Further, NACHC recommends that HRSA revise the first sentence to Section D to indicate that service sites operated by subrecipients would not be operated on behalf of the health center for the reasons previously discussed in our comments for Chapter 1, Section C, and Chapter 3, Section B.

Comment 2: NACHC requests that HRSA define the term “operated entirely by the contractor.” The term “operated entirely by a contractor” is vague. Neither paragraph one, nor any other provision of Section D defines or includes criteria for when HRSA would consider a site “operated entirely by a contractor” (other than subrecipient sites). Would the contractor have to employ all staff (clinical and non-clinical) working at the site or all of the clinical staff? Would the contractor have to provide all services furnished at the site or could there be some health center employees assigned to the site as well? **To avoid confusion, NACHC requests that HRSA either provide a definition for the term “operated entirely by the contractor” or, at a minimum, provide criteria for making such a determination.**

Comment 3: NACHC welcomes and generally supports the considerations and criteria established by HRSA for approval of proposed contractor-operated sites and subrecipient-

operated sites. Notwithstanding, NACHC has some concerns and recommendations regarding a few of the criteria, as noted below.

Paragraph Five, Criterion A: The service site meets all of the criteria outlined in Chapter 1: Definition of Scope of Project and Overview and Chapter 5, Section B: Criteria Required for Service Sites.

NACHC does not object to this requirement *per se*. However, we noted in our comments for Chapters 1 and 5 several concerns regarding the specific requirements included in those Chapters, which may impact contractor-operated sites and subrecipient-operated sites (including, but not limited to, the board's role in approving services provided at a new site, the board's role in approving contracts, criteria for determining when activities are provided "on behalf of" the health center, and maintenance and access to patient records). **NACHC requests that HRSA incorporate and apply those prior comments to this criterion as well.**

In addition to our prior concerns addressed in Chapters 1 and 5, NACHC has an additional concern regarding the application of the following Chapter 1 requirement in a subrecipient setting.

- Chapter 1, Section C, includes several requirements that must be met by the health center to demonstrate that a site is operated, and the services therein are provided on behalf of the health center. However, as previously discussed in our comments for Chapter 1, Section C and Chapter 3, Section B (as well as our Comment 1 above), subrecipients do not operate "on behalf of" the health center. The services provided under subawards are recorded on the health center's Form 5A and included in the health center's UDS reports, and the sites operated by subrecipients are included on the health center's Form 5B. However, unlike contractors providing services to the health center and its patients, the subrecipient establishes its own compliant health center board and maintains its own operations, including employing staff and as necessary, entering into contracts for personnel and services, establishing policies, procedures, etc., to operate the site, establishing direct patient-provider relationships and maintaining medical records for the patients served, billing third-party payors and patients directly for the services rendered under its own billing numbers and otherwise retaining financial, administrative and clinical responsibility for and control over the site and the services it provides. As such, the criteria in Chapter 1, Section C would not apply to subrecipient-operated sites. **For purposes of clarity and to minimize confusion among the health centers as well as HRSA staff and reviewers, NACHC requests that HRSA add a qualification or a footnote to *Paragraph Five, Criterion a* recognizing that the requirements addressed in Chapter 1, Section C would not apply to subrecipient-operated sites.**

Paragraph Five, Criteria d and e:

d. The health center provides good cause justification for operating the service site through a contractor or subrecipient as opposed to the health center operating the service site directly.

e. The health center's good cause justification supports the selection of a specific contractor or subrecipient and demonstrates that the contractor or subrecipient has the capabilities, resources, and experience with the health center patient population necessary to operate the service site on behalf of the health center.

