



April 28, 2011

Office of Quality and Data  
Bureau of Primary Health Care  
Health Resources and Services Administration  
U.S. Department of Health and Human Services  
5600 Fishers Lane, Rm. 15C-26  
Rockville, MD 20857

**RE: Solicitation of Comments on Notice of Proposed Rulemaking – Federal Tort Claims Act (FTCA) Medical Malpractice Regulations: Clarification of FTCA Coverage for Services Provided to Non-Health Center Patients, 76 Fed. Reg. 10825, et.seq. (February 28, 2011)**

To Whom It May Concern:

The National Association of Community Health Centers (“NACHC”) is pleased to respond to the above-cited solicitation of comments from the Health Resources and Services Administration (“HRSA”) within the Department of Health and Human Services (“HHS”) in connection with HRSA’s Notice of Proposed Rulemaking (“NPRM”) to amend the Federal Tort Claims Act (“FTCA”) medical malpractice regulations by: (1) replacing current regulations with the key text and examples of activities that have been previously determined to be covered by FTCA, as published in the September 25, 1995 Federal Register; (2) adding an example of FTCA-covered services involving individual emergency care provided to non-health center patients; and (3) updating the previously published covered immunization example.

NACHC is the national membership organization for federally-supported and federally recognized health centers (hereinafter interchangeably referred to as “health centers” or “FQHCs”) throughout the country, and is an Internal Revenue Code Section 501(c)(3) organization. NACHC also serves as a source of information, analysis, research, education, training, and advocacy regarding medically underserved people and communities.

### **Background**

There are, at present, approximately 1,200 health center entities nationwide, which serve as the health care homes to more than twenty-three (23) million persons at more than 7,500 delivery sites located in all fifty (50) states, Puerto Rico, the District of Columbia, and every U.S. territory.<sup>1</sup> Except for a limited number of public health centers (*i.e.*, health centers operated by local governmental units such as health departments), each health center is a charitable, nonprofit, tax-exempt IRC Section 501(c)(3) corporation formed under the laws of the particular state in which it operates. Most of these health

---

<sup>1</sup> *America’s Health Centers: Fact Sheet #0309* (2010), published by the National Association of Community Health Centers, Inc.

centers receive federal grants under Section 330 of the Public Health Service Act (42 U.S.C. §254b), administered by the Bureau of Primary Health Care (“BPHC”) within HRSA. Under this authority, health centers fall into four general categories: (1) centers serving medically underserved areas and/or populations (invariably poor communities); (2) centers serving homeless populations within a particular community or geographic area; (3) centers serving migrant or seasonal farm worker populations within a particular community or geographic area; and (4) centers serving residents of public housing projects. Although there are some slight differences in the grant requirements for each of these four program types, for all intents and purposes, the ways in which these health centers operate are identical.<sup>2</sup>

To qualify as a FQHC, a health center must (among other requirements) be located in or serve a federally-designated Medically Underserved Area (“MUA”) or Medically Underserved Population (“MUP”). In addition, a health center’s board of directors must be composed of at least fifty-one percent (51%) active consumers of the health center’s services, and the health center must offer a comprehensive array of preventive and primary care and enabling services to all persons in its service area, regardless of their ability to pay or insurance status.

The Section 330 grant funds are intended to support the costs of providing these services to uninsured and underinsured low-income patients, as well as to maintain the health center’s infrastructure. Approximately 71% of health center patients have family incomes at or below the federal poverty level. Patients from eligible communities<sup>3</sup> who are not low-income or who have insurance (whether public or private) are expected to pay for the services rendered. In 2009, on average, 37% of the patients served by health centers were Medicaid/CHIP recipients, 7% were Medicare beneficiaries, 38% were uninsured and the balance were covered through other public insurance programs as well as private insurance.<sup>4</sup>

To assist health center grantees in providing care to their underserved communities, the Federally Supported Health Centers Assistance Act [P.L. 102-501 (1992) and P.L. 104-73 (1995)] amended Section 224 of the Public Health Service Act to extend professional liability coverage under FTCA to Section 330-funded health centers, and their officers, directors, employees (regardless of whether they are full-time and part-time), and certain contracted clinicians. These individuals and entities are treated as federal employees for purposes of professional liability protection (*i.e.*, medical malpractice). Upon enacting P.L. 104-73, Congress recognized that the “[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.” House Report No. 104-398, December 12, 1995 (accompanying H.R. 1747) at p. 5. Citing low participation rates among health centers under the prior legislation, Congress expressed its expectation that the enactment of P.L. 104-73 in conjunction with HHS’ efforts to implement the legislation would “lead many more health centers to

