NATIONAL ASSOCIATION OF Community Health Centers

October 5, 2007

Mr. James Macrae
Associate Administrator
Health Resources and Services Administration
Bureau of Primary Health Care
5600 Fishers Lane
Rockville, Maryland 20857

RE: Comments on the Draft Program Information Notice 2007- xx: *Specialty Services and Health Centers' Scope of Project*

Dear Mr. Macrae:

The National Association of Community Health Care Centers, Inc. (NACHC) is pleased to have the opportunity to provide comments on the proposed draft Program Information Notice (PIN) 2007 – xx: *Specialty Services and Health Centers' Scope of Project*. NACHC is the primary national membership organization representing all types of programs funded under Section 330 of the Public Health Service Act, as well as Federally Qualified Health Center (FQHC) Look-Alike entities.

One of the cornerstones of the health center program is the provision of a wide array of preventive and primary health care and enabling services to medically underserved communities and populations. Most health centers also offer additional health services that support required services, based on the health care needs of their respective patient population(s). Further, health centers:

- Effectively and successfully manage chronic illnesses, which often require access to services in addition to the required primary care services; and
- Play a critical role in removing common barriers to care, thus reducing or even eliminating health gaps and disparities for racial and ethnic minorities, as well as for poor and indigent populations.

To remain responsive to their patient populations, maintain successful health outcomes and continue to reduce health disparities, health centers must be able to ensure that their patients have appropriate access and availability to a full continuum of care, based on their particular needs and priorities. In many communities, health centers represent the only readily available and accessible source health care. Even in areas with additional resources, health center patients (in particular, the uninsured and underinsured) typically

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face challenges in accessing specialty care not provided by the health center, due to a variety of reasons, including a lack of funds to pay for such services or bias on the part of the other providers who do not want to treat such populations.

All too often, health centers are faced with a familiar conundrum. If the health center's patient population requires certain specialty services, which are unavailable elsewhere in the community, does it secure the additional capacity to provide those services internally? If it is unable to do so (or chooses not to do so), what becomes of continuity of care and total patient care? On the other hand, if the health center is able to secure the services of one or more specialists to serve its patients, and thus support and advance its patients' health and well-being, will other limitations prevent it from doing so?

These and other questions illustrate the critical importance of permitting health centers flexibility and discretion to develop rational and logical scopes of project that are beneficial for their particular patient populations and consistent with their overall mission. NACHC applauds HRSA's efforts to create a workable policy and process by which health centers can extend their scopes of project to include additional health care services necessary to ensure appropriate continuums of care for their patients. In particular, NACHC appreciates and supports the following actions:

- Excluding from the definition of "specialty services" (and, thus, from the change in scope policy outlined in this draft PIN) any procedures or services which are provided by primary care clinicians as part of their ordinary scope of practice.

- Recognizing that the "additional health services" necessary to support primary care which are in addressed in Section 330(b)(2) would be appropriate types of specialty services to include in a health center' scope of project.

NACHC believes that the process outlined in the draft PIN will aid health centers in determining whether and which specialty services are appropriate, thus reducing the lengthy, time-consuming, and, often frustrating process health centers currently face when adding specialty services to their approved scopes of project. Nevertheless, NACHC has a few concerns regarding certain requirements of the draft PIN and offers recommendations to resolve those concerns. Each of these concerns and recommendations is summarized below and discussed in greater detail thereafter.

Summary of Concerns and Recommendations

- **Defining Services as Logical Extensions of, and Supportive of, Primary Care Services**: NACHC suggests modifying Section VI.B of the draft PIN, which sets forth examples of services that "function as a logical extension of the required primary care services already provided … and/or that the proposed service complement[s] the required primary care services," to include:

    - The necessary treatment as indicated by the tests and exams already noted in the existing examples; and

- Some or all of the additional examples provided by NACHC in the discussion below, which illustrate a greater and more appropriate breadth of acceptable specialty services, based on appropriate clinical protocols and principles of continuum of care.

- **Clarifying Specialty Care-Related Terminology**: NACHC suggests modifying Sections IV.E and IV.F of the draft PIN to ensure that the definitions of "specialty care" and "specialist" are precise, complete and consistent with their clinical usage, similar to the examples provided by NACHC in the discussion below.

