



NATIONAL ASSOCIATION OF
Community Health Centers

August 9, 2010

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

**RE: NACHC Comments on Policy Information Notice 2010-XX – DRAFT
Federal Tort Claims Act (FTCA) Policy Manual**

Dear Mr. Macrae,

The National Association of Community Health Centers (NACHC) is pleased to have the opportunity to comment on the Policy Information Notice (PIN) 2010-XX: DRAFT Federal Tort Claims Act (FTCA) Policy Manual (hereinafter, referred to as the Draft Manual). NACHC appreciates HRSA's efforts to provide health center grantees and related stakeholders with guidance regarding current FTCA policies and processes by consolidating existing PINs and Program Assistance Letters (PALs) under one "user friendly" manual which will serve as the "primary source for information on FTCA." Notwithstanding, we request certain clarifications of, and modifications to, the Draft Manual, as discussed in detail below.

General Comments

Throughout the Draft Manual, citations to the FTCA statute reference the original and amended Public Laws (the Federally Supported Health Centers Assistance Acts of 1992 and 1995). However, these Public Laws have been codified in the United States Code under 42 U.S.C § 233, which citations are more familiar to health centers. ***Accordingly, NACHC requests that HRSA change all FSHCAA (or Public Law) citations in the Draft Manual to reflect the appropriate section of the U.S. Code.***

Further, throughout the Draft Manual, reference is made to the requirement that activities/services performed by covered individuals must be within such individual's scope of employment to be covered by FTCA. ***Given that many health centers contract for personnel to supplement their employed staffs, and that certain contractors are eligible for FTCA coverage, NACHC requests that HRSA modify these references to include the phrase "within the applicable contract for services" wherever scope of employment is mentioned.***

Finally, when Congress amended the FTCA statute in 1995, statements in the accompanying Congressional record indicated both a clear intent that FTCA coverage provide health centers with relief from the financial burden of purchasing private malpractice insurance, and a presumption that FTCA coverage would be fully comprehensive in its scope, covering all activities included within the health center's scope of project. As a result, Congress anticipated that participating health centers would be able to drop their private malpractice coverage and depend exclusively on FTCA for their professional liability insurance needs.¹

In 2004, when faced with the HHS practice of not providing coverage determinations for health centers' qualified individuals in advance of the filing of a lawsuit, the U.S. District Court for the District of Columbia stated that "[T]his policy is clearly contrary to the statute, which indicates that HHS "shall" make a determination within 30 days of receipt of an application from anyone ... this policy ... completely undermines the purpose of the Act, since the contractor/physicians cannot know if they are covered until after they are sued, and thus, proceed at their own risk if they forego obtaining their own malpractice insurance."²

Nevertheless, since enactment in 1995, various policies have narrowed what was intended as comprehensive malpractice coverage to replace private insurance, ultimately resulting in numerous circumstances under which health centers either knowingly (or unknowingly) lack coverage for certain activities performed in the normal course of business or are unclear as to whether coverage exists. These coverage limitations are forcing health centers either to go without coverage or to purchase costly private "gap" insurance, utilizing scarce resources which could be better spent on providing health care to the growing numbers of uninsured and underinsured populations.

Given both the original Congressional intent and the statement of the District Court, NACHC urges HRSA to explicitly recognize: (1) a presumption of coverage for all providers and activities included within the approved scope of project of a deemed health center; and (2) extension of FTCA to health centers and their qualified individuals to the same extent that private malpractice insurance affords coverage to private physicians and providers.

Comments on Specific Sections of the Draft Manual

SUMMARY

The Summary of the Draft Manual indicates that when claims arise, the Department of Justice (DOJ) and the federal courts assume roles in certifying whether the services/activities in question

¹ "[P]urchase of malpractice insurance is one of the most significant expenses for health centers ... [G]rant funds continue to be used to pay a large percentage of these premium costs – funds that otherwise could be used for patient care ... [T]he Committee expects that the enactment of this legislation ... along with continued efforts by [HHS] to implement the legislation, will lead many more health centers to *drop their private malpractice coverage and participate fully in the program.*" House Report No. 104-398, December 12, 1995 (accompanying H.R. 1747) at pp. 5-6 (emphasis added); Congress also anticipated that the legislation would clarify areas of "uncertainty over the scope of FTCA coverage" by codifying earlier regulations stating, among other things, that "malpractice coverage will be provided under FTCA for acts and omissions *related to the grant-supported activity of the health center.*..." House Report No. 104-398 at p. 7 (emphasis added)