---

<sup>2</sup> In addition to those health centers receiving grant funds pursuant to one or more of the Section 330 funding programs, there are certain entities that are designated by the Centers for Medicare and Medicaid Services (“CMS”) as FQHCs, by virtue of the fact that they meet all of the requirements to receive a Section 330 grant, but do not receive funding from HRSA (FQHC look-alike entities). For purposes of this comment, however, our reference to “health centers” or “FQHCs” only includes 330 grantees as FQHC look-alike entities are not covered under the FTCA.

<sup>3</sup> The term “community” in this context refers to either a geographic area or the specific population toward which the program is aimed.

<sup>4</sup> *America’s Health Centers: Fact Sheet #0309* (2010), published by the National Association of Community Health Centers, Inc., based on estimates from the Bureau of Primary Health Care 2009 Uniform Data System.

*drop their private malpractice coverage and participate fully in the program.”* House Report No. 104-398 at p. 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).

## **Overall Comment**

NACHC appreciates HRSA’s attempt at codifying and expanding FTCA coverage for certain activities and services provided to non-health center patients. Nevertheless, as noted above, legislative history clearly demonstrates that Congress intended FTCA coverage to provide health centers with complete relief from the financial burden of purchasing private malpractice insurance, freeing up significant funds to support health centers’ provision of health care services in their medically underserved communities by allowing them to substantially reduce their expenditures for medical malpractice insurance premiums. Equally clear is the presumption that FTCA coverage should be fully comprehensive in its scope, covering all services and activities included within the health center’s federally-approved scope of project.

Notwithstanding, various rules and policies (including the current NPRM) have narrowed what was intended as comprehensive malpractice coverage to replace private insurance, ultimately resulting in numerous circumstances under which health centers either lack coverage for certain activities performed in the normal course of business or are uncertain as to whether coverage applies to certain activities. These coverage limitations are forcing health centers either to go without coverage (and, thus risk potential malpractice exposure) or to utilize scarce resources which could be better spent on providing health care to the growing numbers of uninsured and underinsured populations in order to purchase costly private “gap” insurance – an action that is plainly inconsistent with Congressional intent.

Given the clear Congressional intent discussed above, NACHC believes that in order to fulfill the original promise of FTCA coverage, it is essential that there be a presumption of coverage for all providers’ services activities included within the health center’s federally-approved scope of project. Rather than simply amending current FTCA regulations by codifying FTCA coverage for existing “examples” of services provided to non-health center patients and by adding one new activity commonly performed by health centers in the normal course of business, NACHC urges HRSA to recognize explicitly that FTCA coverage is extended to health centers and their qualified employees, contractors, and other practitioners to the same level and extent that private malpractice insurance affords coverage to private physicians and providers. In doing so, HRSA would be recognizing the dynamic and ever-changing nature of the health care industry by eliminating the need to amend the FTCA regulations every time there is a change to the “normal course of business.”

NACHC believes that justification for such presumption lies not only in the Congressional intent discussed above, but also in the current FTCA regulations themselves. Regulations set forth in 42 C.F.R. §6.6(d) provide broad regulatory discretion to extend FTCA coverage to services and activities within a health center’s approved scope of project that are furnished by health center providers to non-health center patients in order to promote beneficial service arrangements. Subsequent to promulgation, Congress amended the health center FTCA legislation and incorporated into the law much of what had been included in the regulations with regard to treatment of non-health center patients.

Nevertheless, HRSA has been reluctant to employ the broad regulatory discretion afforded it. Rather, HRSA has interpreted this provision to require specific particularized determinations of coverage, which

are conducted separate and apart from scope of project and deeming approvals, for services and activities that do not fit “squarely within the examples of activities listed ....” See 76 Fed. Reg. 10827 – proposed rule set forth in 42 C.F.R. §6.6(e). For the reasons discussed above, NACHC urges HRSA to reconsider this position and, in lieu thereof, recognize a presumption of coverage for services and activities included within a health center’s federally-approved scope of project and its approved deeming application.

