

The Federal Tort Claims Act Program

Rhode Island Health Center Association

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Martin J. Bree

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PRESENTER: MARTIN J. BREE



**Contact
Information:**
mbree@ftlf.com
202.466.8960

- Marty's practice involves general health law matters with a focus on professional liability and FTCA problems as well as other grant-related compliance issues.
- Marty was a Commissioned Officer of the U.S. Public Health Service from 1976 to 2004. He started his career in Philadelphia as a project officer working with Health Centers and the National Health Service Corps. During his career he held various positions in the HRSA's Philadelphia, New York, Chicago and Kansas City Regional Offices. From 1998 through 2004 he directed the Health Center FTCA program.
- From 2004 to 2010, Marty was the Senior Partner in the Triton Group, LLC providing technical assistance to Health Centers, HRSA, and other federal and state agencies on medical malpractice, risk management and the FTCA program.

AGENDA

08:00 – 09:00	The FTCA Program – How it protects you (the program itself, its rules of coverage and issues to be aware of).
09:00 – 09:10	Break
09:10 – 09:45	The FTCA Program in Action – How it works in practice.
09:45 – 10:00	Gap Insurance
10:00 – 10:10	Break
10:10 – 10:30	Current cases in the FTCA program
10:30 – 11:00	COVID-19 Lessons
11:00 – 11:10	Break
11:10 – 11:15	FTCA Deeming Application
11:15 – 11:45	Issues related to the FTCA Program (Medical Marijuana, Title X Rules, Confidentiality, etc.)
11:30 – noon	Questions and discussion

The Federal Tort Claims Act

FEDERAL TORT CLAIMS ACT



July 28, 1945 – A B-25 Mitchell Bomber, piloted by LTC William Smith, crashed into the Empire State Building causing 14 deaths – the start of the story of the Federal Tort Claims Act.

FEDERAL TORT CLAIMS ACT

- Signed into law on June 25, 1946.
- Waived the sovereign immunity of the United States allowing individuals to sue the United States for negligence of government officers and employees.
- This waiver is limited. The government maintains its sovereign immunity for a variety of offenses committed by its employees, *e.g.*, intentional torts, discretionary functions.
- Plaintiffs must follow specific statutory rules to be successful in seeking monetary damages.

The Federally Supported Health Centers Assistance Act

A BRIEF HISTORY... 1992 LEGISLATION

- In 1992 Congress passes the Federally Supported Health Centers Assistance Act (FSHCAA) of 1992.
- FSHCAA permits health centers and certain staff to be deemed **Public Health Service employees**.
 - Grants **immunity** from suit for professional services (medical, surgical, dental and related activity).
 - Patient's only remedy is a claim under the FTCA.

A BRIEF HISTORY... 1992 LEGISLATION

Flaws with the FSHCAA of 1992

- No advance coverage
- Hospital Acceptance of Coverage
- Expiration of the law in 1995

Regulations released in 1995 attempted to remedy these problems.

A BRIEF HISTORY... 1995 LEGISLATION

Federally Supported Health Centers Assistance Act (FSHCAA) of 1995:

- Signed into law December 26, 1995
- Clarified the 1992 Act (in some respects)
- Made the program permanent
- Incorporated some of the prior regulations into law

1995 – 2016 (PINS & PALS)

PIN 2011-01, the **FTCA Manual** (January 3, 2011).

- “The primary source for information on FTCA for health center program grantees...”(PIN 2011-01).
- BUT “if there are any conflicts between its content and FTCA law **as interpreted by the courts** (including federal statutes, regulations, and case law), the law prevails” (PIN 2011-01). (Updated July 12, 2014)

Updated and Reissued on July 21, 2014 as the “**Federal Tort Claims Act Health Center Policy Manual**”.

- Some requirements of FTCA Policy Manual changed and superseded by Health Center Program Compliance Manual published in August 2017 and updated in August 2018.

1995 – PRESENT (2013: A NEW REGULATION)

- FSHCAA and 42 CFR section 6.6(d) authorize FTCA coverage for services to non-health center patients in certain situations.
- FTCA Program regulatory amendments (September 23, 2013), clarify, and add to the situations identified in the September 1995 Notice.

1995 – PRESENT (2016: VOLUNTEERS ADDED)

