



NATIONAL ASSOCIATION OF  
Community Health Centers

**NACHC ANALYSIS:**

**Managing a Claim and Reducing Gap-Related Exposures Under  
the Federal Tort Claims Act**

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The Federally Supported Health Centers Assistance Act (P.L. 102-501 (1992) and P.L. 104-73 (1995)) extends coverage to Section 330-funded Federally Qualified Health Centers (FQHCs) and to the qualified employees and certain other individuals and independent contractors of eligible FQHCs for malpractice liability under the Federal Tort Claims Act (FTCA) in accordance with Section 224 of the Public Health Service Act.<sup>1</sup> The FTCA provides occurrence-based coverage for professional malpractice to a health center that is “deemed” eligible by the U.S. Department of Health and Human Services (DHHS), Health Resources and Services Administration (HRSA) only for acts or omissions by the health center, its qualified individual providers and/or other eligible individuals that:

- Occur on or after the effective date that HRSA determined the health center met the requirements for FTCA coverage (*i.e.*, approval of the deeming application); AND
- Are within that health center's approved scope of project; AND
- Are within the scope of employment, contract for services, or duties as an officer or director of the corporation.

*See* 42 C.F.R. § 6.6.

When presented with a medical malpractice claim or suit, there are several steps the health center must take to ensure that it and/or its providers are properly protected from liability. Key among them is securing a determination by the DHHS Office of General Counsel (OGC) that, in fact, all FTCA eligibility requirements were satisfied based on a verification of the facts, circumstances and relevant documents related to the services at issue. It is important to keep in mind that, although the health center was “deemed” by HRSA to be eligible for FTCA coverage, HRSA’s implementation of coverage in a specific case first involves such a determination.

Increasingly, FTCA coverage for medical malpractice claims or suits filed against a deemed health center and/or its providers is generating attention in light of the variety of provider arrangements by which health centers deliver services, and recent determinations by DHHS that certain provider activities are outside the scope of what some health centers thought to be FTCA-covered services. Thus, it is important for health centers to understand not only what services, activities and providers generally are

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<sup>1</sup> Grantees eligible to be deemed by the Secretary of Health and Human Services for coverage under the FTCA are: Section 330-funded Community Health Centers [section 330(e)]; Migrant Health Centers [section 330(g)]; Health Care for the Homeless [section 330(h)]; and Health Care for Residents of Public Housing [section 330(i)]. Entities designated as FQHC “Look-Alikes” are not eligible for FTCA coverage. *See* HRSA Program Information Notice (PIN) 99-08 (Health Centers and the Federal Tort Claims Act).

covered by FTCA, but also the areas of concern that may present potential gaps in coverage, resulting in exposure to unanticipated risk and liability for the health center.

This Analysis provides general guidance and advice for FTCA-deemed health centers on how to manage a claim or suit under the FTCA, as well as how to reduce gap-related risk. Specifically, this Analysis explores the following:

- Necessary steps every health center should take to obtain liability protection under the FTCA when presented with a medical malpractice claim or suit<sup>2</sup>; and
- Compliance with FTCA coverage requirements for health center activities at the outset to reduce exposure to risk due to potential gaps in coverage.

## **OBTAINING LIABILITY PROTECTION UNDER FTCA: NECESSARY STEPS EVERY HEALTH CENTER SHOULD TAKE WHEN PRESENTED WITH A CLAIM OR SUIT**

### *Seek and Obtain Prompt Qualified Legal Advice and HRSA Guidance*

When a health center receives any notice, correspondence or documentation related to a medical malpractice claim or suit (including service of process, a summons, complaint or claim form), timely and appropriate action is essential to ensure that the health center and its providers obtain assistance and protection in accordance with their FTCA-deemed status. Any such correspondence or legal documents should immediately be brought to the attention of the health center's Executive Director/Chief Executive Officer, who in turn should contact the health center's field office FTCA coordinator, along with:

U.S. Department of Health and Human Services  
Office of General Counsel, General Law Division, Claims Branch  
Room 4256  
300 Independence Avenue, S.W.  
Washington, D.C. 20201  
(202) 619-2155

and

Office of Quality & Data  
Health Resources and Services Administration  
5600 Fishers Lane  
Room 17C-05  
Rockville, MD 20857

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<sup>2</sup> Because this Analysis provides general information only, health centers should always seek qualified legal counsel concerning issues involving malpractice liability claims and lawsuits.