² See *El Rio Santa Cruz Neighbor. V. Department of HHS* (300 F.Supp.2d 32 (D.D.C. 2004)), footnote #4 (emphasis added)

fall within an individual's scope of employment/contract for purposes of determining the extent of FTCA coverage, consistent with the statutory authority afforded the Attorney General.³ The statute also specifies, however, that if an action is filed in State court, the Attorney General will advise the court within fifteen (15) days of being notified of such filing of the outcome of the scope of employment/contract determination, and that this advice will be considered the required certification. Notwithstanding, in practice, often this certification has taken longer.

Further, on occasion, DOJ has gone beyond its statutory authority to retroactively evaluate whether the underlying service or activity was included within the health center's scope of project (or, if included, whether HRSA was correct in its scope decision). FTCA legislation provides that once HHS determines that a health center, its employees, and its qualified contractors are covered under FTCA "the determination shall be final and binding on the Secretary and the Attorney General" and they "may not determine that the provision of services which are the subject of such a determination are not covered under this section."⁴ This provision reflects clear Congressional intent to ensure that once HHS determines that a particular service or activity is within a health center's scope of project, the health center will be able to rely on that determination. If DOJ is allowed to continue to "second-guess" such determinations, however, health centers will not be able to rely upon FTCA coverage, inconsistent with Congressional intent and potentially resulting in the need to procure unnecessary and costly "gap" insurance.

While we appreciate that HRSA cannot control the actions of other agencies, NACHC requests that HRSA amend the Summary by including a statement encouraging DOJ to make scope of employment/contract determination within a timely manner, not to exceed the statutory limitation of fifteen (15) days, and consistent with the requirements of the final Manual. Further, NACHC urges HRSA to state explicitly that such determinations: (1) should relate solely to a covered individual's scope of employment/contract; and (2) should not retroactively impact HRSA's prior determinations that the underlying activities or services are within the health center's approved scope of project. Given that HRSA intends for the final Manual to be the "primary policy source" of information on FTCA for "related stakeholders" (which we presume includes other federal agencies), NACHC believes that adding such statements is not only reasonable, but also necessary to inform these stakeholders of HRSA's positions with respect to these determinations.

INTRODUCTION

The Introduction to the Draft Manual (pages 4-5) includes an explanation as to the intent behind extending FTCA coverage to health centers and their covered individuals. In particular, the Introduction includes four (4) activities for which additional funding is available due to the savings resulting from reducing the costs of malpractice insurance. As drafted, the activities mentioned appear to limit the potential uses for such savings. ***NACHC requests that HRSA clarify that this section of the Introduction is not intended to reflect an exhaustive list of potential uses of the funds saved by utilizing FTCA coverage rather than purchasing private malpractice insurance, either by explicitly stating as much or by adding another bullet to include "other appropriate Section 330-funded activities."***

³ See 42 U.S.C. § 233(c)

⁴ See 42 U.S.C. § 233(g)(1)(F)

SECTION 1: ELIGIBILITY AND COVERAGE

A. Covered Entities

A.1 – Eligibility for Deeming

The first paragraph of Subsection A.1 of the Draft Manual (page 6) identifies the Section 330 grantees that are eligible to be deemed for FTCA coverage. Each example anticipates that the health center will be comprised of a single corporate entity. Under the public health center model, however, there are two “entities” that jointly apply for the Section 330 grant – the public entity that receives the grant and the “co-applicant” governing Board of Directors that meets the community-based composition requirements and governs the public health center in accordance with established HRSA policy. Historically, both the co-applicant Board and the public entity were identified as “the grantee” on the HRSA Notice of Grant Award (NGA). In recent years, HRSA has identified only the public entity as the grantee; thus, as a technical matter, the basis for conveying FTCA eligibility to the co-applicant Board has inadvertently become attenuated and unclear. ***NACHC requests that HRSA add a sentence at the end of this Subsection clarifying that a co-applicant governing Board that jointly operates a public health center with a public entity, that meets the community-based composition requirements and that exercises the required authorities applicable to all health center boards (with certain statutory exceptions for co-applicant board) are considered entities eligible to be deemed for FTCA coverage along with the public entity grantee of record.***