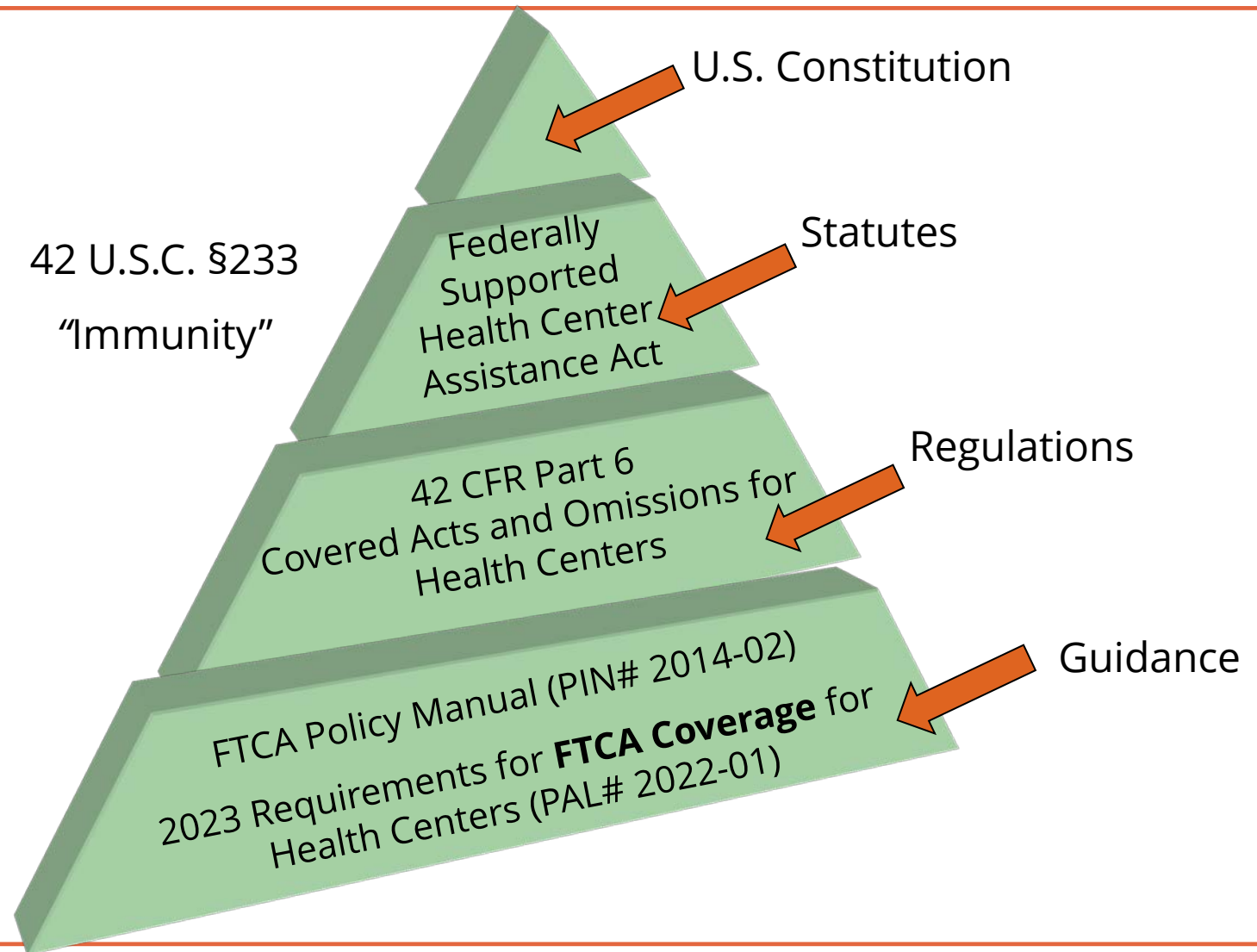
21st Century Cures Act provides for protection for volunteers in health centers (42 U.S.C. 233(q))

- Expires September 30, 2022

A BRIEF LEGAL PRIMER

How do FSHCAA, the regulations, the PINs and PALs, and the FTCA Policy Manual interact with each other?

A BRIEF LEGAL PRIMER



FEDERALLY SUPPORTED HEALTH CENTERS ASSISTANCE ACT – IMMUNITY

What is immunity?

Section 233(a) – The remedy against the United States provided by Sections 1346(b) and 2672 of Title 28, or by alternative benefits provided by the United States where the availability of such benefits precludes a remedy under Section 1346(b) of Title 28, for **damage for personal injury, including death, resulting from the performance of medical, surgical, dental, or related functions, including the conduct of clinical studies or investigation**, by any commissioned officer or employee of the Public Health Service **while acting within the scope of his office or employment**, shall be exclusive of any other civil action or proceeding by reason of the same subject-matter against the officer or employee (or his estate) whose act or omission gave rise to the claim.

FEDERALLY SUPPORTED HEALTH CENTERS ASSISTANCE ACT – IMMUNITY

Key Components of Immunity:

- Damages for personal injury or death
- From the performance of medical, surgical, dental, or related functions
- Within the *scope of employment*

FEDERALLY SUPPORTED HEALTH CENTERS ASSISTANCE ACT – IMMUNITY

What's NOT in FSHCAA:

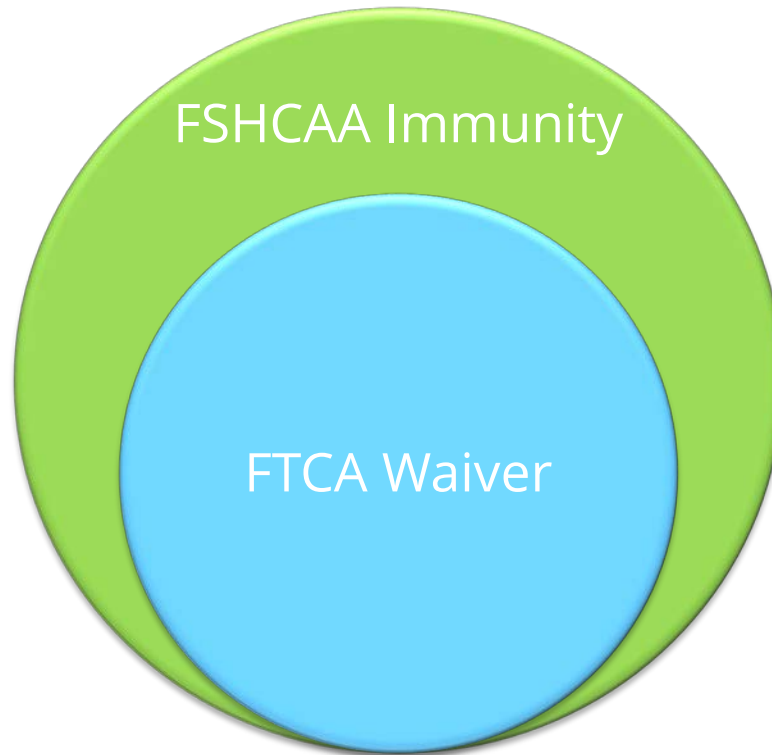
- Any language regarding:
 - Sites
 - Services
 - Scope of Project
 - Form 5A, B, C