NACHC appreciates HRSA's diligence in assuring that there is good cause for including within a health center's scope of project sites operated by a third party – whether a contactor or a subrecipient. As a community-based organization, it is reasonable that HRSA prefers that the health center operates its sites directly, to the extent possible. Such preference facilitates the community “voice” while also protecting the integrity of the Health Center Program. Nevertheless, criteria d and e appear to require information that can be obtained through the change in scope process to add the site and HRSA's review of the related agreement. As such, including these criteria in this requirement is overly burdensome, beyond what is required or necessary. **NACHC requests that HRSA strike these requirements in their entirety.**

Paragraph Five, Criterion f: The contract to operate the service site is made according to the health center's written procurement procedures that comply with all federal requirements, including, as applicable, those set forth in 45 CFR Part 75. Insofar as subrecipient arrangements are sub-awards of grant funds and not procurements or purchases of services, goods, items, etc., this requirement would not apply to subrecipient-operated sites. **NACHC requests that HRSA add a qualification indicating that this requirement applies solely to contractor-operated sites and also recognizes that the procurement requirements per Part 75 are applicable to contracts paid for in part or in full with the federal grant.**

Section D.1.: Requirements for Service Sites Operated by Subrecipients

Comment 1: NACHC recommends deleting the last sentence of Paragraph Three in its entirety. Paragraph three of Section D.1 specifically addresses subrecipient compliance. However, the last sentence of paragraph three appears to broaden its application beyond subrecipients, stating “HRSA reserves the right to disapprove or remove service sites operated by awardees or look-alikes, subrecipients, or contractors, if compliance with applicable Health Center Program requirements is not demonstrated or if the site, service, or activity is inconsistent with scope it's of project policy.” This sentence appears to be a non-sequitur and would be suited for Chapter 1 and/or Chapter 10 of the draft Scope Manual, which already addresses the disapproval or removal of sites. **NACHC recommends deleting this sentence in its entirety.**

Section D.2.: Requirements for Service Sites Operated by Contractors That Do Not Meet All Health Center Program Requirements

Comment 1: NACHC requests that HRSA revise the required contract provisions to include the existing flexibilities allowed in current guidance as well as the Site Visit Protocol.

NACHC appreciates HRSA including in this Section D.2 the required contract provisions that must be included in the written agreement between the contractor and the health center for the operation of a contractor-operated site. NACHC supports the application of the Health Center Program requirements at contractor-operated service sites, to the extent that such requirements apply. Generally, the provisions listed in Section D.2 mirror those Health Center Program requirements that would apply to a contractor. However, some of the requirements do not reflect the current flexibility provided to health centers in demonstrating compliance with such requirements. In particular:

- Requirements a and b address the application of the health center’s sliding fee discount program, including the eligibility verification process, to the patients receiving services under the contract. However, existing guidance allows health centers to present “other documentation” in lieu of provisions in the written agreement.
- Requirements c and d appear to suggest that the contract should include provisions addressing how the contractor will ensure appropriate credentialing and privileging of the providers furnishing services at the contractor-operated site. Similar to the application of the sliding fee discount program, existing guidance allows documentation of this requirement through either contractual provisions or “other means,” such as a review of the contractor’s credentialing and privileging policies or documentation of the contractor’s accreditation from a nationally recognized accreditation organization.

Requiring specific contract provisions in the face of existing guidance that provides additional flexibility would be overly burdensome. NACHC requests that HRSA revise the required contract provisions to include the flexibilities allowed in current guidance as well as the Site Visit Protocol.

Chapter 7: Temporary Service Sites Added in Response to Emergency Events

A: Adding Temporary Service Sites in Response to Emergency Events

Comment 1: NACHC supports HRSA’s proposal to establish that health centers may add temporary sites in response to emergency events, consistent with PAL 2020-05: Requesting a Change in Scope to Add Temporary Service Sites in Response to Emergency Events. Health centers play a critical role in preserving access in response to emergency events. These temporary sites are essential; they not only ensure continuity and minimize disruptions to care, but they also serve a broader purpose of stabilizing the health care infrastructure, which can be fragile during these emergency events. Without these temporary access points, emergency rooms would be even increasingly strained and overwhelmed, further exacerbating the public health crisis. In 2024 alone, there were multiple natural disasters with devastating impacts, displacing whole communities and disrupting the health care infrastructure. The devastation caused by the 2025 California fires is further evidence of the fragility of the health care safety net, and the seminal role health centers play. As always, in all of these emergencies, health centers have been nimble and risen to the challenge, creating temporary locations so as to meet the pressing need for care. As natural disasters and public health emergencies become more frequent and severe, the ability of community health centers to establish temporary sites is more crucial than ever. Preserving health center flexibility to establish (and benefit from) these sites is critical to their ability to effectively respond to emergency events.