A.2 – Application for Deeming

The first sentence of Subsection A.2 of the Draft Manual (page 6) refers to the FTCA deeming process “[A]s required by sections 233(g)(1)(D) and 233(h) of the PHS Act ...” These citations are incorrect – FTCA coverage requirements applicable to commissioned officers or employees of the Public Health Service, including deemed health centers and their covered individuals, are found in section 224 of the PHS Act, which is codified at 42 U.S.C. § 233. ***NACHC requests that HRSA modify this sentence to reflect the correct citations, as well as modify other references throughout the Draft Manual in which the incorrect citations are utilized.***

A.3 – Special Circumstances: Indemnification of Other Entities

Subsection A.3 of the Draft Manual (page 7) addresses the fact that FTCA coverage does not extend to costs associated with a health center’s indemnification of other entities. While the overall policy is consistent with current policy, the manner by which this section is drafted is confusing. Specifically:

- The first sentence indicates that “[M]any managed care organizations and State and local governments ...” insist on including indemnification clauses in contracts with health centers. Managed care organizations and state and local governments, however, are only two examples of other organizations with which health centers contract. ***To ensure that health centers understand that FTCA coverage is not available to cover the costs of indemnification of any other entities contracting with the health center, NACHC***

requests that HRSA modify this sentence to state that “[M]any organizations and entities with which health centers contract ...”

- The second sentence refers to the organizations mentioned in the first sentence, indicating that FTCA does not extend to indemnification of “those other non-deemed entities.” (Emphasis added). Our understanding is that FTCA coverage is not available for indemnification of any other entities, regardless of whether such entity is deemed in its own right (*i.e.*, contracts with other health centers). ***For clarification, NACHC requests that HRSA modify this phrase to reflect that FTCA does not cover indemnification of “those other entities or organizations.”***
- The last sentence indicates that health centers should have indemnification clauses removed from their contracts. Removal of such clauses is a matter of negotiation between the health center and the other entity and in some instances, may not be possible. ***Accordingly, NACHC requests that HRSA add the following alternative to the end of this sentence: “ ... or obtain appropriate private insurance coverage to cover indemnification costs.”***

B. Covered Individuals

As drafted, NACHC believes that the first sentence of the introductory paragraph of Section B (page 7) is vague and thus, requires clarification. In particular, the first sentence states that FTCA coverage is “subject to the requirements of the PHS Act (including subsection 224(i)).” It is unclear as to which requirements this proviso refers. ***NACHC requests that HRSA modify this sentence to include citations to the specific PHS requirements to which FTCA coverage is subject.***

B.1 – Governing Board Members and Officers

Subsection B.1 of the Draft Manual (page 7) states that governing board members and officers are covered “only for medical malpractice.” This sentence could be misleading insofar as all covered individuals are covered solely for medical malpractice. ***NACHC requests that HRSA modify this statement by adding: (1) to the beginning of the sentence: “Similar to all covered individuals ...”; and (2) a second sentence stating that “As such, FTCA should not be considered a substitute or replacement for Directors’ and Officers’ insurance.”***

B.2 – Employees

Subsection B.2 of the Draft Manual (page 7) indicates that HRSA utilizes “the Internal Revenue Service (IRS) definition to establish who is an employee.” It is unclear as to whether this references the current definition in the Internal Revenue Code (IRC) only or to the definition as they may be amended in the future. ***NACHC requests that HRSA amend this sentence by: (1) including citations to the specific IRC provisions to which it refers; and (2) adding “as they may be amended from time to time.”***

B.3 – Contractors

Subsection B.3 of the Draft Manual (pages 8) indicates that HRSA utilizes “IRS definitions to differentiate contractors and employees.” It is unclear as to whether this references the current definitions in the Internal Revenue Code (IRC) only or to the definitions as they may be amended in the future. ***NACHC requests that HRSA amend this sentence by: (1) including citations to the specific IRC provisions to which it refers; and (2) adding “as they may be amended from time to time.”***