FEDERALLY SUPPORTED HEALTH CENTERS ASSISTANCE ACT – IMMUNITY

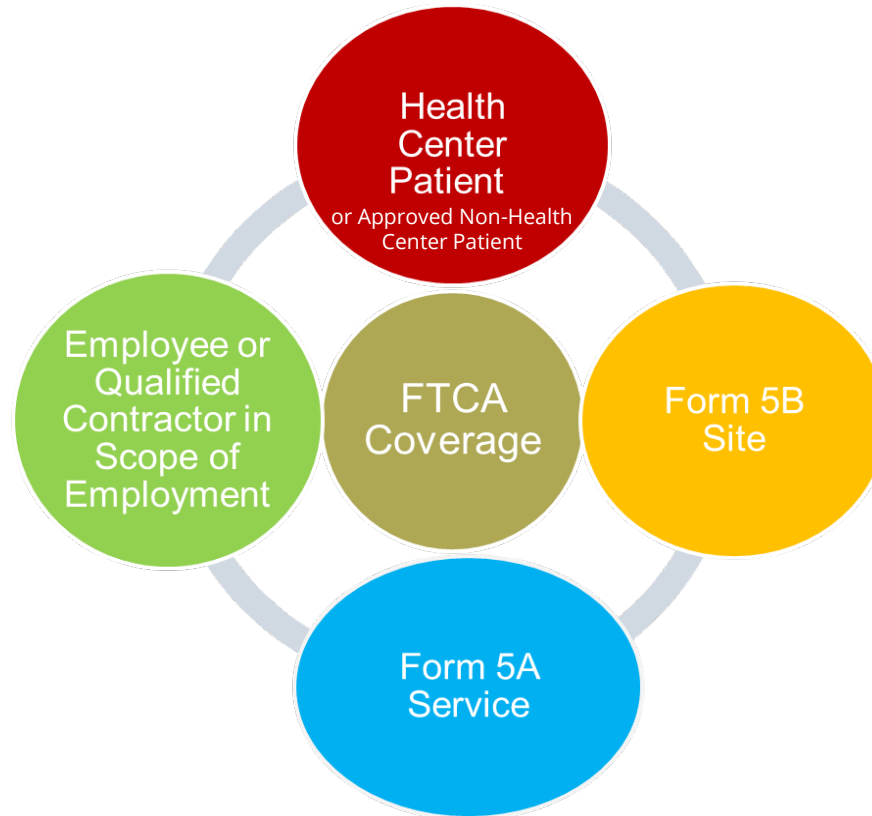
Reasons why the FTCA Program fails to achieve its objective eliminating the need for malpractice insurance

- It's Flaws:
 - Disconnect between the concepts of waiver and immunity
 - United States waives its sovereign immunity to permit suits against it (FTCA)
 - Public Health Service employees are immune from suit for actions in scope of employment (FSHCAA)
- The FTCA Program is implemented by policy/guidance “requirements” (an oxymoron).

FEDERALLY SUPPORTED HEALTH CENTERS ASSISTANCE ACT – IMMUNITY



FEDERALLY SUPPORTED HEALTH CENTERS ASSISTANCE ACT – IMMUNITY



FEDERALLY SUPPORTED HEALTH CENTERS ASSISTANCE ACT – IMMUNITY

- Who has immunity?
 - Deemed health centers;
 - Board members, officers, directors;
 - All employees, full-time or part-time;
 - Full-time contract providers (at least 32.5 hours per week for the period of the contract); and
 - Part-time contract provider of services in the fields of family practice, ob-gyn, general internal medicine, or general pediatrics.
 - Volunteers sponsored by deemed health centers who have been approved by HRSA. (21st Century Cures Act)

FEDERALLY SUPPORTED HEALTH CENTERS ASSISTANCE ACT – IMMUNITY

- Contractors
 - 42 U.S.C. §233(g)(1)(A) “...any contractor of such an entity who is a physician, or other licensed or certified health care practitioner.”
 - 42 U.S.C. §233 (g)(5) “an individual may be considered a contractor.”

FEDERALLY SUPPORTED HEALTH CENTERS ASSISTANCE ACT – IMMUNITY

Scope of Employment

- Governed by state law.
- Acting on behalf of the deemed entity.
- Documentation should be “of sufficient detail to provide clarity in determining if the individual in question was acting within the scope of his employment” and therefore “covered under FSHCAA and the FTCA.” (FTCA Policy Manual)

FEDERALLY SUPPORTED HEALTH CENTERS ASSISTANCE ACT – IMMUNITY

- HRSA Policy: Immunity limitations
 - To actions within the **Scope of Project**.
 - Activities must be *“within the approved Federal section 330 grant project, which includes sites, services, and other activities and locations as defined in the covered entities grant application and any subsequently approved change in scope requests”*. PIN 2014-02 (FTCA Manual)
 - **But**, *“Only acts or omissions related to the grant-supported activity of entities are covered”* – 42 CFR Part 6 §6.6(d) published May 8, 1995).

Only services to the covered entity’s patients and, in certain circumstances, to non-health center patients.

FEDERALLY SUPPORTED HEALTH CENTERS ASSISTANCE ACT – IMMUNITY

“Scope of Project”

- Forms 5A, 5B and 5C.
- PIN 2008-01, *“Defining Scope of Project & Policy for Requesting Changes”*.
- FTCA coverage for new services and sites is dependent on HRSA/BPHC approval of a change in scope.

FEDERALLY SUPPORTED HEALTH CENTERS ASSISTANCE ACT – IMMUNITY

- Services
 - Only services listed in Form 5A in EHB are covered.
 - Form 5A lists services, not procedures.
 - See *Service Descriptors for Form 5A: Services Provided and Service Delivery Methods*.
 - To add or delete a service, a health center **must** go through the “Change in Scope” process.

FEDERALLY SUPPORTED HEALTH CENTERS ASSISTANCE ACT – IMMUNITY

- Sites
 - Only the provision of services at sites within the scope of project (with exceptions) are covered.
 - Exceptions (from FTCA Health Center Policy Manual).
 - Form 5C, Intermittent sites (PIN 2008-01).
 - Only care delivered to **existing health center patients** at Form 5C sites is covered (with exceptions).