Section B: Criteria for Adding Temporary Service Sites in Response to Declared Emergencies

Comment 1: NACHC requests that HRSA establish that temporary service sites in response to declared emergencies may provide services at specific locations on an ad-hoc basis rather than

on a regularly scheduled basis. The first sentence under Section B establishes that an emergency temporary service site must meet the criteria set forth in Chapter 5, Section B. *Criteria Required for Service Sites*. Such criteria include that “[s]ervices are provided to health center patients at the service site on a regularly scheduled basis.” This requirement is inconsistent with Chapter 9, Section B *Health Center Services Provided to Individuals Who Are Not Established Health Center Patients*, which states that “[t]he health center may provide services at specific locations on an ad-hoc basis rather than on a regularly scheduled basis.” NACHC believes that mandating a regular schedule of operations imposes unnecessary rigidity in the middle of an emergency response, hindering the ability of these temporary service sites to meaningfully respond to declared emergencies. To be effective and efficient, it is essential that these sites are operationally nimble. **NACHC requests that HRSA establish that temporary sites in response to emergency events may operate on an ad-hoc basis, consistent with Chapter 9, and remove the requirement that these temporary service sites operate on a regularly scheduled basis.**

Comment 2: NACHC requests that HRSA policy not impose a rigid geographic service area limitation for the temporary emergency service site criteria. Section B.a states that the purpose of the temporary service site must be to provide in-scope services to the patient population, other residents of the service area, or the community at large impacted by the emergency. The second sentence states that “this is limited to serving communities within the health center’s service area or adjacent areas.” NACHC is concerned that this geographic restriction, per the second sentence, may inadvertently hinder health centers’ ability to effectively and swiftly respond to emergency events through the establishment of temporary clinical sites.

Recent natural disasters, such as the flooding caused by Hurricane Helene, have extensively damaged health center sites and displaced many, if not most, of their staff. In many instances, neighboring health centers often rise to the challenge, establishing temporary sites to continue critical care during the declared emergency and provide capacity to avoid overwhelming hospital emergency rooms.

HRSA policy should not hinder this essential collaboration among health centers through the imposition of a geographic limitation for emergency service sites. Rather, HRSA policy should preserve flexibility for health centers to respond to catastrophic emergency events. It is also important to note that the establishment of a temporary emergency service site is subject to HRSA approval. HRSA could, therefore, reject a request on the grounds that there is too much disconnect between the emergency event and the health center seeking to establish the temporary site. Making these decisions on a case-by-case basis with all of the facts available would be a much better way to protect flexibility that will likely be needed in certain circumstances while still staying true to HRSA guidance.

NACHC recommends that HRSA (a) strike the second sentence limiting temporary service sites to serving communities within the health center’s service area or adjacent areas or (b) modify Section B.a to: “The purpose of the temporary service site is to provide in-scope services to the patient population, other residents of the service area or adjacent areas, or the community at large impacted by the emergency (which must include residents of the service area or adjacent areas).” If HRSA opts to retain the reference to “adjacent” areas, NACHC requests that the definition is modified to align with PIN 2024-05: *Health Center Program Policy Guidance Regarding Services to Support Transitions in Care for Justice-Involved*