Subsection B.3 also states that compensation under the contract should be paid “by the covered entity directly to the individual contract provider in most cases.” (Emphasis added). Given that current policy prohibits FTCA coverage for services provided pursuant to a contract between a health center and another entity that employs the contracted personnel, it is unclear as to when exceptions to direct compensation would occur. ***NACHC requests that HRSA clarify this sentence by including the specific exceptions to which it refers by the phrase “in most cases.”***

Finally, NACHC recognizes that the prohibition against FTCA coverage for services provided pursuant to a contract between a health center and another entity reflects current policy based on a literal interpretation of the statute which provides coverage for “any contractor of [the deemed entity] who is a physician or licensed or certified health care practitioner” (subject to certain limitations).⁵ However, many sole practitioners and provider partnerships incorporate to protect themselves from personal liability. Insofar as the incorporation is purely a case of form over substance, contracting with these “entities” essentially is the same as contracting with the individual providers. ***Accordingly, NACHC urges HRSA to reconsider its existing policy with respect to contracting with eponymous corporations owned and staffed entirely by sole practitioners or corporations established by providers in lieu of developing partnerships, and allow such arrangements to be eligible for FTCA coverage.***

C. Covered Activities

In addressing covered activities, Section C of the Draft Manual (pages 9-16) appears to indicate that there is coverage only for those acts or omissions for which both the health center and the provider who furnishes the services in question are covered by FTCA. For example, the first sentence of the introductory materials to Subsection C states that “FTCA coverage is restricted to acts or omissions of a covered entity that are within the scope of employment of a covered individual.” Similarly, the last sentence states that coverage is dependent in part on the individual meeting all FTCA requirements such as “providing services within the scope of deemed employment.”

As drafted, these statements (and others throughout Section C) imply that the health center entity will not have FTCA coverage for acts or omissions by a non-covered individual or by a covered individual who did not act within his/her scope of employment (or contract), regardless of whether the underlying activities/services are included within the health center’s approved scope of project. Such implication is inconsistent with the FTCA regulations which require that services be within an individual’s scope of employment solely to convey coverage for that

⁵ See 42 U.S.C. § 233(g)(1)(A)

individual.⁶ Further, Subsection C appears inconsistent with the statement in Subsection B.5 that “[I]n the case of non-covered individuals ... the covered entity remains covered, while the individual is not.”

NACHC requests that HRSA modify Subsection C by adding a statement similar to the one in Subsection B.5. This statement should explicitly recognize that: (1) FTCA coverage for the deemed health center is not dependent on whether the individual providing services is covered and/or acting within his/her scope of employment (or contract); and (2) lack of individual coverage, by itself, will not impact, affect or negate the health center’s coverage as the covered entity.

C.2 – Scope of Employment

Subsection C.2 of the Draft Manual (page 10) indicates that when claims arise, DOJ and the federal courts assume roles in certifying whether the services/activities in question fall within an individual’s scope of employment/contract for purposes of determining the extent of FTCA coverage. ***For the reasons discussed under the Summary section of this comment, and consistent with our suggestions thereunder, NACHC urges HRSA to include statements in Subsection C.1 that: (1) encourage DOJ to make scope of employment determinations within a timely manner, not to exceed the statutory limitation of fifteen (15) days, and consistent with the requirements of the final Manual; and (2) assure that such determinations will relate solely to a covered individual’s scope of employment/contract and will not retroactively impact HRSA’s prior determinations that the underlying activities or services are within the health center’s approved scope of project.***

Further, in addressing documentation to assist in determining whether an individual acted within his/her scope of employment (or contract), Subsection C.2 of the Draft Manual states that “[D]ocumentation of services and sites/locations in the job description, including cross-coverage agreements, should be of sufficient detail to provide clarity” Cross-coverage agreements, however, are only one example of services provided to non-health center patients that may be covered by FTCA. ***To ensure that this example does not result in restricting health centers, NACHC requests that HRSA modify this sentence by either striking the example or qualifying that documentation should include, but is not limited to, cross-coverage agreements. Further, NACHC requests that HRSA provide additional examples of documentation that would be considered “of sufficient detail”***