FEDERALLY SUPPORTED HEALTH CENTERS ASSISTANCE ACT – IMMUNITY



42 U.S.C. 233

Statute

"scope of employment"

42 CFR Part 6

Regulations

"grant supported activity"

Policy Manual

"scope of project"

FEDERALLY SUPPORTED HEALTH CENTERS ASSISTANCE ACT – IMMUNITY

- Who is a “Health Center Patient”?
- Turns on the establishment of a **patient/provider relationship which occurs when (per FTCA Policy Manual)**:
 - “Individuals access care for initial or follow-up visits at approved sites that are owned or operated by the covered entity”;
 - “Individuals access care at approved sites even if they are not permanent residents of the service area or may only be receiving care temporarily”; or
 - “Health center **triage services** are provided by telephone or in person, even when the patient is not yet registered with the covered entity but is intended to be registered”.

FEDERALLY SUPPORTED HEALTH CENTERS ASSISTANCE ACT – IMMUNITY

- No immunity for care to non-health center patients unless approved in advance by Secretary of DHHS.
- Except:
 - HHS has pre-approved situations where care is delivered to non-health center patients.
 - These examples must be **strictly interpreted**. You must be “**painstakingly exact**” to make certain that what you do “fits squarely” within the examples.
 - Examples are found in September 23, 2013 Federal Register Notice.

FEDERALLY SUPPORTED HEALTH CENTERS ASSISTANCE ACT – IMMUNITY

- Examples of care to non-health center patients that the Secretary has approved:
 - School-based clinics
 - School-linked clinics
 - Health fairs
 - Immunization campaigns
 - Migrant camp outreach
 - Homeless outreach
 - Periodic hospital call or emergency room coverage
 - Cross-coverage activities
 - Individual emergencies

FEDERALLY SUPPORTED HEALTH CENTERS ASSISTANCE ACT – IMMUNITY

No immunity:

- Volunteers (unless specifically applied for and approved under 233(q)).
- Incidents typically covered by state Good Samaritan laws.
- Providers billing directly (*for exceptions, see FTCA Policy Manual*) ?
- Part-time contract providers not in primary care specialties.
- Health professional students.

FEDERALLY SUPPORTED HEALTH CENTERS ASSISTANCE ACT – IMMUNITY

No Immunity:

- Contracts between a deemed health center and a corporation (including PCs).
- Sub-grantees (unless an application has been submitted for them by the grantee).
- Third parties seeking indemnification.
- Providers acting outside the scope of project.
- Providers acting outside the scope of employment.

FEDERALLY SUPPORTED HEALTH CENTERS ASSISTANCE ACT – IMMUNITY

No Immunity:

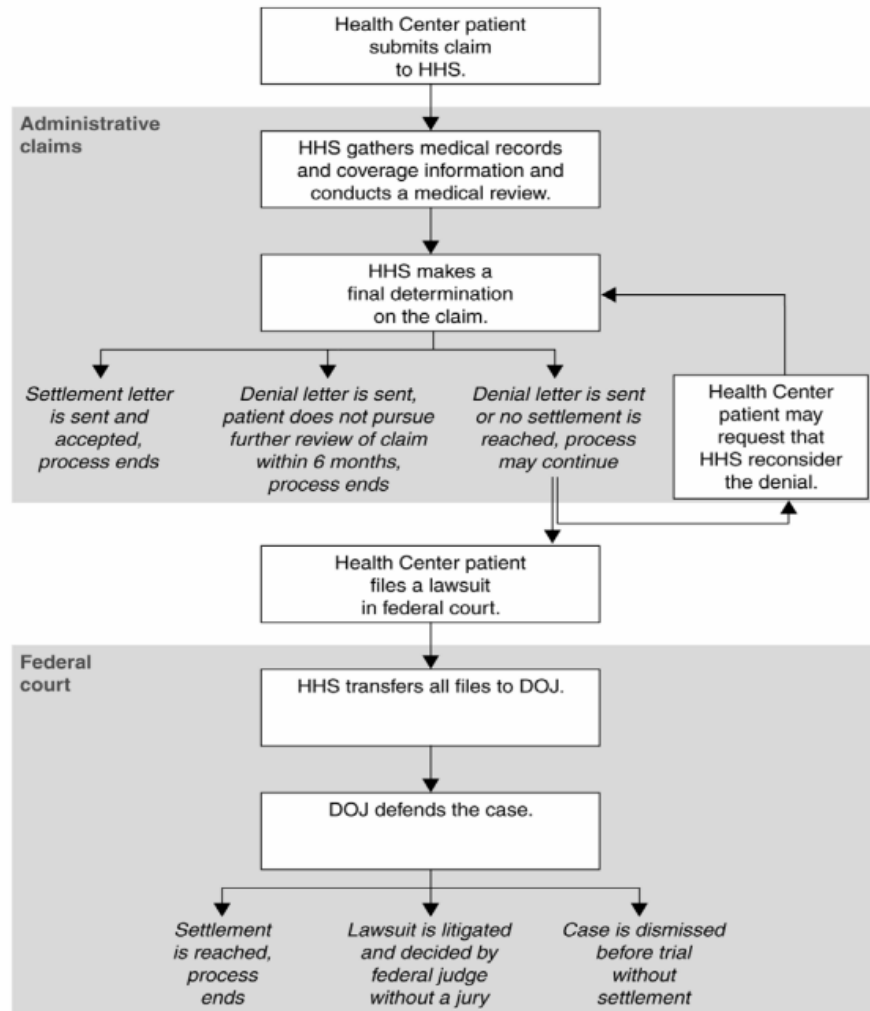
- Prior Acts – incidents occurring before initial deeming or hiring
- Moonlighting (scope of employment)
- Intentional torts
- Criminal activities
- General Liability (e.g., motor vehicle accidents, slip and fall)
- Failure to have written employment agreements
- Contracts with hospitals and other providers of services

Time for a Break!

**We will return in 10
minutes**

FTCA Claims Process

FTCA CLAIMS PROCESS/PROCEDURE



FTCA CLAIMS PROCESS/PROCEDURE

What's an FTCA administrative claim?