***Individuals Reentering the Community*, footnote 25, as we have recommended for purposes of Chapter 4: Telehealth.**

Comment 3: NACHC requests that the Scope of Project Policy Manual supersedes PAL 2020-05. It appears that HRSA intends to preserve PAL 2020-05: *Requesting a Change in Scope to Add Temporary Service Sites in Response to Emergency Events*. Such PAL includes text inconsistent with the proposed Scope Manual (for example, the definition of a “service site” in PAL 2020-01 aligns with PIN 2008-01). In addition, PAL 2020-05 includes extensive text that is redundant with Chapter 7 of the draft Scope of Project Policy Manual. Having two separate guidance documents regarding temporary service sites in response to declared emergencies could result in confusion among health centers. This is particularly detrimental to health centers that are trying to react quickly in response to a natural or manmade disaster, as they will need clear and immediate guidance to determine their responses. **NACHC urges HRSA to consolidate PAL 2020-01 into the draft Scope Manual, as it doesn’t appear to include information that is not already addressed in Chapter 7 of the draft Scope of Project Policy Manual.**

Chapter 8: Providers, Patients, and Visits

Section B: Patients and Visits

Comment 1: NACHC has a minor revision regarding the reference to telehealth. The criteria to establish a patient-provider relationship include the following: “An individual receives an in-scope service either in-person or via telehealth where the individual is physically located within the health center’s service area or within an area adjacent to the health center’s service area (refer to Chapter 4: Services Provided via Telehealth).” This description of services by telehealth is inconsistent with Chapter 4, Section B(d), which contemplates that a health center may, for a limited period of time, provide in-scope services by telehealth to patients who no longer live in the service area or an adjacent area. **For clarity and consistency, NACHC requests that HRSA revise the text, as follows: “An individual receives an in-scope service either in-person or via telehealth, consistent with Chapter 4: Services Provided via Telehealth.”**

Chapter 9: Services Provided at a Location Other Than a Health Center Service Site

A: Health Center Services Provided to an Established Health Center Patient

Comment 1: NACHC supports that HRSA would no longer require health centers to list the various locations where they serve established patients, other than Form 5B sites. Specifically, Section A establishes that services provided to established patients at locations that are not HRSA-approved service sites are within scope, assuming the three criteria are satisfied. This is a deviation from the current HRSA scope policy, which requires that such “other activities” for serving established patients be listed on Form 5C and approved by HRSA. For example, health centers would no longer be required to specify if they conduct home visits and/or list the various hospitals where their providers round on established patients. Such activities would be in scope, assuming the individual served is an “established patient” and the three criteria are satisfied. **NACHC applauds this change, as it removes an unnecessary operational burden of documenting these activities in Form 5C.**

Comment 2: NACHC requests clarification regarding the examples in Section A. Section A lists the following as examples of non-service sites locations that serve established patients: “the health center provider conducts home visits for primary care or the provider rounds on hospitalized health center patients after labor and delivery.” Health centers sometimes provide services to established patients who transition to a senior community or assisted living facility, similar to home visits. **NACHC requests that HRSA confirm that rounding on established patients at other residency settings, such as senior communities and assisted living facilities, would also be in scope, assuming the three criteria are satisfied.**

B: Health Center Services Provided to Individuals Who Are Not Established Health Center Patient

Comment 1: NACHC supports that HRSA would no longer require health centers to list the various locations where they serve individuals who are not established patients, per the 5 categories. However, NACHC has recommendations to ensure consistency and preserve flexibility. Subsection (e) sets forth a list of 5 “categories” applicable to providing in-scope services to individuals who are not established patients: (i) portable care and outreach (which must be within the services area), (ii) hospital-related activities, (iii) coverage-related activities, (iv) emergency response activities, and (v) certain individual emergencies. With certain exceptions, as described in separate comments, these categories align with the FTCA regulations, per 42 CFR § 6.6(e)(4). If a service fits within one (or more) of the 5 categories, it is in scope. If it does not, the service is de facto out-of-scope.

The alignment with 42 CFR § 6.6(e)(4) is important because the Federally Supported Health Centers Assistance Act (FSHCAA) and 42 CFR §6.6(d) authorize FTCA coverage for services to non-health center patients in certain situations including specific examples described in 42 CFR §6.6(e)(4) as long as there is compliance with all other coverage requirements under FSHCAA. Despite these regulatory provisions, the Office of General Counsel will assess whether an activity is in the federal scope by reviewing a health center’s Form 5C. With the elimination of Form 5C, alignment with the FTCA regulations will be important to safeguard FTCA coverage during the scoping process.