- **Ensuring Approval of Existing Arrangements**: NACHC requests modifying Section IX of the draft PIN to include an explicit assurance that specialty services currently furnished by a health center will be grandfathered into its scope of project (effective the initial approval date) regardless of policy changes, provided that the health center can demonstrate adequate justification for the service and that it was previously approved by HRSA. Under such circumstances, health centers should be exempted from submitting a formal Change in Scope Request; rather, HRSA should provide an acknowledgement that such services are properly included (or "grandfathered") in the health center's scope of project.

- **Clarifying Acceptable Service Locations**: NACHC suggests modifying Section VI.D of the draft PIN to explicitly permit the provision of specialty services at any service site that can be properly included in-scope (such as categorical sites) as well as at locations at which in-scope services are provided but that do not meet the definition of a site or where services are conducted on an irregular timeframe/schedule (other activities/locations), as defined in PIN "*Defining Scope of Project and Policy for Requesting Changes.*" HRSA should clarify that such sites/other locations be identified on scope forms consistent with instructions of the aforementioned policy.

- **Making Scope Determinations Binding for Purposes of Professional Coverage under the Federal Tort Claims Act (FTCA)**: NACHC suggests modifying Section VII of the draft PIN to clarify that for purposes of FTCA coverage, the HRSA-approved scope determination will be recognized and binding, and FTCA coverage could be available so long as the particular requirements specific to FTCA are satisfied. HRSA should clarify that, for circumstances under which the specialty arrangement does not meet appropriate requirements to qualify for FTCA coverage, health centers should ensure that the specialty provider who is retained as an independent contractor provides evidence of sufficient private malpractice insurance, at a level consistent with prevailing community standards, to cover the specialty services that are provided.

- **Distinguishing between Required Primary Care and Additional Health Services**

- NACHC suggests modifying Section IV.B of the draft PIN by deleting "additional health services" from the list of "required" services, and noting that health centers "may provide" such services as appropriate (consistent with statute).

- NACHC suggests modifying Section IV.E of the draft PIN by deleting the phrase "mental health/substance abuse treatment (including psychiatry services)" from the list of "required" primary care services for all but Section 330(h) grantees, and replacing it with "referrals to mental health/substance abuse treatment (including psychiatry services."

- **Revising the References to "Services" to include both Medical and Dental Services**: NACHC suggest revising the references to "primary services" or "services" throughout the draft PIN to explicitly include both medical and dental services.

- **Reconciling Inconsistencies between HRSA-Approved Specialty Services and Specialty Service Requirements under State/Commonwealth Law**: NACHC suggests modifying the draft PIN to recognize circumstances under which inconsistencies exist between HRSA-approved specialty services and unique State/Commonwealth specialty service requirements and either to: (1) recognize such services as in-scope for this limited purpose; or (2) work with the State/Commonwealth to exempt health centers from the requirement.

Defining Services as Logical Extensions of, and Supportive of, Primary Care Services

Section VI.B requires that the proposed specialty service support the provision of required primary care services provided by the health center by demonstrating that the proposed service "function[s] as a logical extension of the required primary care services already provided … and/or that the proposed service complement[s] the required primary care services." HRSA includes three common examples of specialty services that may be considered appropriate based on this criterion.

While these examples are helpful, NACHC believes that they are too limiting and insufficient to demonstrate the breadth of acceptable specialty services, based on appropriate clinical protocols and principles of continuum of care. For example, the first 2 bullets indicate that certain consultations, examinations, screenings and diagnoses may be appropriate, but fail to include the necessary treatment resulting from these tests and exams. This is a major omission. Specialists may be needed to complement and complete primary care provided to individual patients not only to test and arrive at a diagnosis but also to develop an ongoing treatment regimen. There is little value in informing a low-income, uninsured patient or a resident of an isolated rural community that they have a major, chronic inflammatory bowel disease or chronic lung disease, while neglecting to provide them with needed treatments. There should be a clinical feedback loop between

the specialist and the primary care physician, but the specialist may well need to continue to be involved, as needed, in the treatment of particular conditions.