C.3 – Provision of Services to Health Center Patients

Subsection C.3 of the Draft Manual (pages 10-11) provides various considerations for determining when the patient-provider relationship is established for purposes of determining whether services were provided to health center patients (one of the FTCA general coverage requirements). While NACHC generally agrees with the considerations listed in this Subsection, some clarification and/or modification is required. In particular:

⁶ See 42 C.F.R. § 6.6(c)

- The third consideration states that the triage could be performed in-person, but does not clarify whether the in-person triage must be provided at the health center site or at another location, such as a health fair.
- None of the considerations contemplate individuals who access care at facilities that are not approved “health center sites,” but rather approved as part of the health center’s scope of project as an “other activity/location” (*i.e.*, contracted sites at which the contractor provides services to health center patients on behalf of the health center on an as needed, rather than regularly scheduled, basis).

NACHC requests that HRSA modify Subsection C.3: (1) clarifying that in-person triage services can occur either on-site or off-site as part of an activity included within the health center’s approved scope of project (e.g., health fairs); and (2) recognizing that the patient-provider relationship can be established when an individual accesses care at an approved “other activity/location.”

C.4 – Covered Services to Non-Health Center Patients

Generally, Subsection C.4 of the Draft Manual (page 11) is consistent with existing policy, with one exception – the school-linked clinic example is limited to services provided “at a site not located on school grounds.” FTCA regulations, upon which this example is based, however, provide coverage for services furnished at a “school-based or school-linked” health center.⁷ Traditionally, school-based health centers are located either in a school or on school grounds, while school-linked health centers are adjacent to or near the school grounds. ***NACHC requests that HRSA correct the “school-linked clinic” example by modifying the language to indicate that services provided “at a site located in a school, or on, adjacent to or near school grounds.”***

Subsection C.4 (pages 12-13) also addresses the requirements and criteria used by HRSA to approve requests for particularized determinations of FTCA coverage for services provided to non-health center patients that do not fit squarely within the examples provided. In addition to the regulatory criteria, Subsection C.4 includes a requirement to provide sufficient detail in connection with an additional five (5) questions, one of which is “[H]ow these services benefit the patients of the covered entity?” Given that the purpose of the determination is approval of FTCA coverage for services provided to non-health center patients, the relevance of this question is unclear. Further, while Subsection C.4 includes instructions regarding what information should be included in a particularized determination request, it does not identify to whom a determination request should be submitted, or any details regarding the HRSA review process to ensure a timely response. Based on experience, HRSA has taken at least 6 months, and sometimes over to a year, to approve the requests. ***NACHC requests that HRSA modify the particularized determination process set forth in Subsection C.4 by: (1) either eliminating the question requesting information on the benefit to the health center’s patients or by broadening it to include information on the benefit provided to the community at large, in addition to or in lieu of the benefit to the existing patients; and (2) including additional detail regarding the review process itself (e.g., who reviews the requests and average timelines).***

⁷ See 42 C.F.R. § 6.6 (e)(1)

In addition, the FTCA statute indicates that FTCA coverage will apply to services provided to non-health center patients “if the Secretary, determines, after reviewing an application submitted under subparagraph (D), that the provision of the services to such individuals” (emphasis added) satisfies one of three criteria.⁸ The application to which the statute refers is the deeming application. Thus, based on the statutory language, service arrangements for non-health center patients that do not fit within certain pre-approved regulatory examples should be covered under FTCA if approved as part of the initial deeming or annual re-deeming application. Nevertheless, HRSA has interpreted the statutory language to require a separate “particularized determination” application in order to extend FTCA coverage to those arrangements. ***NACHC urges HRSA to reconsider its position and modify its current policy, which requires health centers to submit particularized determination applications to obtain approval for service arrangements provided to non-health center patients that do not fit squarely within a regulatory example, so that it is consistent with the plain language of the statute, thus allowing health centers to obtain such approvals through the deeming process.***

Finally, NACHC recognizes that the pre-approved examples provided in Subsection C.4 of covered activities/services provided to non-health center patients are based on the examples set forth in both the FTCA regulations⁹ and the Federal Register Notice from September 1995. These arrangements, however, were provided merely as examples of the types of activities/services that could be covered. The determination criteria, which are set forth in 42 C.F.R. § 6.6(d), thus preceding the examples, afford HRSA broad regulatory discretion in approving arrangements – discretion that HRSA has been reluctant to employ. Rather, HRSA has primarily limited itself to those arrangements which comply with all requirements of one of the examples.

