

Learning Objectives

- ▶ Achieve familiarity with FTCA
- ▶ Identify the participants in the process of FTCA claims
- ▶ Identify documents for FTCA claim evaluation
- ▶ Understand the importance of securing records
- ▶ Recognize the importance of maintaining information and contacts

See PIN 2011-01 for more information

Primary Sources for FTCA Information:

▶ **Health Centers**

- See: Policy Information Notice (PIN) 2011-01
- FTCA Policy Manual

See PIN 2011-01, January 3, 2011

▶ **Free Clinics**

- See: Policy Information Notice (PIN) 2011-02
- Free Clinics FTCA Program Policy Guide

See: PIN 2011-02, March 22, 2011

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The Story Begins

A patient presents...



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Why a Suit: The Top Reasons Patients Sue

1. Failure to diagnose or a delay in diagnosis (cancer).
2. Maternity care, delivery (improper use of oxytocin) and birth injury.
3. Wrong diagnosis and misdiagnosis (assuming that a fracture is a sprain or minor injury).
4. Failure to consult/followup in a timely manner (communication).
5. Surgical errors (wrong procedure, wrong site, unnecessary procedure).
6. Medication errors and problems with prescribing. Lack of patient education about the medications prescribed.
7. Medical record issues (documentation, inadequate history-taking)
8. Failure to obtain informed consent.

See PIN 2011-01 for more information

<http://www.articlesbase.com/personal-injury-articles/seven-reasons-physicians-are-sued-for-medical-malpractice-832271.html> (last accessed 6/5/2013)

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How the Process Starts: Receipt of Legal Documents

- ▶ Administrative claim is filed with HHS/OGC (Standard Form-95)
- ▶ HHS/OGC issues a final decision on SF-95
- ▶ Service of process
- ▶ Summons
- ▶ Complaint
- ▶ Claim form



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Federal Tort Claims Act (FTCA)

- ▶ Our focus: FTCA Medical Malpractice Coverage
- ▶ 28 U.S.C. §§1346(b), 2401(b) and 2671-2680; 42 U.S.C. § 233



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Purpose of the Health Center FTCA Medical Malpractice Program

Increasing the availability of funds to health centers to provide primary healthcare services frees monies to:

- Increase the number of patients served
- Increase enabling services (case management and health education)
- Reduce financial, geographic, and cultural/linguistic barriers to care
- Implement and expand programs such as quality improvement and risk management

See: FTCA Policy Manual, p. 4; also see PIN 2011-01 for more information

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FTCA Coverage

- ▶ FTCA covers malpractice suits or claims arising from services that are properly within FTCA guidelines and the health center’s HRSA-approved scope of project.



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Is it Possible to Anticipate Litigation?

- ▶ It is reasonable to anticipate litigation:
 - Once a claim (SF-95) or a lawsuit is filed
 - Once you are aware of a patient’s dissatisfaction or complaints
 - When signaled by flags in clinical decision support tools
 - Through quality reporting processes
 - If using event reporting tools

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Covered Individuals

- ▶ Governing board members
- ▶ Officers/directors
- ▶ Employees (full or part-time, W-2)
- ▶ Certain individual contractors (full-time 32.5 hrs per week, 1099)
- ▶ Part-time individual contractors in family practice, general internal medicine, general pediatrics and obstetrics and gynecology



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Covered Entities

- ▶ Health centers that receive §330 funds and have been approved for coverage or “deemed” as employees of the Public Health Service by the Secretary.
- ▶ Note: unlike health centers, free clinics are not deemed as an entity.

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Covered Activities

- ▶ Act or omission in the performance of medical, surgical, dental or related functions
- ▶ Resulting in personal injury (including death)
- ▶ And occurring within the scope of employment
 - Activities within an applicable individual contract for services
 - Within the scope of approved federal §330 grant projects
 - Take place during the provision of services to health center patients

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Health Center FTCA Coverage Exclusions

- ▶ Individuals who do not meet the statutory requirements for covered individuals
- ▶ Volunteer physicians
- ▶ Moonlighting activities
- ▶ Clinicians contracted through another entity, not individually
- ▶ Most part-time contract specialists (averaging less than 32.5 hours/week)

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FTCA Coverage Exclusions

- ▶ FTCA coverage does not extend to indemnification of other entities or organizations arising under hold harmless or indemnification clauses in contracts with provider organizations
- ▶ FTCA is not a substitute or replacement for directors' and officers' insurance
- ▶ FTCA is not a substitute or replacement for general liability coverage/fire or theft

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Verification of Eligibility for FTCA Medical Malpractice Coverage

A health center's eligibility for coverage depends on:

- FTCA-deemed status
- Continuing compliance with eligibility requirements (statutory, regulatory and HRSA policy requirements)
- Determination that the services that are subject of the claim are within
 - the health center's HRSA-approved scope of project
 - an eligible health center provider's scope of employment under the contract.