Further, insofar as the examples listed are common among health centers, the draft PIN should include additional examples that are uncommon or less definitive from a "lay person" perspective, but fit within the criterion from a clinical perspective. For example, a group of health center clinicians – after careful review of the draft PIN - have suggested that, based on clinical standards, the following specialty services would be reasonably considered as logical extensions and supportive of required primary care services:

- As an extension of breast health screenings, a surgeon/breast surgeon or oncologist/surgical oncologist to accept referrals of patients that have positive mammograms and to provide appropriate ongoing care and treatment.
- As an extension of colorectal cancer screenings, a GI specialist (gastroenterologist) or a colo-rectal surgeon to perform colonoscopy screening and treatment as appropriate of positive findings.
- As an extension of pediatric dentistry, including a pediodontist (graduate of pediatric dental residency) for appropriate restorative treatment where the health center has a significant population of children with poor oral health.
- As an extension of managing complex infections, a consulting infectious disease specialist where a health center has a significant population of persons with complicated infectious diseases such as HIV/AIDS.

As an alternative (or in conjunction with) the aforementioned, HRSA may want to consider providing examples of specialty care services that support primary care grouped by the category of primary care services to which they are related. For example:

- Gynecological Care: specialty services could include gynecological oncology; reproductive endocrine infertility; and urogynecology.
- Obstetrical Care: specialty services could include genetic counseling and perinatal services including antenatal testing and diagnosis and co-managing high risk pregnancies.
- Pediatric Care: specialty services could include allergy; cardiology; endocrinology; gastroenterology; hematology; nephrology; neurology; pulmonary; ophthalmology; pediatric surgery.
- Dental Care: specialty services could include endodontics; oral surgery; orthodontics; pediodontics; periodontics; prosthodontics.

NACHC strongly recommends modifying the draft PIN to include: (1) the necessary treatment as indicated by the tests and exams already noted in the existing examples; and (2) some or all of the additional examples presented above (or similar examples).

Clarifying Specialty Care-Related Terminology

Sections IV.E and IV.F define the terms "specialty services" and "specialist." From a clinical perspective, these definitions are imprecise and incomplete. For example, the definitions as drafted indicate that a specialist is a clinician who provides health center services other than primary care services. However, in clinical terms, a specialist could provide both primary care and specialty care services, if he/she has the appropriate licensure and training.

To avoid potential confusion regarding terminology, NACHC believes that the final PIN should include revised definitions that ensure consistency with clinical usage. For example, a group of health center clinicians suggested the following definitions:

- "Specialty Services" – diagnostic and treatment services which are provided by an appropriately trained, certified and credentialed medical or dental specialty provider, as defined below, that are within … (continue with current definition).

- "Specialty Provider" – a duly licensed medical or dental provider with evidence of completion of additional post-graduate training (fellowship or otherwise) and applicable national certification or recognition by the medical or dental specialty or sub specialty and who has been granted appropriate specialty-specific privileges by the health center. [Note: might also include reference to "as recognized by the American Board of Specialty Medicine (for medical specialties) or by the American Dental Education Association (for dental specialties).]

- "Specialty Procedures" – diagnostic/screening procedures (*e.g.*, colonoscopy), as well as treatment procedures (*e.g.*, polypectomy); the former may be performed by duly trained and certified providers (for example, a primary care provider in internal medicine or family practice may perform a colonoscopy), while the treatment would be performed by a GI specialist (gastroenterologist) or by a general or colo-rectal surgeon.

  NACHC suggests modifying the draft PIN to ensure consistency between the stated definitions and their clinical usage, as indicated above.

Ensuring Approval of Existing Arrangements

Section IX recognizes that, once the new policy is effective, some health centers may determine that certain specialty services currently provided do not meet the newly enunciated criteria to be included in their scopes of project. The draft PIN affords health centers "an opportunity" to ensure that their scopes are consistent with the new policy and states that HRSA will work with health centers to resolve issues with discrepancies between existing scopes and the new policy.

However, it is unclear whether HRSA would require a health center to cease providing an existing specialty service if it determines that the service would not be considered in-scope based on the new policy. Typically, health centers provide specialty services to ensure that their patients receive services not otherwise available, thus facilitating an

appropriate continuum of care based on the special or unique needs of the patient population. Applying the final policy on a retrospective basis by requiring a health center to terminate such services could have devastating health effects on patients, potentially resulting in significant deterioration (and, ultimately inconsistent with positive outcomes associated with providing continuous care). Thus, if the service had previously been approved within scope, it should be grandfathered. The new policy should be prospective, affecting scope decisions from the effective date of the final PIN into the future.

