

# **Federal Tort Claims Act (FTCA) and Utah's Medical Candor Act**

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# Disclaimer

Today's presentation is general in nature and should not be taken as legal advice.



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# FTCA

Federal Tort Claims Act



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# Pre-1946

- Any US citizen injured by the negligence of a federal employee had to petition Congress for relief
  - John Quincy Adams: “A deliberative assembly is the worst of all tribunals for the administration of justice.”
  - Multiple sessions of Congress disliked process but failed to act



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# Federal Tort Claims Act

- Title IV of the Legislative Reorganization Act of 1946
  - Allowed federal government to be sued for negligent acts of its employees (with limits)
- FQHCs: Federally Supported Health Centers Assistance Act (FSHCAA) signed in 1992
  - HC patients must use this to sue for medical malpractice
  - Deeming process
  - Made permanent in 1995

# HRSA's FTCA Manual

- Current version published in 2014  
<https://bphc.hrsa.gov/sites/default/files/bphc/technical-assistance/ftcahc-policy-manual.pdf>
- HRSA Compliance Manual published in August 2017  
(updated in August 2018)
- Where there are conflicts between the two, the Compliance Manual supersedes the FTCA manual



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# What does FTCA cover?

Medical malpractice events for:

- Deemed HCs
  - Deemed individuals – Board, employees, some contractors
- Covered activities
  - In individual's scope of employment;
  - Within the scope of the health center's project; and
  - During the provision of services to **health center patients** and, in certain circumstances, to non-health center patients.
- Occurrence coverage – no need for tail coverage

# What doesn't FTCA cover?

Lots of things, including:

- Health Centers that are not deemed
- Events that do not meet all FTCA requirements
- Ineligible contractors
- Events besides medical malpractice, such as:
  - Assault;
  - Financial misconduct; etc.



# Scope of Employment

- In a written job description
  - Categories of care, not lists of procedures
  - Job description must comply with licensing/certification limits
- Must include services provided outside of the health center – especially hospital coverage, cross-coverage, and emergency coverage



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# Scope of Project

- Includes health center sites, services, providers, service area, and target populations
  - Service area – where most of the health center's patients live
  - Target populations – must include medically underserved



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# Provider-patient relationship is formed when:

- Individuals access care from provider at health center site
  - Need not be permanent patient
  - Need not be living in health center's service area
- Individuals receive triage services by phone or in-person even if no care is received yet
  - Person intends to become a health center patient

# When is a non-patient covered by FTCA?

- Non-patient exceptions must be followed EXACTLY as written\*
  - Community health-related events
  - Outreach to underserved communities
  - Hospital, cross-coverage, and certain emergencies – when spelled out in employment contracts and hospital agreements
- Can request particularized determination

\*FTCA manual or September 13, 2013 Federal Register

# Contractors – who's covered

- Full-time contractors – 32.5 hours a week or more
- Part-time contractors in the following fields: Family Medicine, general Internal Medicine, general Pediatrics, or OB/Gyn
- Contractor must bill as individual and not business entity
  - Must have written contract between health center and provider

# What about volunteers?

- Historically these were not covered
- 21<sup>st</sup> Century Cures Act provided volunteer FTCA deeming process
- Set to expire at end of September
  - Hopefully, this will get renewed... but this is not guaranteed

# Other people and things not covered include:

- Students (should bring coverage with them)
- Contracts between health center and corporations
- Indemnification of other organizations
- Moonlighting of covered providers
- Prior acts
- Failure to have written employment contracts with providers

# FTCA Process

When patients sue



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# Patient gives notice of lawsuit – what's next?