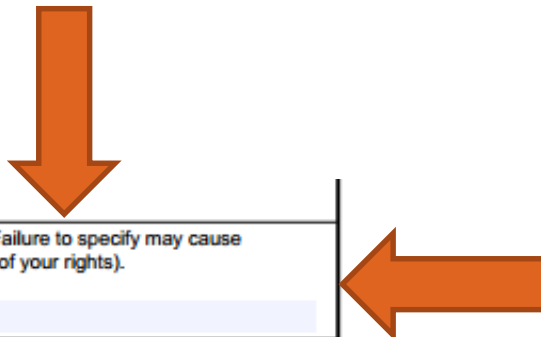
A claim against the United States under the Federal Tort Claims Act for property damage, **personal injury**, or **death** allegedly caused by a **federal employee's negligence** or wrongful act or omission occurring **within the scope of the employee's federal employment**.

A claim shall be deemed to have been presented when a federal agency (HHS) receives from a claimant, his duly authorized agent, or legal representative, an executed **Standard Form 95** or other written notification of an incident, accompanied by a claim for money.

FTCA CLAIMS PROCESS/PROCEDURE

CLAIM FOR DAMAGE, INJURY, OR DEATH		INSTRUCTIONS: Please read carefully the instructions on the reverse side and supply information requested on both sides of this form. Use additional sheet(s) if necessary. See reverse side for additional instructions.		FORM APPROVED OMB NO. 1105-0008	
1. Submit to Appropriate Federal Agency:			2. Name, address of claimant, and claimant's personal representative if any. (See instructions on reverse). Number, Street, City, State and Zip code.		
3. TYPE OF EMPLOYMENT <input type="checkbox"/> MILITARY <input type="checkbox"/> CIVILIAN	4. DATE OF BIRTH	5. MARITAL STATUS	6. DATE AND DAY OF ACCIDENT	7. TIME (A.M. OR P.M.)	
8. BASIS OF CLAIM (State in detail the known facts and circumstances attending the damage, injury, or death, identifying persons and property involved, the place of occurrence and the cause thereof. Use additional pages if necessary).					
9. PROPERTY DAMAGE					
NAME AND ADDRESS OF OWNER, IF OTHER THAN CLAIMANT (Number, Street, City, State, and Zip Code).					
BRIEFLY DESCRIBE THE PROPERTY, NATURE AND EXTENT OF THE DAMAGE AND THE LOCATION OF WHERE THE PROPERTY MAY BE INSPECTED. (See instructions on reverse side).					
10. PERSONAL INJURY/WRONGFUL DEATH					
STATE THE NATURE AND EXTENT OF EACH INJURY OR CAUSE OF DEATH, WHICH FORMS THE BASIS OF THE CLAIM. IF OTHER THAN CLAIMANT, STATE THE NAME OF THE INJURED PERSON OR DECEDENT.					

FTCA CLAIMS PROCESS/PROCEDURE



12. (See instructions on reverse).				AMOUNT OF CLAIM (in dollars)	
12a. PROPERTY DAMAGE	12b. PERSONAL INJURY	12c. WRONGFUL DEATH	12d. TOTAL (Failure to specify may cause forfeiture of your rights).		
I CERTIFY THAT THE AMOUNT OF CLAIM COVERS ONLY DAMAGES AND INJURIES CAUSED BY THE INCIDENT ABOVE AND AGREE TO ACCEPT SAID AMOUNT IN FULL SATISFACTION AND FINAL SETTLEMENT OF THIS CLAIM.					
13a. SIGNATURE OF CLAIMANT (See instructions on reverse side).			13b. PHONE NUMBER OF PERSON SIGNING FORM	14. DATE OF SIGNATURE	
CIVIL PENALTY FOR PRESENTING FRAUDULENT CLAIM The claimant is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, plus 3 times the amount of damages sustained by the Government. (See 31 U.S.C. 3729).			CRIMINAL PENALTY FOR PRESENTING FRAUDULENT CLAIM OR MAKING FALSE STATEMENTS Fine, imprisonment, or both. (See 18 U.S.C. 287, 1001.)		

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 28 CFR 14.2

FTCA CLAIMS PROCESS/PROCEDURE

How the Claims Process Should Work:

- The plaintiff files an **administrative claim** against the United States.
- The HHS Office of General Counsel (OGC) notifies the health center about the claim and the health center provides OGC with all of the necessary documentation.
- HHS gets expert opinion on standard of care.
- HHS reviews the claim and may deny it, pay it, or offer a settlement.

FTCA CLAIMS PROCESS/PROCEDURE

How the Claims Process Should Work (continued):

- If HHS denies the claim or does not act on a claim within **six months**, the plaintiff may file a lawsuit in federal court.
- When suit is filed, the case is transferred from DHHS to the DOJ. DOJ may attempt to settle the suit, otherwise the lawsuit will proceed in litigation against the **United States** in federal court.
- If payment is made on an FTCA claim, the Medical Claims Review Panel (MCRP) determines whether the standard of care was met for purposes of National Practitioner Data Bank (NPDB) reporting.

FTCA CLAIMS PROCESS/PROCEDURE

How the Claims Process Usually Works:

- The plaintiff files a medical malpractice lawsuit against the health center in state court (referred to as a “premature lawsuit” or “preemie”).
- The health center notifies HHS OGC of the lawsuit and provides OGC with all of the necessary documentation **as quickly as possible**.
- The health center proceeds in state court (motions to extend deadlines, etc...) while waiting for the OGC to verify the applicability of the FTCA to a particular claim.
- HHS verifies the applicability of the FTCA to a claim and refers the case to the DOJ, who assigns an Assistant U.S. Attorney (AUSA) to the case.

FTCA CLAIMS PROCESS/PROCEDURE

How the Claims Process Usually Works (continued):

- The AUSA removes the case to federal court and files a motion to dismiss the case against the health center.
- The U.S. District Court dismisses the health center from the case and substitutes the United States as the defendant.
- The AUSA moves to dismiss the case against the United States for plaintiff failing to exhaust his/her administrative remedies.
- The U.S. District Court dismisses the case against the United States and the case proceeds as an FTCA claim as described in the “How the Claims Process Should Work” slide.