> **NACHC requests modifying the draft PIN to include an explicit assurance that specialty services currently furnished by a health center will be grandfathered into its scope of project (effective the initial approval date) regardless of policy changes, provided that the health center can demonstrate adequate justification for the service and that it was previously approved by HRSA. Further, under such circumstances, health centers should be exempted from submitting a formal Change in Scope Request; rather, NACHC suggests that HRSA provide an acknowledgement that such services are properly included (or "grandfathered") in the health center's scope of project.**

Clarifying Acceptable Service Locations

Section VI.D requires that the proposed specialty service be provided at "an approved site" within the health center's existing scope of project or at a proposed new site that will be proximate in distance to the full scope of services offered by the health center. To a certain extent, "approved site" is defined consistent with the definition in the draft PIN "*Defining Scope of Project and Policy for Requesting Changes.*" However, the draft PIN appears to exclude or, at best, is silent regarding other types of service sites (*e.g.*, categorical sites, such as intermittent and migrant voucher sites) and/or locations at which in-scope services are provided but that do not meet the definition of a site or where services are conducted on an irregular timeframe/schedule (*e.g.*, other activities/locations), as permitted under Draft PIN "*Defining Scope of Project and Policy for Requesting Changes*."

> **NACHC suggests modifying the draft PIN to explicitly permit the provision of specialty services at any service site that can be properly included in-scope (such as categorical sites) as well as at locations at which in-scope services are provided but that do not meet the definition of a site or where services are conducted on an irregular timeframe/schedule (other activities/locations), as defined in PIN *"Defining Scope of Project and Policy for Requesting Changes."* Further, NACHC suggests that HRSA clarify that such sites/other locations be identified on scope forms consistent with instructions of the aforementioned policy.**

Making Scope Determinations Binding for Purposes of Professional Coverage under the Federal Tort Claims Act (FTCA)

Section VII claries that, while health centers must identify and describe specialty services added to their scopes of project in the funding applications subsequent to approval, doing so (in and of itself) is not sufficient for FTCA coverage. NACHC recognizes that additional requirements (*e.g.*, services are performed either by an employee or a contractor who qualifies for FTCA; services are included in the provider's scope of employment/contract; provider is not a volunteer) must be met for the service to be eligible for FTCA. However, it has come to NACHC's attention that in certain circumstances HRSA's scope determinations regarding certain services were challenged subsequent to HRSA's approval of health center scope changes, specifically the time at which the health center attempted to avail itself of its FTCA coverage. The consequences of such "second guessing" of scope of project approvals after a suit has been filed are potentially disastrous for a health center that has relied upon FTCA coverage for certain acts or omissions. Because the health center typically will not have commercial insurance coverage for those situations, it will be solely responsible for any judgments. One could imagine the consequences – at best, the health center may need to re-allocate certain financial assets for settlement and, at worst, it could experience significant financial hardship ultimately impacting its ability to maintain needed services. Likewise, health center clinicians affected could experience significant financial damage, making it more difficult to recruit and retain clinicians. "Second guessing" of approved scopes of project at the time of an FTCA claim should be prohibited. Additionally, authority for interpretation of whether a particular "malpractice event" giving rise to a FTCA claim is within scope or not should be retained at the Bureau of Primary Health Care which is the cognizant federal agency that approves scope of federal project, and therefore is the agency best suited to interpret the application of scope in event of a claim. That process should not be delegated to the Department of Justice whose role should be to defend claims against the government under FTCA.

> **NACHC suggests modifying the draft PIN to clarify that for purposes of FTCA coverage, the HRSA-approved scope determination will be recognized and binding, and FTCA coverage could be available so long as the particular requirements specific to FTCA are satisfied (*e.g.*, specialty services are performed by a specialist as part-time or full-time employee or by a contractor who works on behalf of the health center for an average of 32 ½ hours per week; services are specified in the specialist provider's scope of employment and/or contract). NACHC also suggests clarifying that, for circumstances under which the specialty arrangement does not meet appropriate requirements to qualify for FTCA coverage, health centers should ensure that the specialty provider who is retained as an independent contractor provides evidence of sufficient private malpractice insurance, at a level consistent with prevailing community standards, to cover the specialty services that are provided.**

Distinguishing between Required Primary Care and Additional Health Services

Section IV.B includes as services that health centers must provide "additional health services in support of required primary health services and as appropriate for the health

center population." However, Section 330(a) (1) explicitly distinguishes between required primary health services and additional services which may be provided "as may be appropriate for particular centers ...."