These offices provide specific guidance on what documentation to submit, and how to proceed in a particular situation.

### *Preserve Records, Documents and Witness Statements*

Generally, the OGC Claims Office will want the health center to fax and/or express mail the claim or complaint along with documents related to the services at issue promptly to its office, so that the OGC can confirm that all FTCA eligibility requirements were satisfied based on verification of the facts, circumstances and relevant documents.

Further, all existing records, documents, notes and written statements relevant to the claim should be gathered and safeguarded. Because such documents may be subject to disclosure unless a specific legal privilege applies, no new statements or records (including declarations and/or narrative statements from the health center practitioner(s) named in the complaint and other health center staff) should be created before consulting the OGC Claims Office (to verify coverage) and/or qualified legal counsel.<sup>3</sup>

#### **Records and Witness Statements:**

- Health centers have a legal obligation to preserve documents and other evidence relating to a medical malpractice claim or suit.
- Creating additional records and/or statements after an incident should be done only with legal advice and counsel, and possibly within the scope of the attorney-client privilege.
- Disclosures of adverse outcomes to patients and family members should be made in accordance with health center policy and clinical protocols and only by designated individuals

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<sup>3</sup> HRSA Policy Information Notice (PIN 99-08): *Health Centers and The Federal Tort Claims Act* (April 12, 1999) at pp. 10-11, indicates that health centers should develop and send copies of declarations and narratives along with the complaint. However, due to the sensitivity around asserting legal privilege, in a communication with the OGC Claims Office on June 5, 2008 the authors confirmed that it is best to wait before creating any new documents.

## *Ensure Coverage and Coordinate with Federal Agencies*

The health center will need to verify with the DHHS OGC Claims Office that all FTCA eligibility requirements are met in the particular case, and provide DHHS with supporting documents<sup>4</sup>, which may include the following:

- The health center's Notice of Grant Award
- The health center's deeming letter
- Employment agreements/clinical services contracts and job descriptions
- Relevant hospital staff bylaws
- Credentialing and privileging documents
- Patient records
- Documentation of compliance with other HRSA FTCA eligibility requirements such as ongoing quality assurance and peer review programs

In the case of a suit filed in state court, the health center should also consult with qualified local counsel to determine whether obtaining a stay in the proceedings is necessary (to avoid a summary/default judgment) until the U.S. Department of Justice (DOJ) files for the case to be removed to Federal District Court and the United States is substituted as the defendant. If an administrative claim filed in accordance with the FTCA is denied (or remains unsettled after 6 months), a health center patient can properly file suit, but only against the Federal Government, and only in Federal District Court.<sup>5</sup>

The health center should confirm with the DHHS OGC Claims Office when and under what circumstances the health center and/or individual providers may contact and/or respond to DOJ or U.S. Attorney inquiries and requests. *It is essential that the DHHS OGC confirm that a health center is covered in a particular case before communicating with a U.S. Attorney's office about a claim or suit – information provided to a U.S. Attorney prior to determination of FTCA status may not be protected by the attorney-client privilege.*

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<sup>4</sup> See HRSA PINs 95-29, 97-6, and 99-08.

<sup>5</sup> The proper agent for service of process on the Secretary of Health and Human Services is set forth at 45 C.F.R. § 4.1 (Note that this is a different address from the OGC Claims Branch at 300 Independence Avenue, S.W.):

General Counsel  
U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

## ***Monitor the Settlement Process and Comply with Any Reporting Obligations***

Many claims under the FTCA are settled by DHHS OGC or by DOJ if suit has been properly bought.<sup>6</sup> Prior to agreeing to settlement terms, the DHHS OGC Claims Office or DOJ may seek input from the health center, but the final settlement decision rests with DHHS.<sup>7</sup> It is important to note that settlement of a malpractice claim or suit may have National Practitioner Data Bank (NPDB) reporting implications for the health center and provider(s) involved. Clinicians must be reported to the NPDB whenever a payment is made and HRSA determines that the standard of care was not met. In such circumstances, health centers should verify reporting requirements and procedures with the HRSA Office of Quality & Data.