Since the development of the regulatory examples, the health care industry has evolved and several of the specific requirements are no longer consistent with current practice. For example, FTCA coverage for hospital or emergency room call coverage is predicated on a requirement that participation in such on-call activities is a condition of obtaining hospital admitting privileges. However, recent trends indicate that many hospitals no longer require participation in on-call as a condition of admitting privileges. Similarly, cross-coverage arrangements are no longer limited to “after-hours” as required by the regulatory example. Finally, HRSA has been reluctant to extend FTCA coverage for “reciprocal assistance” provided by health center clinicians who are already on-site in a hospital for the purpose of providing in-scope care to health center patients (which is covered by FTCA), and who are asked to treat or assist in treating a non-center patient in that hospital – a standard practice customarily followed by all or most clinicians who practice in the hospital.

Despite these changes in current practice, an arrangement which does not fit squarely within a pre-approved regulatory example must be individually approved through the particularized determination process (or, if HRSA accepts our previous comment, through the deeming or re-deeming application). By continuing to rely on outdated preapproved examples that do not reflect conditions required in practice, HRSA forces many health centers to proceed with an additional approval process that is both unnecessary and at times administratively burdensome. ***NACHC urges HRSA to modify the examples set forth in Subsection C.4 by removing the***

⁸ See 42 U.S.C. § 233(g)(1)(C)

⁹ See 42 C.F.R. § 6.6(e)

specific conditions no longer required by or consistent with current practice and broadening them include arrangements that are similar (but not necessarily equivalent) to the arrangements described in the outdated regulatory examples.

C.5 – Additional Activities

Subsection C.5 (page 13) provides examples of additional off-site activities provided by the health center that may be covered by FTCA. However, some of the examples provided are not limited to off-site activities; rather, they can be conducted on-site as well (*i.e.*, clinical research, activities under other grant funding). ***NACHC requests that HRSA modify the introduction to Subsection C.5 to recognize that the activities can be provided on-site or off-site, as well as to clarify upfront that these examples are illustrative only and not intended as an exhaustive list of additional activities that may be covered by FTCA.***

Subsection C.5.4 (page 15) – activities under other grant funding – extends FTCA coverage to services supported by funds through other HRSA grant funding if the services are within the health center’s approved scope of project. Insofar as health centers receive grant funds from various federal, state, local and private sources to support their section 330-related programs, limiting coverage to services supported by other HRSA funding is unnecessarily restrictive and inconsistent with health center operations. ***NACHC requests that HRSA modify the example in Subsection C.5.4 to include activities supported by any non-section 330 funds used to support, and pledged to, the section 330-related project.***

Subsection C.5.5 (page 15) extends FTCA coverage to certain clinical research activities provided that “participation in the study is incident to the medical treatment of the covered entity patients.” The meaning of the phrase “incident to” in this context is unclear – does it refer to the formal Medicare definition of “incident to,” or does it mean that the study must be related to the medical treatment of a patient? ***NACHC requests that HRSA modify the example in Subsection C.5.5 to clarify the meaning of “incident to.”***

D. Third Party Acceptance of Coverage and Verification of Coverage

At this time, NACHC does not have any comments regarding Section D of the Draft Manual.

E. Coverage under Alternate Billing Arrangements

Section E of the Draft Manual (pages 16-17), which addresses circumstances under which covered individuals are required to bill directly for the services they provided on behalf of the health center, is consistent with current policy in all but one aspect. Current policy (PIN 2001-11) addresses situations under which the covered individual “bills for a service delivered at or away from the health center site (emphasis added). On the other hand, the Draft Manual requires that such services be “delivered at a location not identified as a covered entity site within its approved scope of project,” thus not allowing coverage for otherwise acceptable alternate billing arrangements for services provided on-site (which are allowed under current policy). ***NACHC requests that HRSA modify Section E to allow alternate billing arrangements for services provided either on or off-site, consistent with the current policy set forth in PIN 2001-11.***