FTCA CLAIMS PROCESS/PROCEDURE – FROM OGC LETTER

PRACTITIONER NARRATIVE

Practitioner Information				
Practitioners Name:				
Gender:			Date of Birth:	
School:			Year of Graduation:	
School:			Year of Graduation:	
School:			Year of Graduation:	
Home Address:				
Organization Name:				
Work Address:				
Practitioner Field of Practice				
	Physician	Dentist	Allied Health	
Specialty:				
Board Certification & Year Certified:				
Certification:				
State's Licensed & License #:				
State's Licensed & License #:				
State's Licensed & License #:				
Patient Information				
Patient Name:				
Date of Birth:		Gender	Male	Female
Marital Status:	Married	Divorced	Widowed	Single
Employed ?	Yes	No	Treatment Dates:	
Narrative				
Provide an objective description of this patient's course of treatment under your care. Include the patient's chief complaint, the plan of care, a description of the incident, and the patient's present status, if known. Also indicate any other factors that you consider relevant to this incident (i.e., patient compliance; conversations subsequent to the care provider, etc.)				



FTCA CLAIMS PROCESS/PROCEDURE

OGC LITIGATION HOLD LETTER

- Identify all employees who have information related to the litigation and provide it to OGC.
- Issue written notification to all health center employees (sample litigation hold notice provided by OGC).
- Identify and provide OGC with a list of relevant health center IT and HIMs supervisors who have responsibility for IT systems. Send IT department litigation hold memo and discuss record retention, backup practices and related items.
- Provide OGC with information related to the health center's document retention policies.
- Re-issue litigation hold notice to all health center employees every **three months**.
- Provide OGC with a copy of the health center's litigation hold notice.

FTCA CLAIMS PROCESS/PROCEDURE

OGC LITIGATION HOLD LETTER

- All medical records.
- All billing records.
- All communications between patient and health center (and any of its employees).
- All communications between any third party and the health center (and any employees concerning patient's medical care and treatment).
- All records pertaining to health center's employee(s) named in the complaint licensure, certification, and employment history with the health center, including any personnel files maintained by the health center.
- Any documentation the health center and/or its employees distributed to the patient.
- Any policies of the health center in effect during the time the patient was being treated by the health center that bear upon standards for medical treatment.

FTCA CLAIMS PROCESS/PROCEDURE

Who to Contact if You Receive Notice of a Claim or Lawsuit:

U.S. Department of Health and Human Services

Office of the General Counsel

General Law Division

Attention: CLAIMS

330 C Street SW

Switzer Bldg, Suite 2600

Washington D.C. 20201

202-619-2155

202-619-2922 (fax)

HHS-FTCA-Claims@hhs.gov

****IMPORTANT- CONFIRM RECEIPT OF
ALL DOCUMENTS E-MAILED OR FAXED**

CLAIMS DATA

Very limited claims data has been published. We do know:

- Lack of board certification may be associated with higher rate of claims.
- Common reasons for losses: labor and delivery complications, missed diagnosis (cancer), mis-prescribing of medication, delayed treatment, lost to follow-up.
- Documentation is still important.
- Approximately 680 claims filed in CY 2018.

MEDICAL CLAIMS REVIEW PANEL

Purpose:

The MCRP assists HHS in meeting its responsibility to provide quality health care in its facilities and by its practitioners. The collective clinical knowledge and expertise of the membership shall be applied to the review of claims of medical negligence and substandard practice, addressing issues such as standards of care and provider competence.

MEDICAL CLAIMS REVIEW PANEL

Function:

After a claim has been paid pursuant to a settlement or adverse judgment, identify the clinician(s) who provided the treatment giving rise to the claim and determine whether the standard of care was breached.

MEDICAL CLAIMS REVIEW PANEL

Reports:

The Chairperson of the MCRP shall transmit a report to the agency Claims Officer on each claim reviewed. This report shall include the name(s) of the provider(s) who provided the treatment giving rise to the claim for use in the event of a report to the NPDB. In the event the Panel determines that the adverse event was the result of a systems failure, no provider of record shall be named.

NPDB – MEDICAL MALPRACTICE

- All malpractice payments, in any amount, made for the benefit of any type of licensed practitioner:
 - Both settlements and judgments.
 - No dollar threshold for reporting.
 - A report does not mean that actual malpractice occurred, only that a payment was made.
- HRSA voluntarily participates in the NPDB.

NPDB – HRSA REPORTING TO NPDB

- In general, if the HHS MCRP reviews an FTCA claim and finds that the standard of care was met, despite a payment being made in settlement of the claim, that payment is not reported to the NPDB.

Gap Insurance

GAP INSURANCE

- Summary of Potential Gaps in FTCA
 - Prior Acts – (“Claims Made” Policies).
 - Moonlighting Activities – outside scope of employment with health center.
 - Coverage for part-time contractors (working less than 32.5 hours per week) in fields other than FP, IM, OB, and Pediatrics.
 - Volunteers (but see 233(q)).
 - Activities not approved/listed under the grantees scope of project (See Form 5, Part A).

GAP INSURANCE

- Potential Gaps (continued)
 - Coverage for Residents in training.
 - Coverage for contract professionals who are employed by a corporation that contracts with the health center.
 - Teaching activities off health center premises on non-health center patients, or with non-health center employees.
 - Treatment of non-center patients in hospital or in hospital emergency room when not required by the hospital to obtain admitting privileges.
 - Other care to non-health center patients (See Federal Tort Claims Act Health Center Policy Manual for definition of health center patient).

GAP INSURANCE

- Potential Gaps (continued)
 - Indemnification of third parties (Managed Care and other Contracts).
 - Alleged criminal activities (sexual abuse or molestation).

GAP INSURANCE

- Potential Gaps (continued)
 - Non-health center peer review.
 - Coverage for contracted (non-employed) healthcare providers who are not licensed or certified.
 - Strange coverage decisions.

GAP INSURANCE

- Potential Limitations of Gap Insurance:
 - Claims of discrimination.
 - Violations of civil rights.
 - Violations of the federal Anti-Kickback statute or False Claims Act.
 - Breach of electronic data security.
 - Violations that result in a fine, penalty, or other sanction.
 - Certain criminal or intentionally wrongful acts.