> **To make the PIN consistent with statutory language, NACHC recommends modifying the draft PIN by deleting "additional health services" from the list of required services, and noting that health centers may provide such services as appropriate (consistent with statute).**

Section IV.E defines required primary care services to include, among other things, "[H]ealth services related to … mental health/substance abuse treatment (including psychiatry services …." However, Section 330(b) (1) requires community health centers to provide referrals to providers of "other health-related services (including substance abuse and mental health services," not the services themselves. (According to statute, only health care for the homeless programs receiving grant funds under Section 330(h) are required to provide substance abuse services). Further, Section VI indicates that the additional services listed in Section 330 (and requiring prior approval as a specialty service) include, among other services, "[B]ehavioral and mental health and substance abuse services." Similar to the aforementioned issue, inconsistencies such as these could result in unintended requirements for health center programs. While NACHC is supportive of provision of mental health/substance abuse treatment, as needed, in health centers, we believe that the contradictions in the PIN further confusion in the field around whether such services are required for other than the Health Care for the Homeless Program, and are not consistent with the language of the statute.

> **NACHC recommends modifying the draft PIN by deleting the phrase "mental health/substance abuse treatment (including psychiatry services)" from the list of required primary care services for all but Section 330(h) grantees, and replacing it with "referrals to mental health/substance abuse treatment (including psychiatry services)."**

Revising the References to "Services" to include both Medical and Dental Services

The references to "primary services" or "services" throughout the draft PIN should explicitly include both medical and dental services. NACHC suggests the following specific revisions (added language is underlined):

- Section IV.B, second sentence: "… [S]ection 330-funded health centers must provide certain services, including primary medical and dental health care services …"
- Section IV.C, first sentence: "The term "provider" refers to individual health care professionals (including physicians, physician assistants, nurse practitioners, certified nurse midwives, dentists, and dental hygienists) …"
- Section IV.E, first sentence: " Health services related to … obstetrics and gynecology, ~~preventive~~ dental (preventive, restorative and emergency) …"

- Section VI, third paragraph, first sentence: "When reviewing a request to add medical or dental services …"
- Section VI.A, second paragraph, first sentence: "In addition, when proposing the addition of a specialty medical or dental service …"
- Section VI.B, second sentence: "Therefore, when requesting a change in scope to add a specialty medical or dental service …"
- Section VI.D, first sentence: "In order to ensure that the proposed new medical or dental specialty service …"
- Section VI.E(1), first sentence: "State Licensing: Medical or dental providers …"
- Section VI.E (2), first sentence: "All medical and dental providers …" Additionally, we suggest including a reference in this paragraph to national-level certification by applicable authorities relating to completion of applicable medical or dental specialty or sub-specialty fellowship training and certification.

Reconciling Inconsistencies between HRSA-Approved Specialty Services and Specialty Service Requirements under State/Commonwealth Law

While not a universal issue, the health centers located in Puerto Rico have indicated a concern regarding a unique requirement of the Commonwealth of Puerto Rico, under which the health centers are required to operate 24/7 emergency services either to obtain operational licenses and/or to comply with contractual requirements if located in buildings previously owned by the Department of Health. However, it has been difficult for the centers to obtain approval to include 24/7 emergency services in their scopes of project, leaving the health centers at financial risk for such services and exposed to other liabilities associated with providing out-of-scope services.

> **NACHC suggests modifying the draft PIN to recognize circumstances under which inconsistencies exist between HRSA-approved specialty services and unique State/Commonwealth specialty service requirements and either to: (1) recognize such services as in-scope for this limited purpose; or (2) work with the State/Commonwealth to exempt health centers from the requirement.**

Thank you for your consideration and favorable action on these comments. Please do not hesitate to contact me at (301) 347-0400 or at FMitchem@NACHC.com if you have any questions or would like further clarifications.

Sincerely,

Freda Mitchem

Freda Mitchem
Associate Vice President
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