NACHC supports the alignment with existing regulations, per 42 CFR § 6.6(e)(4). We also appreciate that it would no longer be required to list such activities in Form 5C and obtain HRSA approval. However, NACHC is concerned that the list is finite, and there is no stated approach to include additional “other activities.” This is a deviation from the current Form 5C: Other Activities, which includes an option of “[] Other – Please Specify.” It is also important to note that the FTCA regulations contemplate that there may be other care for non-health center patients that could be approved by the Secretary through the particularized determination process. Specifically, 42 CFR § 6.6(d) states the following:

“(d) Only acts and omissions related to services provided to individuals who are not patients of a covered entity will be covered only if the Secretary determines that:

- (1) The provision of the services to such individuals' benefits patients of the entity and general populations that could be served by the entity through community-wide intervention efforts within the communities served by such entity;
- (2) The provision of the services to such individuals facilitates the provision of services to patients of the entity; or
- (3) Such services are otherwise required to be provided to such individuals under an employment contract or similar arrangement between the entity and the covered individual.”

NACHC requests that the 5 categories be drafted to align with 42 CFR § 6.6(e)(4) and further requests that HRSA provide a method for health centers to request HRSA’s approval to include additional activities in recognition of the HRSA particularized determination process described above.

Comment 2: NACHC requests that HRSA remove the requirement that “portable care and outreach” and “certain individual emergencies” occur within the service area. Section B.c establishes that, for purposes of serving individuals who are not established health center patients via “portable care and outreach” and/or “certain individual emergencies,” the service must be provided within the health center’s service area. This distinction is inconsistent with 42 CFR § 6.6(e)(4) which provides no geographic limitations. Furthermore, as described in the draft Scope of Project Manual, these “portable care and outreach” efforts are often at locations that serve the most underserved and vulnerable individuals, including homeless shelters, outdoor encampments, and farm fields. This rigid geographic limitation would have the unintended consequence of restricting these critical outreach efforts. For example, if a health center were to provide outreach and care at a soup kitchen that is outside of the service area, the activity would be deemed out-of-scope which could also affect the health center’s ability to have FTCA coverage for such activity. Further, agricultural camps for migrant and seasonal workers are often located on the outskirts of a health center’s services area. If a health center were to provide portable care to these camps, that activity would also be deemed out-of-scope and would create FTCA coverage issues for the health center and its staff members. HRSA policy should promote, not hinder, these health center efforts to locate and serve the populations with the highest need, recognizing that these individuals often have significant barriers to accessing care through traditional means, such as scheduled visits. It is also important to note that “individual emergencies” may arise in the course of conducting these “portable care and outreach” efforts. **NACHC requests that HRSA strike sub-section (c), thereby removing that “portable care and outreach” and “certain individual emergencies” must occur within the service area in order for such activities to be in scope.**

Comment 3: NACHC requests that HRSA modify sub-section (e) to include school-based clinics and school-linked clinics. It is NACHC’s understanding that sub-section (i), portable care and outreach, is intended to cover the various “community-wide interventions” set forth in 42 CFR § 6.6(e)(4)(i), such as health fairs, immunization campaigns, migrant camp outreach, and homeless outreach. Notably, the draft Scope of Project Policy Manual’s description of “portable care and outreach” does not include “school-based clinics” or “school-linked clinics,” both of which are included as types of “community-wide interventions” in 42 CFR § 6.6(e)(4)(i), and are also incorporated into current HRSA policy, per PIN 2008-01. The absence of these categories is concerning and inconsistent with regulation and long-standing HRSA policy. **NACHC requests that sub-section (e) be modified to include school-based clinics and school-linked clinics, as such activities are described in 42 CFR § 6.6(e)(4)(i) and PIN 2008-01.**