GAP INSURANCE

- Potential Limitations of Gap Insurance (continued):
 - Acts covered by the FSHCAA and the FTCA.
 - If dual coverage exists, the United States has a right of subrogation with respect to any FTCA claims.
42 U.S.C. §233(g)(2).
 - Violations of any statute, ordinance, or regulation that result in a fine, penalty, or other sanction (including attorney fees).
 - Employees or facilities not named in the policy.
 - Audits or investigations.

GAP INSURANCE

BUT:

While certain claims may not be covered under the basic gap insurance policy, the health center may be able to add coverage for various claims, employees, or facilities not included in the basic policy, in the form of a rider to the policy or complimentary policies.

Time for a Break!

**We will return in 10
minutes**

FTCA Case Law

NEGATIVE DECISIONS OF AGENCY

- Denial of **Deemed Status**:
 - Rejecting deeming application, **or**
 - Revoking deeming after FTCA Site Visit
- Denial of **FTCA Coverage** in Medical Malpractice Claim:
 - OGC determines that a particular malpractice claim is not covered by the FTCA, **or**
 - DOJ refuses to defend a claim that HHS OGC determines is covered by FTCA

OTHER CASES

- Coverage of health center physician providing **employee health services**.
- Disclosure of protected health information of health center **employee/breach of confidentiality**.
- Coverage of **case management services** (especially housing assistance).
- Coverage of care provided to a health center patient when **site does not appear in Form 5, Part B**.
- Coverage of health center physician for care provided when **default judgment is entered in state court**.
- Coverage of health center physician when **physician bills for service**.

OTHER CASES

- “Serial” plaintiffs in multiple states have threatened and filed suits alleging inaccessible websites to visually impaired persons in violation of the Americans with Disabilities Act (ADA).
- Suits filed against mental health providers following homicides by patient.
- Suits filed against health center physicians who providing services based on health center contracts with hospitals.

COVID-19 and FTCA

DETERMINATION OF COVERAGE FOR COVID-19 RELATED ACTIVITIES BY HEALTH CENTER PROVIDERS

COVID-19 Particularized Determination

*“This sets forth my determination, in accordance with 42 U.S.C. § 233(g)(1)(B) and (C), and under regulations set forth in 42 CFR § 6.6, that the provision of grant-supported health services by individuals who have been deemed as Public Health Service employees through the Health Center FTCA Program and the Health Center Volunteer Health Professional (VHP) FTCA Program, and **who provide grant-supported health services to prevent, prepare or respond to COVID-19** (including but not limited to, screening, triage, testing, diagnosis, and treatment) **to individuals who are not established patients of the health center, whether at the health center or offsite** (including at offsite programs or events carried out by the health center), and whether in person or through **telehealth**, benefits patients of these entities and general populations that could be served by these entities through community-wide intervention efforts within the communities served by such entities, **and therefore is eligible for liability protections for the provision of such services under section 42 U.S.C. § 233(g)-(n) and (q).**”*

DETERMINATION OF COVERAGE FOR COVID-19 RELATED ACTIVITIES BY HEALTH CENTER PROVIDERS

*“Services provided by health center providers must continue to comply with applicable Health Center and Health Center FTCA Program requirements. **The health center should also maintain a record of each encounter that identifies the patient, the service(s) provided, the location where services were administered, the name of the provider(s) administering the services, and the date and time the services were administered.**”*

COVID-19 AND FTCA

“Determination of Coverage for COVID-19 Related Activities by Health Center Providers”

Describes situation under which care to non-health center patients is protected by FTCA with some **limitations**:

- Provision of grant supported services
- Prevent, prepare or respond to COVID-19
- Including but not limited to screening, triage, testing, diagnosis and treatment
- Provided at health center or offsite programs or events carried out by the health center
- In person or through telehealth
- Should maintain a record of each encounter
- **Expiration date not clear**
- **Geographic scope not clear**

COVID-19 AND FTCA

- HRSA defines telehealth as the use of electronic information and telecommunications technologies to support and promote long-distance clinical health care, patient and professional health-related education, public health and health administration. Technologies include videoconferencing, the internet, store-and-forward imaging, streaming media, and terrestrial and wireless communications.

NOVEL CORONAVIRUS (COVID-19) FREQUENTLY ASKED QUESTIONS

During the declared COVID-19 emergency, do FTCA protections apply to health center providers who provide telehealth services to health center patients located across state lines?

Health Center FTCA Program regulations at 42 CFR Part 6 provide that coverage applies to “grant-related activities.” Therefore, a key determinant for FTCA coverage is whether the covered entity is providing services within the health center’s scope of project, under the Health Center Program authorizing statute.

[PAL 2020-01: Telehealth and Health Center Scope of Project](#) (PDF - 517 KB) highlights some of the relevant considerations for health centers in providing in-scope services through telehealth. Among other things, all providers must comply with applicable state requirements. If they do not—for example, if a provider uses a state license to provide services in a different state where doing so is unlawful under applicable state law—this may jeopardize eligibility for FTCA liability protection. However, some states may have temporarily amended their requirements for providing health care through telehealth to address the needs of the COVID-19 public health emergency.

Health centers that are uncertain of the applicable legal requirements for the provision of health services through telehealth across state lines should consult their private counsel for advice. HRSA cannot provide general assurance of FTCA coverage in all situations, as such determinations are fact-specific. As stated in the [FTCA Health Center Policy Manual](#) (PDF - 407 KB), “[w]hen FTCA matters become the subject of litigation, the Department of Justice and the federal courts assume significant roles in certifying or determining whether or not a given activity falls within the scope of employment for purposes of FTCA coverage.”

(Added: 4/8/2020)

Many states relaxed licensing requirements to permit provision of services via telehealth to patients in their jurisdiction by physicians in another state. However, states are rescinding these temporary requirements. Check the Federation of State Medical Boards for latest information.

NOVEL CORONAVIRUS (COVID-19) FREQUENTLY ASKED QUESTIONS

Does FTCA coverage extend to telehealth visits with both established patients and non-health center patients?