## ***Other Actions Required in Response to a Malpractice Claim or Suit***

In addition to actions directly related to the claim or suit, health centers should also take the following actions:

- Comply with federal (*e.g.*, Health Insurance Portability and Accountability Act, or HIPAA) and state medical and/or mental health privacy laws and regulations. Note that some state laws may be more restrictive than HIPAA, and a release of information that is permitted under HIPAA may be prohibited under other federal and/or state law, especially where behavioral health records or the treatment of minors is concerned.
- Follow the health center's media response plan and seek legal and public relations advice, as appropriate. Health centers should confirm who may speak on behalf of the organization, and to which outside entities. It is important to remind front desk staff of the proper procedures for handling inquiries and requests for information regarding a claim or potential claim.
- Consider the possibility of whether the circumstances may involve related claims that have yet to be filed and seek DHHS and legal guidance on how to proceed with records retention, disclosures to potentially affected patients, *etc.*
- Review the terms of any gap insurance policies and the role of any insurer vis-à-vis DOJ requirements for notice, document access, *etc.*

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<sup>6</sup> 28 U.S.C. § 2677 provides the Attorney General, or his/her designee, with FTCA settlement authority, and 42 U.S.C. § 233 extends that authority to cases involving deemed health centers and their covered providers.

<sup>7</sup> *See* HRSA PAL 95-29.

# REDUCING EXPOSURE TO RISK DUE TO POTENTIAL GAPS IN COVERAGE: COMPLYING WITH FTCA COVERAGE REQUIREMENTS FOR HEALTH CENTER ACTIVITIES FROM THE OUTSET

## *General FTCA Coverage Requirements*

As noted above, FTCA coverage issues are generating increased attention for health centers and HRSA. It is helpful to remember that FTCA “coverage” is not the same as commercial malpractice insurance. In general, FTCA only covers malpractice claims or suits arising from services and sites that are properly within the health center’s HRSA-approved scope of project. Actual coverage “eligibility” depends on:

- The health center’s FTCA-deemed status;
- Continuing compliance with all statutory, regulatory and HRSA policy coverage eligibility requirements; and
- Whether the services that are the subject of the claim are within the health center’s HRSA-approved scope of project and within an eligible health center provider’s scope of employment or contract.

With regard to this last point, it is important to remember that in addition to covering the deemed health center, FTCA coverage extends to:

- The HRSA-deemed health center’s employees, whether full-time or part-time; and
- Individually contracted clinicians who otherwise meet FTCA eligibility requirements and who provide services to health center patients at the health center site for at least 32 ½ hours a week. An exception to the “full-time” provider requirement exists for individually contracted clinicians who provide services in the fields of family practice, general internal medicine, general pediatrics, and obstetrics/gynecology.<sup>8</sup>

Further, under limited circumstances, certain inpatient provider services furnished to health center patients (*e.g.*, rounding activities) and certain services to non-health center patients and/or at non-health center sites (*e.g.*, on-call or cross coverage arrangements that meet specific regulatory requirements, as discussed in greater detail below) may be covered.

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<sup>8</sup> See HRSA PAL 99-15, and HRSA PINs 99-08 and 2001-11.

## *Areas of Concern that May Present FTCA Coverage Gaps*

The variety of provider arrangements by which health centers deliver services, and recent determinations by DHHS that certain provider activities are outside the scope of what some health centers considered to be FTCA-covered, reveal a need for increased scrutiny by health center management to ensure services are, in fact, covered under the FTCA. Particular areas of concern that could present coverage gaps include:

- Health center provider services furnished off-site (*i.e.*, at sites not within the approved scope of project).
- Health center provider services furnished to non-health center patients.
- Employment and contracting arrangements with health center providers.
- Billing by individual health center providers.