F. FTCA Coverage When Responding to Emergency Events

Subsection F of the Draft Manual (pages 17-23), which addresses FTCA coverage in emergency situations under which the health center provides services in temporary locations, is primarily consistent with current policy set forth in PIN 2007-16. However, a significant difference appears to exist regarding the process by which the temporary locations will be considered part of the health center's scope of project. PIN 2007-16 states that a temporary location either within or outside of the health center's service area will be considered part of its scope of project if the health center meets certain criteria, contacts its project officer, and either: (1) provides certain information by fax or by e-mail regarding the health center and the activities to be furnished (for temporary sites within the service area); or (2) submits a written request to add the site, with the goal of the processing the request within 48 hours (for temporary sites outside the service area). Subsection F, however, appears to link approval of temporary sites to the process described in PIN 2008-01 – the lengthy, formal change in scope process typically used to process requests for permanent changes to a health center's approved scope. ***NACHC requests that HRSA modify Subsection F to ensure consistency with the scope process outlined in PIN 2007-16, which is more appropriate for emergency situations.***

NACHC understands that the purpose of this manual is to compile existing policy rather than establish new policy. Notwithstanding, portions of the existing policy are unnecessarily restrictive and are simply not realistic in the face of widespread and long-lasting emergencies, disasters, or other crises. For example:

- Current policy precludes non-impacted health centers and their covered individuals from availing themselves of FTCA coverage if they assist in emergencies that occur outside of their service areas and neighboring or adjacent areas. However, non-impacted health centers may be the only clinics in a position to furnish services given that their capacity has not been affected by the emergency.
- Current policy requires health centers operating temporary sites beyond 90 days to request a formal change in scope to convert the site to a permanent in-scope facility. Given that the formal change in scope process requires at least 60 days, and it is highly unlikely that health centers operating temporary sites will know within their first 30 days whether they will need to remain open beyond the initial 90 days, a question arises as to whether the health center will lose coverage in the interim between the end of the 90 day period and the approval of the formal change in scope request. Further, forcing a health center to make a temporary site permanent simply because an emergency or disaster exists for more than 90 days is unnecessary and administratively burdensome.

NACHC urges HRSA to re-consider its existing policy which precludes FTCA coverage for non-impacted health centers and their covered individuals if they assist in emergencies that occur outside of their service areas and neighboring or adjacent areas, provided that there is a written agreement in place between the health center and a sponsoring organization (such as another health center, a public health agency, etc.) under which the health center's covered individuals furnish services under the auspices of the health center that employs them (not as volunteers to the affected organization). NACHC also urges HRSA to re-consider the policy requiring health centers that must continue to operate their temporary sites beyond the initial 90 days to request a change in scope, which would convert the temporary site to a permanent

in-scope facility; rather, HRSA should allow health centers in that position to request an extension of the temporary change in scope for the duration of the emergency.

G. The Deeming Application Process

G.1 – Impact of Mergers and Acquisitions on Deeming

Subsection G.1 of the Draft Manual (page 24) indicates that a new corporation resulting from the merger of two or more health centers must apply for FTCA coverage separately and will not have coverage until a deeming application is approved. Typically, however, when two health centers merge, they do not form a new corporation – rather, one of the health centers becomes the surviving corporation with all of its rights, responsibilities, assets and liabilities remaining intact. The surviving health center maintains its corporate identity while absorbing the sites and services of the other health center (which dissolves).

It is unclear from the language of Subsection G.1 whether the surviving health center, if already deemed, would be required to submit a new FTCA deeming application or whether the approved change in scope request to add the sites and services of the dissolved health center and effectuate the merger would be sufficient to convey coverage to the entire organization, including the new sites and services. ***Given that the surviving health center is the same organization that it was prior to the merger with the addition of the sites and services of the dissolving health center, NACHC requests that HRSA modify Subsection G.1 to clarify that under a health center-to-health center merger: (1) the surviving health center will not lose its existing FTCA coverage and thus, will not be required to submit a new deeming application; and (2) similar to a health center adding a new site/service through the regular change in scope request, the dissolving health center’s sites/services will be covered under the surviving health center’s existing FTCA coverage upon HRSA approval of the change in scope necessary to add the sites/services and effectuate the merger.***