- FTCA manual: Get notice to HHS Office of General Counsel
- **But** Utah requires prelitigation hearing prior to plaintiff filing a suit
  - Without a lawsuit filed, OGC does not act
  - Touhy regulations

# Touhy Regulations

- Applies when physician or other provider is asked to give testimony in litigation when neither they nor the federal government is a party
- Prohibits federal employees from giving testimony (including records) without prior approval from their agency head (HRSA)
- If you receive pre-litigation notice, send it to HHS OGC
  - You will not hear back before the pre-litigation hearing



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# What to do at the pre-litigation hearing

1. Appear at the stated time and place unless advised by OGC that responding to the subpoena would be inappropriate;
2. Produce a copy of the Touhy regulations; and
3. Respectfully decline to testify or produce any documents on the basis of the regulations

Or, if the plaintiff's attorney knows you are a deemed entity or individual, ask them to agree to waive the pre-litigation hearing

# When else might Touhy apply?

Requests for records or testimony:

- Health center patient is suing another provider, hospital, etc.
  - Possible/probable you may be brought into lawsuit
- What about when a health center patient is involved in civil issue?
  - Generally OK to respond
  - Be wary of questions regarding your care of the patient

# Record Hold

- All records related to the lawsuit are on hold for the duration of the process
  - Medical, lab, billing, communications records, etc.
  - Policies and procedures in place at time of event
  - Credentialing/privileging records of all involved employees
  - Responsibility lies with senior administration
- Notify all employees with potential access to the records of the 'hold'
  - Re-notify employees every three months

# HHS Administrative Review

HHS gathers medical records and coverage information

(1) Was this a covered event?

(2) Three outcomes for medical review:

(a) Settlement offered and accepted; case closed

(b) Denial sent to plaintiff; if no challenge in 6 mos, case closed

(c) Plaintiff does not accept settlement OR challenges denial

# Next Step: HHS DOJ

DOJ will defend the case – 3 outcomes:

- (1) Settlement offered and accepted; case closed
- (2) Case is dismissed without settlement offer; case closed
- (3) Lawsuit decided by federal judge but no jury
  - (1) Favorable to plaintiff
  - (2) Favorable to health center



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# Medical Claims Review Panel

- Review cases
  - Standards of care
  - Provider competence
  - Other causal factors
- Was the standard of care breached?
  - If yes, report provider to NPDB
  - If not, often no report to NPDB



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# What does gap insurance/coverage do?

Fills in what FTCA does not cover, e.g.:

- (1) Outside coverage issue not spelled out in employment contract
- (2) Something HHS deems to be out of scope
- (3) Volunteers, ineligible contracted providers
- (4) Residents, students
- (5) Teaching activities
- (6) Indemnification of third parties

But read the coverage terms to know for sure



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# COVID-19 particularized determination

- Coverage of non-health center patients expanded for pandemic-related care
  - Activities: “Prevent, prepare or respond to COVID-19...”
  - Services provided in person (on- or offsite) or via telehealth
  - Likely for duration of Public Health Emergency (but that is not clear)

# Utah Medical Candor Act

A brief introduction



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# What is it?

- Enacted in May 2022 as HB 344
- Voluntary process for providers to undertake when a patient experiences an adverse event
- <https://www.callcopic.com/resource-center/guidelines-tools/utah-medical-candor-act-resources>



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# How does it work?

- Provider sends written notice to patient/patient's family within 365 days of adverse event
  - Patient/family can choose to engage or not
  - Patient/family can withdraw at any stage
- If patient/family engages, any communications, materials, etc. exchanged are inadmissible in a Utah court



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# Patients/families can get compensation

- Offer must be in writing
- If patient/family does not have an attorney:
  - Must advise patient/family to seek legal representation to review offer
  - Must notify patient/family about possible need to make payments for expenses paid by third parties (e.g., private insurance, Medicaid)
- Offer can include release of further liability



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# When Medical Candor process cannot happen:

- If a summons or complaint (lawsuit) has already been filed
- If a written demand for compensation has already been filed
- If there is no injury or suspected injury to the patient



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# Can FQHC providers use this?

- Yes, per the terms of the law, but...
- No HHS representation
  - Gap coverage?
- May lose privilege protection in federal court



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# Federal privilege protection uncertain

- Rules of evidence dictate what can/cannot be admitted in court
- All states have peer review protection laws
  - State rules of evidence = peer review records protected
- There is not a federal peer review protection law
  - Federal evidence rules (e.g., FTCA) = peer review records may not be protected
- Medical Candor records? Unknown



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# Should FQHC providers do this?

- Maybe not
- At least for now
- More to come...



# QUESTIONS?



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