### **Comments on Specific Provisions of the NPRM**

Notwithstanding the aforementioned, at a minimum, NACHC requests that HRSA consider the following comments on specific provisions of the NPRM and modify the proposed regulations as recommended.

#### ***Community-Wide Interventions: 42 C.F.R. §6.6(e)(1)***

The NPRM provides FTCA coverage for certain community-wide services, such as health fairs and immunization campaigns, provided that health center staff conducts such events. See 42 C.F.R. §§6.6(e)(1)(iii) & (iv). Often, a health center’s involvement in a particular event results not from the health center “conducting” the event but rather from it simply participating in an event planned and conducted by other community providers or by the community at large. Accordingly, NACHC recommends that HRSA modify both of these provisions by adding the phrase “or participate in” after the word “conduct.” In doing so, HRSA would eliminate the need for unnecessary coverage determination requests while maintaining the intent behind the provisions.

#### ***Hospital-Related Activities: 42 C.F.R. §6.6(e)(2)***

The NPRM codifies the existing regulatory “example” that provides FTCA coverage for periodic hospital or emergency room call coverage, provided that such coverage is required by the hospital as a condition of obtaining admitting privileges. However, unlike 1995 (when this example was initially crafted) when hospital’s commonly conditioned the granting of admitting privileges on a provider’s agreement to participate in the hospital’s on-call or emergency room coverage rotations, increasingly hospitals have not retained this condition. In response to the requests of many providers to be paid for time expended providing on-call or emergency room coverage, along with recent trends towards hospitalist and other more efficient staffing models, many hospitals have established new arrangements that have caused the widespread elimination of medical staff bylaws requiring such coverage as a condition of granting admitting privileges.

To date, the inclusion of this out-of-date proviso as a condition of FTCA coverage has been extremely limiting, forcing numerous health centers to request particularized determinations of coverage or arrange for costly “gap” insurance for arrangements that substantively are the same, and effectively have the same result, as the example provided, but that do not fit squarely within the example itself. NACHC believes that to continue including a requirement that no longer comports with current industry practice would amplify this issue exponentially as an increasing number of hospitals modify their internal practices to fit industry trends.

Thus, to maximize the utility of this provision by eliminating the need for unnecessary coverage determination requests (or “gap” insurance policies) for what are essentially common call coverage arrangements, NACHC requests that HRSA modify this provision by eliminating the language indicating that the on-call or emergency room coverage in question must be required as a condition of obtaining

hospital admitting privileges. Rather, NACHC recommends that HRSA draft the provision broadly to cover health center providers who, as a condition of employment, participate in on-call or emergency room coverage arrangements included within the health center's scope of project that ultimately facilitate the continuum of care provided to health center patients.

NACHC also recommends that HRSA delete the word "periodic" as it adds nothing of meaning to the provision, while creating ambiguity (*i.e.*, does it refer to the specific provider's "occasional" participation in call coverage or to an arrangement that is periodic in nature?). Further, in practice, most on-call or emergency coverage arrangements are crafted based on a rotation schedule, and thus would not be considered "periodic" but rather "on-going." To ensure that health centers are not forced to request unnecessary coverage determination requests simply due to an ambiguity in drafting, NACHC recommends eliminating the word "periodic" as a means to describe the on-call or emergency room coverage arrangement.

### ***Coverage-Related Activities: 42 C.F.R. §6.6(e)(3)***

Similar to the hospital-related activities discussed above, the NPRM codifies the existing regulatory "example" that provides FTCA coverage for periodic or occasional cross-coverage provided as part of after-hours coverage arrangements between health centers and other local community providers. However, since 1995, health centers increasingly have established broader cross-coverage arrangements that go beyond after-hours coverage. These arrangements embrace community coverage arrangements with local providers as a means of filling capacity gaps during regular business hours, thus ensuring continuous access to care while utilizing provider time in the most efficient and cost-effective manner. In particular, many health centers have established twenty-four hour coverage arrangements with local providers to eliminate the practice of health center physicians leaving the health center during regularly-scheduled sessions to admit or otherwise treat health center patients presenting at emergency rooms or inpatient facilities. Further, many health centers utilize community coverage arrangements as a cost-effective approach to ensuring sufficient capacity when health center providers are absent on a temporary basis due to vacation or illness, or for business-related purposes.