HRSA has set forth detailed FTCA eligibility requirements that must be satisfied for malpractice coverage in all cases, and has established additional requirements that apply to those areas that could present coverage gaps listed above. HRSA will verify compliance with the applicable eligibility requirements in each particular claim or suit,<sup>9</sup> which may involve a review of:

- Contract and employment agreement terms, including billing arrangements.
- Hospital by-laws requirements.
- Informal customary consultation and cross-coverage agreements/arrangements.
- Requirements regarding supervision of non-health center staff by health center personnel.
- Arrangements to provide services during emergencies.

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<sup>9</sup> The requirements regarding FTCA coverage for health centers are set forth in the following references: HRSA PAL 99-15, and PINs 99-08 and 2001-11 (discussing the requirements for health center coverage under the FTCA); PIN 2008-01 (Scope of Project guidance); and PINs 2001-16 and 2002-22 (discussing FQHC Credentialing and Privileging requirements for health center FTCA coverage that must comply with the Federally Supported Health Centers Assistance Act, which applies to a broader range of health practitioners than JCAHO or AAAHC standards). These references are available at: <http://www.bphc.hrsa.gov/policy/>. It is anticipated that HRSA will soon issue a new draft PIN that consolidates and updates these prior PINs, however, this anticipated document will not necessarily revise or add new HRSA FTCA policy. NACHC will alert health centers when that draft PIN is published.

As noted above, typically services provided to non-health center patients and/or at non-health center sites will not be covered by the FTCA, unless the health center obtains specific approval of such arrangements. Notwithstanding, DHHS has published rules which establish that certain health center activities involving the provision of services to non-health center patients and/or at non-health center sites will be covered under the FTCA, without the need to obtain specific clarification or a particularized determination of coverage<sup>10</sup>, provided that such activities are documented and described in detail in health center's Section 330 grant narrative and listed and described on the applicable scope Form 5.<sup>11</sup> These regulatory examples include:

- A health center requires its physicians to obtain staff privileges at a community hospital. As a condition of obtaining such privileges, and thus being able to admit the center's patients to the hospital, the physicians must agree to provide periodic hospital call or hospital emergency room coverage. (Note: The health center provider's employment agreement or contract for services must clearly require that such privileges are a condition of employment or required under the contract).
- A health center makes arrangements with local community providers for after-hours coverage of its patients, and agrees to provide after-hours cross-coverage. (Note: Similar to on-call requirements, the health center provider's employment agreement or contract for services must clearly require periodic cross-coverage for the patients of the community providers, in order to make this arrangement feasible).
- The health center's staff members provide primary and preventive health care services at a facility located in a school or on school grounds based on a written affiliation agreement with the school.
- The health center's staff members conduct an event to immunize children against infectious childhood illnesses, or a health fair to attract community members for purposes of performing health assessments. Such events may be held in the health center, outside on its grounds, or elsewhere in the community.
- The health center's staff members travel to a shelter for homeless persons, a street location where homeless persons congregate, or a migrant farmworker residence camp to conduct intake screening to determine those in need of clinic services (which may mean health care is provided at the time of such intake activity or during subsequent clinic staff visits at the same location).

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<sup>10</sup> See 42 C.F.R. § 6.6(e); Regulatory notice published at 60 Fed. Reg. 49417 (Sept. 25, 1995).

<sup>11</sup> PIN 2008-01.

HRSA expressly warns that that “entities should be painstakingly exact” to ensure that their proposed activity “fits squarely” within a pre-approved regulatory example,<sup>12</sup> and in cases where such activity does not fit squarely, a particularized determination “should be sought.”<sup>13</sup> For example, if health center’s cross coverage arrangement does not fit “squarely” within the regulatory example because is not expressly limited to “after hours” situations, the only way to be absolutely “sure” of FTCA coverage of such a cross-coverage arrangement is to seek a particularized determination of coverage (as authorized under the applicable regulations).<sup>14</sup>

### *Particularized Determinations of FTCA Coverage*

The regulations establish three criteria for approval of a request for a particularized determination of FTCA coverage for services provided to non-health center patients and/or at non-health center sites that do not meet the coverage requirements or one of the specific examples described above. Any of these three can be used to justify a determination of coverage:

- The provision of the services to non-health center patients benefits the health center’s patients as well as the general populations that could be served by the health center through community-wide intervention efforts conducted within the communities served by the health center.
- The provision of the services to non-health center patients facilitates the provision of services to the health center’s patients.
- The services rendered are otherwise required to be provided to the non-health center patients under an employment contract or similar arrangement between the health center and the covered provider.

