

## Comments & Response on DRAFT Policy Information Notice, “Federal Tort Claims Act (FTCA) Health Center Policy Manual”

On May 28, 2010, the Health Resources and Services Administration (HRSA) made the draft consolidated Health Center Federal Tort Claims Act (FTCA) Policy Manual available for public comment on HRSA's web site. The Policy Manual is meant to clarify and consolidate existing FTCA policy into a more user friendly document. Comments were due to HRSA by August 6, 2010.

HRSA received comments from 14 health centers, 3 PCAs, 1 consulting firm and the National Association of Community Health Centers (NACHC) regarding the draft. After review and careful consideration of all comments received, HRSA amended the draft FTCA Manual to incorporate certain recommendations from the public. The final FTCA Policy Manual reflects these changes.

The purpose of this document is to summarize the major comments received and convey the agency's response. Moreover, it should be noted that the consolidated FTCA Manual was not intended to create new policy, but rather to consolidate and clarify existing policy. Some comments focused on changing or amending current policies. While these recommendations were not incorporated into the manual, HRSA intends to continually review its current policies and issue new policy guidance that will be added to future versions of the FTCA Policy Manual.

### Issue: Adding the Term “Within the Applicable Contract for Services”

#### Comments

One comment requested that HRSA modify all references to “scope of employment” to also include the phrase “within the applicable contract for services.”

#### HRSA Response

There are significant legal differences in the meanings of the phrases “within the applicable contract for services” and “scope of employment” in varying contexts. To provide assistance in understanding why the term “scope of employment” is used, the Policy Manual defines “scope of employment” and includes a discussion that clarifies what that definition entails.

### Issue: Coverage for Volunteers and Part-time Dentist and Behavioral Health Specialist

#### Comments

Several comments suggested that HRSA reconsider its existing policy and the commentators suggested the following:

1. Extend FTCA coverage to volunteers and/or;
2. Extend FTCA coverage to part-time contractors in the fields of dentistry and behavioral health.

#### HRSA Response

The current FTCA policies related to volunteers and specific part-time contractors are addressed in statute 42 U.S.C. sec. 233 (Section 224 of the Public Health Service Act), and exceptions to statutory requirements cannot be modified by issuing a PIN. Any changes to the current FTCA volunteer and part-time contracting policy would require a statutory change. Additionally, it should be noted that the FTCA Manual was intended to consolidate existing policy, not create new policy.

### **Issue: Modification of Specific Terms that Appear Throughout the Manual**

#### **Comment**

Some comments requested that HRSA make various changes to the phrase “performance of medical, surgical, dental, or related functions”. Suggestions included adding “mental health” to the phrase.

#### **HRSA Response**

This is a statutory reference, specifically, it is a phrase contained within sec. 233. Therefore, any changes to the phrase “performance of medical, surgical, dental, or related functions” would require a statutory change. Additionally, it should be noted that the FTCA Manual was intended to consolidate existing policy, not create new policy.

### **Issue: State Imposed Medical Malpractice Caps**

#### **Comment**

One comment requested clarification regarding state imposed medical malpractice caps and regulations.

#### **HRSA Response**

Medical malpractice caps and regulations vary by state. HRSA recommends that each health center consult with its private counsel for clarifications on specific state medical malpractice caps and other related regulations.

### **Issue: Claims Flow Chart**

#### **Comments**

Several comments requested a flow chart detailing the claims process.

#### **HRSA Response**

HRSA agrees with the recommendation and has added a flow chart to the final document. However, HRSA encourages health centers to discuss the claims process with their private counsel and utilize the BPHC Helpline if additional questions related to the claims process arise. Questions can also be e-mailed to the General Law Division of the Department of Health and Human Services at [gcgl@hhs.gov](mailto:gcgl@hhs.gov).

### **Issue: Premature Lawsuit and Claims Disposition Required Documents**

#### **Comments**

Several comments asked for guidance in preparing or obtaining required documents related to premature lawsuits and claims dispositions.

#### **HRSA Response**

Most of the required documents can be obtained through HRSA’s Electronic Hand Book (EHB). Due to the fact that claims are very fact specific, HRSA suggests that health centers seek guidance from their private counsel in obtaining or drafting any additional documents.

### **Issue: The Applicability of Touhy Regulations**

## **Comments**

Several comments asked for clarifications on Touhy regulations.