However, the inclusion of the out-of-date "after-hours" requirement has resulted in many health centers submitting requests for particularized determinations of coverage or arranging for costly "gap" insurance for arrangements that substantively are the same, and effectively have the same result, as the example provided, but that do not fit squarely within the example itself. NACHC believes that, similar to the hospital-coverage provision, to continue including a requirement that no longer comports with current industry practice would amplify this issue exponentially.

Accordingly, to maximize the utility of this provision while minimizing the burden on both health centers and HRSA of having to submit and respond to unnecessary FTCA coverage determination requests, NACHC requests that HRSA modify this provision by deleting the phrase "after-hours" from this provision. Rather, NACHC recommends that HRSA draft the provision broadly to cover all in-scope cross-coverage arrangements with local community providers in which health center providers participate as a condition of employment, regardless of when the coverage occurs, provided that the arrangement ultimately facilitates the continuum of care provided to health center patients.

NACHC also recommends that HRSA delete the phrase "periodic or occasional," for the reasons discussed above.

### ***Coverage in Certain Emergencies***

In addition to codifying existing regulatory “examples,” the NPRM adds a new example of FTCA-covered services provided to non-health center patients pursuant to certain unanticipated emergency situations. NACHC believes that this new example is critically needed and must be retained in the final regulation. Under current rules, absent a particularized determination of FTCA coverage, health center providers are denied FTCA coverage if while treating health center patients (or non-health center patients under one of the provisions discussed above), they are asked by another provider to treat or assist in treating a non-health center patient. Nevertheless, this “reciprocal assistance” provided by clinicians to one another’s patients benefits both health center patients and the patients of the other physicians alike, as well as the community from which health center patients are drawn. As such, treatment in such instances is customarily provided by all or most clinicians.

Under the new rule, FTCA coverage is available to the health center provider if, among other requirements, a non-health center patient has an “emergency situation.” The NPRM, however, neither defines “emergency situation” nor includes “urgent situations,” which also may precipitate immediate treatment/assistance. This could put a health center provider in the difficult position of having his/her decision regarding the existence of an “emergency or urgent situation” debated months or even years after the fact to determine FTCA coverage.

To ensure that such lack of clarity does not result in an unanticipated chilling effect, thus negating any benefit afforded by adding this new provision, NACHC recommends that HRSA modify this provision to include “urgent situations” as well as to more clearly define what would constitute an “emergency or urgent situation.” Given the wide variety of definitions found in both federal and state law and regulation, as well as in common usage of the terms “emergency” and “urgent,” NACHC believes that HRSA should defer to the health center provider at the scene of the incident in determining if an “emergency or urgent situation” that required the intervention of the health center provider existed at the time. Accordingly, NACHC recommends that HRSA modify this provision by adding the phrases “or urgent” and “as determined by the health center provider at the scene of the incident,” as indicated in italics below:

**Coverage in Certain Individual Emergencies.** A health center provider is providing or undertaking to provide covered services to a health center patient within the approved scope of project of the center, or to an individual who is not a patient of the health center under the conditions set forth in this rule, when the provider is then asked, called upon, or undertakes, at or near that location and as the result of a non-health center patient's *emergency or urgent situation, as determined by the health center provider at the scene of the incident*, to temporarily treat or assist in treating that non-health center patient ...

NACHC notes that, in our experience, health care providers as a matter of practice are loath to interfere in the care of patients who are not theirs and only do so in very unusual circumstances. NACHC believes that our recommendation will not alter this provider behavior. Thus, any abuse of the exception due to this minor modification will be minimal at best while at the same time minimizing the need for health centers to obtain unnecessary coverage determination requests, procure costly “gap” insurance policies, or, worst case, choose to not participate in what is considered customary practice, with potentially adverse consequences to health center patients.

Thank you for the opportunity to comment on HRSA's NPRM to amend the FTCA medical malpractice regulations to clarify FTCA coverage for certain services provided to non-health center patients. If you have any questions about the comments presented herein, please call or email me at 202-296-0158 or [rschwartz@nachc.com](mailto:rschwartz@nachc.com)

Sincerely,

A handwritten signature in black ink, appearing to read "Roger Schwartz". The signature is fluid and cursive, with the first name "Roger" and last name "Schwartz" clearly distinguishable.

Roger Schwartz  
Associate Vice President  
Executive Branch Liaison, Public Policy and Research Division  
National Association of Community Health Centers, Inc.