Comment 4: NACHC applauds HRSA’s proposed policy that emergency response activities (and, therefore, limited service sites in response to emergency events) may occur on an ad-hoc basis. Sub-section (iv), which describes “emergency response activities,” cross references Chapter 7 of the draft Scope of Project Policy Manual, which describes “temporary service sites in response to emergency events.” Unlike Chapter 7, this sub-section contemplates that the health center may provide emergency response services at specific locations on an *ad-hoc basis* rather than on a regularly scheduled basis. **NACHC appreciates this flexibility; requiring that temporary emergency service sites operate in accordance with a regularly scheduled basis would have the unintended consequence of limiting their efficiency and effectiveness.**

Chapter 10: Changes in Scope of Project

Section A: Overview

Comment 1: NACHC appreciates HRSA’s commitment to compliance with the Health Center Program requirements. However, NACHC requests clarification that HRSA will follow the current Progressive Action Process set forth in the Health Center Program Compliance Manual to correct a health center’s scope of project, rather than taking unilateral action. Footnote 92 in Chapter 10 indicates that “HRSA may take administrative action to correct a health center’s Form 5A: Services Provided or Form 5B: Sites, with notice to the health center so that the health center’s scope of project is consistent with scope of project policy.” NACHC supports HRSA’s role in monitoring health centers’ compliance with the essential requirements that form the core of the Health Center Program. Further, NACHC acknowledges the importance of maintaining an accurate scope of project and welcomes HRSA’s support in maintaining overall compliance as well as an accurate scope of project. However, as drafted, it is unclear whether HRSA intends to (i) take such corrective action on a unilateral basis with only retrospective notification to the health center or (ii) communicate the alleged non-compliance to the health center and follow the Progressive Action Process set forth the Health Center Program Compliance Manual.

If HRSA acts unilaterally, such action could be substantially detrimental to a health center’s operation, ultimately resulting in potential harm to the patients served by the health center. We are seeking clarity that HRSA would provide advance written notice before removing from a health center’s scope a service or site that was previously approved by HRSA. Health centers deserve their due process, and we are concerned that unilateral action could result in an additional administrative burden and unanticipated costs to work through an appeals process. HRSA should keep in mind that in terms of modifications to Form 5B sites, it has been previously adjudicated that any decision to remove such site from a health center’s scope of project must meet requirements of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A). While HRSA can reverse course on an agency decision, it is required to provide a reasoned explanation for the change. If it does not provide a certain level of analysis associated with a change, the removal of a site would be arbitrary and/or capricious and would not be permitted to carry the force of law. Furthermore, HRSA will have to contend with the Supreme Court’s recent decision in *Loper Bright Enters. v. Raimondo* 603 U.S. —, 144 S.Ct. 2244 (U.S. June 28, 2024) and the end of Chevron deference towards the decisions it makes in administering the Health Center Program. **NACHC recommends that HRSA modify this section to indicate that if it determines that a health center’s scope requires modification or correction, HRSA will follow the process set forth in the “Progressive Action Overview” Section of Chapter 2 of the Health Center Program Compliance Manual, which provides for the placement of a condition that describes the nature of and reason for the condition, the action needed to remove the condition and the time allowed to take corrective action.**

Section B: Changes to Services and Sites:

Comment 1: NACHC requests confirmation from HRSA that the current Scope Adjustment process will be used for adding or deleting “other” non-service sites identified in Chapter 5, Section E, consistent with current policy. Section B indicates that a health center must request prior approval from HRSA to add or delete sites on its Form 5B. Further, the streamlined scope adjustment process can be used for minor changes to sites, such as “updating hours or months of

operation for a service site.” Current policy also allows the use of the scope adjustment process for adding or deleting administrative sites and other non-service sites, such as those addressed in Chapter 5, Section D of this draft Manual. It is important to maintain the ability to utilize this streamlined process (rather than a full change in scope) to add or delete these types of sites that are not classified as service sites. **NACHC requests that HRSA explicitly confirm that it will continue to utilize the current scope adjustment process or a similar streamlined process when approving the addition and deletion of such other non-service sites.**