H. Insurance Considerations

H.3 – Gap Coverage

Subsection H.3 of the Draft Manual (page 25) indicates that health centers should “consider gap or wrap-around coverage to provide private insurance for activities not subject to FTCA coverage.” When contracting for services in a manner which would preclude FTCA coverage for the contractor (*i.e.*, contracting with an organization or with an individual who does not meet the requirements for coverage), rather than purchasing gap insurance, many health centers require the contractor to maintain their own insurance. ***NACHC requests that HRSA recognize this common alternative to gap insurance by adding a proviso at the end of the last sentence stating the following: “or to require the non-covered individual to secure and maintain, or cause to be secured and maintained, insurance to cover activities not covered by FTCA.”***

SECTION II: CLAIMS AND LAWSUITS

Similar to Section C, Section II of the Draft Manual appears to address only those incidents under which both the health center and the provider who furnished the services in question are covered by FTCA. For example, Subsection K, which addresses required documentation for

claims processing, requires submission of documentation verifying that the individual who furnished the services acted within his/her scope of employment. Subsection K further indicates that the verification process will be used to confirm that “the covered entity and the covered individuals” provided services within the health centers scope of project and the individual’s scope of employment, and requires submission of certain forms of documentation that apply solely to the covered providers.

By focusing on claims under which both the health center and the provider are covered by FTCA, Section II appears to imply that there is coverage only under those circumstances. Nevertheless, as stated in Subsection B.5 of the Draft Manual, there are circumstances under which the health center will be covered by FTCA even when non-covered individuals furnish the services. *Accordingly, NACHC requests that HRSA modify this Section by adding a sentence upfront recognizing coverage for the deemed health center regardless of whether the individual providing services is covered and/or acting within his/her scope of employment (or contract). NACHC further requests that HRSA add appropriate qualifications/clarifications throughout Section II (in particular, in Section K) acknowledging that: (1) certain requirements apply only when the individual providing services is covered by FTCA; and (2) lack of individual coverage, by itself, will not impact, affect or negate the health center’s coverage as the covered entity.*

I. Operation of FTCA for Health Centers

Section I of the Draft Manual (pages 25-26) indicates that “FTCA coverage is comparable to an occurrence type of malpractice policy . . . and does not have a specific coverage limit with a monetary cap.” However, there can be damage caps in FTCA cases because courts apply the substantive law of the state where the malpractice allegedly occurred. (*See* 28 U.S.C. § 1346(b), governing personal injury cases in which the United States is a defendant; *FDIC v. Meyer*, 510 U.S. 471, 478 (1994) (“§ 1346(b)’s reference to the “law of the place” means law of the State – the source of substantive liability under the FTCA”). Therefore, if the FTCA action is brought in a state which has a statutory cap on damages in medical malpractice cases, then there could be a cap on damages. In fact, federal courts have roundly rejected the argument that the imposition of caps in some states but not in others is contrary to the purpose of the FTCA. *Accordingly, NACHC requests that HRSA modify Section I to recognize that caps could be imposed if the court applies the substantive law of the state in which the claim arose.*

J. Overview of Claim Filings

Section J of the Draft Manual (pages 26-27) indicates that if a “claim is denied or a settlement is not reached within six months [of being presented to OGC], the claimant can sue the United State in the appropriate Federal district court.” In reality, OGC often takes longer than six months to reach a decision on an initial claim. *NACHC requests that HRSA modify Section J to emphasize the importance of a timely response and by including language to encourage OGC to review claims within the six month timeframe.*

M. Medical Claims Review Panel (MCRP)

Many questions have arisen from health centers regarding the procedural process involved in the review conducted by the MCRP (page 30), including the criteria utilized and the timelines under

August 9, 2010

Page 14 of 14

which such review is conducted. *NACHC requests that HRSA expand Section M to include such additional detail. Further, NACHC requests that such process specifically include a procedure by which decisions can be appealed to the MCRP prior to it reporting an incident to the National Practitioner Data Bank.*

Thank you for the opportunity to comment on the Policy Information Notice (PIN) 2010-XX: DRAFT Federal Tort Claims Act (FTCA) Policy Manual. If you have any questions about the comments presented herein, please call or email me at 202-296-0158 or rschwartz@nachc.com

Sincerely,



Roger Schwartz
Associate Vice President of Executive Branch Liaison
Public Policy and Research Division