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Type of Coverage

- ▶ FTCA coverage is comparable to occurrence coverage
 - No specific coverage limit
 - No tail coverage required
 - No punitive damages allowed

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Other Insurance Coverage

It is important to regularly review your general liability insurance, worker's compensation insurance and any other necessary insurance policies to assure that appropriate coverage is in place for your health center.

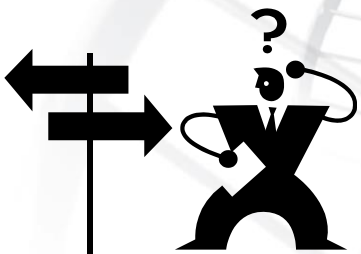
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Understanding the Claims Process

The only remedy for a claimant alleging medical malpractice relating to covered health center activities is under FTCA

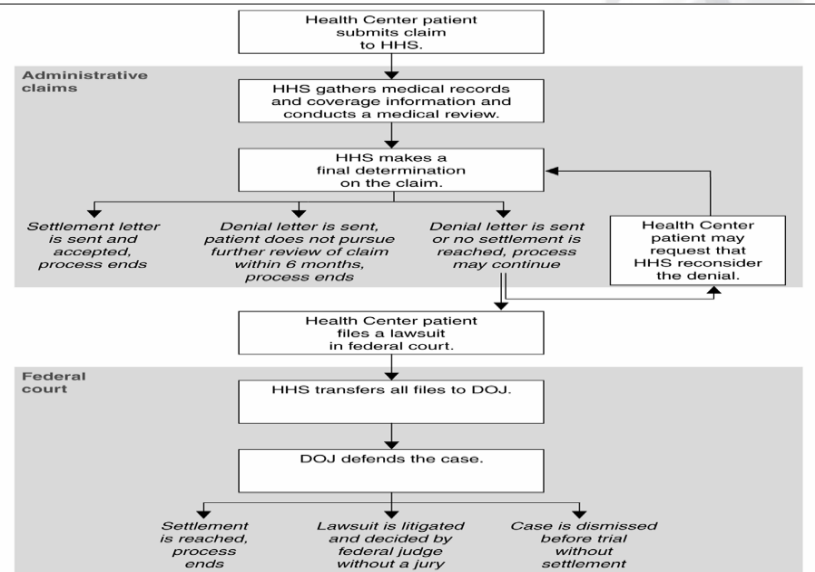


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How does the Process Work?



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Participants in the Claim Process

- ▶ Claimant
- ▶ Office of General Counsel (OGC)
- ▶ Department of Justice (DOJ) is responsible for the defense of all litigation arising from acts or omissions covered under FTCA
- ▶ Health center
- ▶ FTCA program staff

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To Begin the Process of Filing an FTCA Claim

- ▶ A claimant:
 - Must first seek an administrative remedy by presenting their claim (SF-95) to the HHS Office of the General Counsel (OGC), General Law Division (GLD), Claims and Employment Law Branch (CELB).
 - HHS/OGC reviews the claim (SF-95) (denying it, paying it, or offering to settle it).
 - Once an administrative claim (SF-95) is denied by HHS/OGC, the claimant must file suit within six months in the appropriate Federal district court (or seek reconsideration by HHS/OGC).

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The Health Center's Role when Receiving a Medical Malpractice Claim:

Health center steps taken to ensure protection from liability:

- Securing a determination by HHS that all FTCA eligibility requirements were satisfied
- Gathering and securing all records, documents, and notes relevant to the claim
- Notifying health center field office, HHS/Office of General Counsel (OGC), and HRSA Office of Quality & Data

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Documents Supporting Eligibility Would Include:

- ▶ The health center's initial deeming letter, Notice of Deeming Action (NDA), redeeming documentation
- ▶ Employment agreements/clinical services contracts
- ▶ Job descriptions
- ▶ Relevant hospital staff bylaws

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Record Management

- ▶ Ensure that the dates of the documents confirm the date of the incident.
- ▶ Ensure preservation and prevent destruction of any potentially relevant documents



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Preserve Records

- ▶ All existing records, documents, notes and written statements relevant to the claim should be gathered and safeguarded
- ▶ No new statements or records should be created before consulting the OGC Claims Office (to verify coverage) and/or qualified legal counsel.
- ▶ Practitioner narrative should not be filed with the medical record but in a separate folder or system.