### *Activities and Providers Not Covered by the FTCA*

Health centers should recognize that certain providers and some common services are not covered by FTCA, regardless of their specific circumstances. These include:

- Services or sites that are not within the health center’s HRSA-approved scope of project, including specialty services and certain locations (*e.g.*, corrections

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<sup>12</sup> See 42 C.F.R. § 6.6(e); Regulatory notice published at 60 Fed. Reg. 49417 (Sept. 25, 1995).

<sup>13</sup> See 60 Fed. Reg. 49418.

<sup>14</sup> 42 C.F.R. § 6.6(d).

institutions, nursing homes, homeless shelters), unless within the examples discussed above.<sup>15</sup>

- Clinicians contracted through another entity, not individually.
- Part-time contractors (working less than 32.5 clinical hours a week) who do not work in the practice areas specialties discussed previously.
- Arrangements in which health center providers (employed or contracted) bill and retain third party payments for inpatient services.
- Physicians acting as the Chief Medical Officer of a network or of another organization (*e.g.*, a nursing home or home health agency).
- Services provided to non-health center patients, unless within the examples discussed above.
- Physicians supervising non-health center employees, unless done as part of an on-call arrangement.
- Health center volunteers (while the health center itself may be covered, commercial malpractice insurance would have to be obtained to cover individual volunteer providers who lack their own coverage).
- Residents, medical students and other students unless employed by the health center.
- Any agreements by the health center to “hold harmless” (*i.e.*, a promise not to sue or raise legal defenses against another party) or indemnify (*i.e.*, a promise to compensate another party for claims against them) a third party.
- Moonlighting (*i.e.*, outside activities conducted by health center providers involving the provision of health care, whether or not compensated).
- Any activities conducted prior to the effective date of the “deeming” letter from HRSA.
- Any claims unrelated to medical malpractice.

Given the numerous potential gaps in FTCA coverage, health centers engaging in any of the activities described above (or in “questionable” activities) should assess their need for

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<sup>15</sup> HRSA clarification should be sought as to whether such sites should be included in the health center’s approved scope of project.

both general liability insurance and “gap” malpractice insurance, and secure private coverage as necessary.

## CONCLUSION

FTCA coverage for claims and suits filed against deemed health centers and/or their providers is always contingent upon prompt notification of such claim or suit to the DHHS OGC Claims Office by the health center, and a determination by DHHS OGC that all FTCA eligibility requirements were, in fact, met. Whether activities, services and/or providers are covered by the FTCA is generating increased attention in light of the variety of provider arrangements by which health centers deliver services, and recent determinations by DHHS that certain provider activities are outside the scope of what some health centers thought to be FTCA-covered services. As such, in addition to understanding what services, activities and providers generally are covered by FTCA, health centers should be aware of areas of concern that may present potential gaps in coverage.

To reduce the risk that FTCA coverage could be denied after a claim or suit is filed, health centers and their providers should ensure that all relevant documents meet FTCA coverage standards. In particular, the health center’s provider employment agreements and contracts for services should address all activities required of such providers.<sup>16</sup> Further, in order for a health center or an individual health center provider to be eligible for professional malpractice liability coverage under the health center's FTCA-deemed status for any services provided, all of the FTCA coverage requirements applicable to the health center, or its provider, and contained in the respective employment agreement, contract for the purchase of clinical services, or call/cross coverage arrangement must be met in practice (and not simply on paper).

NACHC has requested that HRSA develop further guidance and policies to clarify and simplify FTCA coverage of health center activities. NACHC staff members are available to assist with general questions and provide resources concerning health center FTCA coverage. In particular, for additional information on FTCA, please contact Roger Schwartz, NACHC’s Associate Vice President of Executive Branch Liaison, at 202-296-0158 or [rschwartz@nachc.com](mailto:rschwartz@nachc.com), or the authors of this Analysis.

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<sup>16</sup> This is a complex area of the law, and consultation with legal counsel familiar with health center and FTCA compliance requirements is strongly recommended.