## **HRSA Response**

To provide greater clarification on this issue, HRSA has included clarifications on when Touhy regulations apply and has provided examples listing situations when Touhy regulations are inapplicable. However, health centers should still follow guidance set forth in the Policy Manual that instructs health centers to contact OGC/HHS when they receive any requests for testimony.

## **Issue: Medical Claims Review Panel (MCRP)**

### **Comments**

Several comments asked for clarifications regarding the MCRP and FTCA's role in the MCRP process.

### **HRSA Response**

MCRP assists the Department of Health and Human Services in meeting its responsibility to provide quality health care in its facilities and by its practitioners, including health centers and their providers who are "deemed" to be employees of the Department for FTCA coverage. As stipulated in the charter of the MCRP, the chairperson submits an annual report to the Secretary and the Agency Heads represented on MCRP regarding the issues brought before the membership, as well as decisions and any recommendations it makes.

The following duties describe the functions of the MCRP as articulated in its charter.

The Panel:

1. Reviews standard of care analyses performed by HHS or consultant physicians and other health care professionals on claims for damage, injury, or death filed under the Federal Tort Claims Act (FTCA) against a facility or healthcare practitioner covered under the FTCA;
2. After a claim has been paid pursuant to a settlement or adverse judgment, identifies the clinician(s) who provided the treatment giving rise to the claim and determines whether the standard of care was breached;
3. Provides professional recommendations to HHS clinical programs and personnel systems on matters of quality assurance.

The FTCA Branch within BPHC's OQD identifies and designates medical experts to present medical and risk management reviews to the Panel to assist in their determinations. The FTCA Branch in OQD ensures:

1. Appropriate content in each case file;
2. Appropriate assignment of cases to medical experts; and
3. Timely delivery of cases (panel packages) to reviewers.

## **Issue: Coverage when Responding to Emergency Events**

### **Comments**

Several comments requested changes be made to the coverage requirements for responding to an emergency. The comments specifically requested deleting conditions requiring that the temporary location must be within the health center's service area or an adjacent/neighborhood county/parish/political subdivision.

### **HRSA Response**

Section F, “FTCA Coverage When Responding to Emergency Events,” of the FTCA Policy Manual outlines HRSA’s current policies related to coverage when responding to emergency events as originally stipulated in PIN 2007-16. As previously stated, the FTCA Manual was intended to consolidate existing policy, not create new policy.

### **Issue: The Particularized Determination (PD) Process**

#### **Comments**

Several comments requested modifications to the particularized determination process, modifications to the particularized determination application questions and a general clarification of how a particularized determination is reached.

### **HRSA Response**

Depending on the complexity of the issue, determinations are reached through a collaborative process between individuals in the OQD and OGC/HHS. Decisions are based on statute, policy, and service to the community as well as a risk assessment. Once a determination is reached, the applicant is notified of the outcome. The particularized determination (PD) process is currently under review. HRSA is considering future alterations to the process and will issue a draft PIN for public comment in the future if changes in policy are being proposed. The current policy is outlined in 42 CFR section 6.6(d). All PD requests and questions can be sent to [FTCAPD@hrsa.gov](mailto:FTCAPD@hrsa.gov). As previously stated, the FTCA Manual was intended to consolidate existing policy, not create new policy.

### **Issue: Role of Department of Justice and HHS Office of the General Counsel**

#### **Comments**

There were a few comments requesting that the roles of the Attorney General, the Department of Justice (DOJ) and the DHHS Office of the General Counsel (OGC) be delineated in determining coverage.

### **HRSA Response**

All FTCA coverage, not just for health centers, requires a determination by the DOJ that activities fall within the scope of employment in order for cases to be defended by an Assistant U.S. Attorney. For health center FTCA coverage, scope of employment also includes whether an activity is within the scope of project and therefore is a covered activity under FSHCAA. For a claim to follow the FTCA process, both the OGC and the DOJ must first determine that a claim is related to a covered activity. For the role of DOJ, please refer to section II of the Policy Manual entitled “Claims and Lawsuits.”

### **Issue: Coverage for Health Centers in a Claim Involving Non-covered Individuals**

#### **Comments**

There were many comments seeking clarification on whether a covered entity remains covered in instances of claims against non-covered providers.

### **HRSA Response**

HRSA added language into the manual explaining that lack of individual coverage for a non-covered provider, by itself, will not necessarily impact the health center’s coverage as the covered entity.