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Documents Needed May Include the Following:

- ▶ **Copies of the summons and complaint**
- ▶ **Deeming Letters:** and redeeming materials as applicable
- ▶ **Wage and Tax Forms:** W-2s for each individual involved in the incident who was employed at the time of the alleged negligence; 1099s if the individual was a contractor and copies of the contract covering the date of the incident.
- ▶ **Declaration verifying employment and no private billing:** signed by the provider
- ▶ **Copies of other insurance or gap insurance policies**
- ▶ **All correspondence received from the claimant**
- ▶ **Claimant's medical records:** include x-rays, laboratory reports, and other results and treatments from private facilities that might be involved

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Claims Considerations

- ▶ If a claim is denied by HHS/OGC or a settlement is not reached within six months of presentment, the claimant can sue the United States in the appropriate Federal district court.
- ▶ Alternatively, the claimant may request reconsideration by HHS/OGC of the denial of an administrative tort claim within six months after issuance of the denial

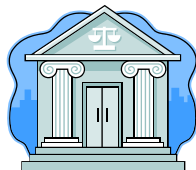
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Litigation: Cases in Federal District Court

- ▶ Once an administrative claim has been denied by HHS/OGC, the claimant must file suit within six months in the appropriate Federal district court or the action will be barred
- ▶ Cases are heard in Federal district court without a jury and they are defended by the Department of Justice (DOJ)



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Premature Lawsuits

- ▶ Claims erroneously filed in State court (in lieu of filing an administrative claim with HHS)
- ▶ Claims erroneously filed in State court less than six months after filing an administrative claim with HHS.



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Addressing Premature Lawsuits

- ▶ The health center or free clinic should fax or e-mail a copy of the documentation to OGC
- ▶ Have private counsel arrange to obtain at least a 60-day extension from the state court to answer the complaint.
- ▶ Call or e-mail OGC to discuss how to proceed

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All State Court Complaints and Notices of Intent Should be Sent Immediately Upon Receipt to:

U.S. Department of Health & Human Services
Office of the General Counsel
General Law Division
330 Independence Ave., S.W.
Room Number 4760
Mail Stop: Capitol Place
Washington, D.C. 20201
Phone : 202-233-0233
Fax: 202-233-0227
E-mail: gcgl@hhs.gov

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How to Avoid Premature Lawsuits

In order to help avoid premature lawsuits, HRSA strongly suggests that FTCA deemed health centers add the following language to their websites:

This health center is a Health Center Program grantee under 42 U.S.C. 254b, and a deemed Public Health Service employee under 42 U.S.C. 233(g)-(n).

**For more information, please see "Notice to FTCA Deemed Health Centers" in the handouts and on the conference webpage:
<https://members2.ecri.org/Components/HRSA/pages/virtualconference2013.aspx>.*

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Statute of Limitations

- ▶ A claim SF-95 must be presented within two (2) years after the claim accrues.



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Other Considerations

- ▶ HIPAA (especially if behavioral health records)
- ▶ Follow the center’s media response/crisis communication plan (seek legal and public relations advice, as appropriate)
- ▶ Consider the possibility of related claims
- ▶ Review any gap insurance policies

See PIN 2011-01 for more information

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Case Outcomes

- ▶ Settlement
- ▶ Judgment for the United States or against the United States
- ▶ Notification of health center of paid claims

See PIN 2011-01 for more information

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Other Requests for Testimony

- ▶ Touhy regulation (45 CFR Part 2) (2008) prohibits Federal employees from giving testimony without prior approval by the appropriate HRSA Administrator.
- ▶ The regulation applies to:
 - Current and former employees
 - Qualified contractors of covered entities

See PIN 2011-01 Section O of FTCA Policy Manual for more information

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Touhy Regulation

- ▶ Develop policies and procedures in line with PIN 2011-01 to address requests for testimony by health center employees
- ▶ Contact the HHS Office of General Counsel/General Law Division to determine if the Touhy regulation applies

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Lessons Learned

- ▶ Familiarize yourself with PIN 2011-01
- ▶ Understand your role in the claims process
- ▶ HRSA does not provide a claims history for providers. To obtain a claims history in the form provided by the National Practitioner's Data Bank, please access their website at:
<http://www.npdb-hipdb.hrsa.gov/>

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BPHC Helpline

- ▶ BPHCHelpline@hrsa.gov
- ▶ 1-877-974-2742 (1.877.974.BPHC)

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Resources

- ▶ PIN 2011-01 (Health centers)
- ▶ PIN 2011-02 (Free clinics)
- ▶ For updates on FTCA
- ▶ Federal Tort Claims Act (FTCA) Health Center Policy Manual
 - Section I: Eligibility and Coverage
 - Section II: Claims and Lawsuits
 - Section III: AppendixSee: <http://bphc.hrsa.gov/policiesregulations/policies/pdfs/pin201101manual.pdf>
- ▶ For updates on FTCA see
<http://bphc.hrsa.gov/ftca/about/didyouknow.html>

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- ▶ ECRI, Legal Basics, at:
<https://members2.ecri.org/Components/HRSA/Pages/LB1.aspx#responding>
- ▶ ECRI, Regulations and Standards, at:
<https://members2.ecri.org/Components/HRSA/Pages/RS1.aspx>
- ▶ ECRI, Managing Administrative Risks at:
<https://members2.ecri.org/Components/HRSA/Pages/OA2.aspx>

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