When in-scope services are provided through telehealth on behalf of a deemed health center to either established patients or individuals who are not patients of the health center, and all other FTCA Program requirements are met, such services are eligible for liability protections under 42 U.S.C. 233(g)-(n), pursuant to 42 CFR 6.6. Health centers and providers are encouraged to consult with private counsel and/or consider the purchase of private malpractice insurance when undertaking activities that may not be within the health center's scope of project.

(Updated: 3/27/2020)

While this Q&A from HRSA seems clear enough, it does not explain why the non-health center patients are covered. It is only a Q & A, not a policy, regulation nor statute. The statement's reliability is questionable.

NOVEL CORONAVIRUS (COVID-19) FREQUENTLY ASKED QUESTIONS

Can a health center use telehealth to provide services to a patient at a location that is not an in-scope service site? Can this occur if neither the health center provider nor the patient is at an in-scope service site (e.g. both the provider and patient are at their respective homes)?

From a Health Center Program scope of project policy perspective, using telehealth to provide services to a patient at a location that is not an in-scope service site is allowable if:

1. The service being provided via telehealth is within the health center's approved scope of project (recorded on Form 5A);
2. The clinician delivering the service is a health center provider working on behalf of the health center; and
3. The individual receiving the service is a health center patient.

HRSA strongly encourages health centers that provide, or are planning to provide, health services via telehealth to consult with professional organizations, regulatory bodies, and private counsel to help assess, develop, and maintain written telehealth policies that are compliant with Health Center Program requirements; federal, state, and local requirements; and applicable standards of practice. HRSA also encourages health centers to consider the range of issues that would support successful implementation of telehealth. Please review [PAL 2020-01: Telehealth and Health Center Scope of Project](#) (PDF – 520 KB) for more information.

For questions about FTCA coverage, please contact [Health Center Program Support](#) online or call for FTCA assistance at 877-464-4772, 8:00 a.m. to 5:30 p.m. ET, Monday-Friday (except federal holidays).

(Updated: 4/7/2020)

COVID-19 – OTHER QUESTIONS

Can someone who is employed by one health center volunteer at another health center? **Yes, but there will be no FTCA protection under the employers deeming.**

- Other health center can sponsor volunteer
- Cares Act protections
- State volunteer/provider protections

LIABILITY COVERAGE FOR COVID-19 VACCINE ADMINISTRATION AT DEEMED HEALTH CENTERS

NEW What liability protections apply to health center providers when an individual who receives a vaccine has an adverse reaction? —

Health centers that have been deemed as federal employees through the Health Center FTCA Program are eligible for liability protection for grant-supported activities by “covered providers” and deemed volunteer health professionals. Deemed health centers that receive a claim or a legal summons and complaint involving the administration of a vaccination should promptly provide such documentation to the HHS OGC General Law Division, as described in the [Health Center FTCA Policy Manual](#) (PDF - 358 KB), Section II. Claims and Lawsuits.

Pursuant to the Public Readiness and Emergency Preparedness (PREP) Act, the Secretary of HHS has also issued a declaration (and amendments) concerning medical countermeasures against COVID-19, which declared that COVID-19 vaccines are also covered countermeasures for the purposes of liability protection under the PREP Act. If all requirements set forth in the Secretary’s declaration are met, a covered person is immune from liability except for “willful misconduct” with respect to all claims for loss caused by, arising out of, relating to, or resulting from the manufacture, testing, development, distribution, administration, and use of a COVID-19 vaccine.

An individual who sustains a covered serious physical injury or death as a direct result of the administration or use of a covered countermeasure (or estates and survivors of such individual) may be eligible for certain benefits under the Countermeasures Injury Compensation Program (CICP), which is administered by HRSA. Information about the CICP and filing a claim are available toll-free at 1-855-266-2427, or at the [CICP website](#).

(Added: 1/5/2021)

Liability Protections:

- FTCA Program (for deemed entities)
- PREP Act (for qualified persons)
- CARES Act (for volunteers)
- State Laws

FTCA COVERAGE FOR COVID VACCINE ADMINISTRATION

Section 330(b)(1)(A) “(i) Basic Health Services:...
(III) Preventive Health Services, including:
(aa) prenatal and perinatal services;
(bb) appropriate cancer screening;
(cc) well child services;
(dd) **immunizations against vaccine-preventable diseases**;
(ee) screenings for elevated blood lead levels, communicable diseases, and cholesterol”

DO WE HAVE FTCA COVERAGE FOR COVID VACCINE ADMINISTRATION FOR NON-PATIENTS?

Short Answer: **Yes**

Longer Answer: **Yes, for several reasons**

- 42 CFR §6.6(e)(4)(i)(D)
 - <https://www.govinfo.gov/content/pkg/CFR-2013-title42-vol1/pdf/CFR-2013-title42-vol1-sec6-6.pdf>
- Determination of Coverage for COVID-19-Related Activities by Health Center Providers under 42 U.S.C. § 233(g)(1)(B) and (C)
 - <https://bphc.hrsa.gov/sites/default/files/bphc/ftca/pdf/COVID19GeneralDeterminationHC.pdf>
- PREP Act

Time for a Break!

**We will return in 10
minutes**

The FTCA Deeming Application: How To Obtain Immunity

CY 2023 DEEMING APPLICATION

- **PAL 2022-01** Calendar Year 2023 Requirements for Federal Tort Claims Act (FTCA) Coverage for Health Centers.
- EHB open to accept applications May 13, 2022
- Re-deeming applications are due July 8, 2022
- CY 2023 application is similar to CY 2022
- Deeming applications are discoverable in an FTCA case

2023 DEEMING APPLICATION

APPLICATION SECTIONS

- Contact Information
- Review of Risk Management Systems
- Quality Improvement/Quality Assurance
- Credentialing and Privileging
- Claims Management
- Certification and Signatures

CHANGE FROM CY2022

Risk Management question 5(A) clarifies that the annual report to the board must not be a compilation of the quarterly risk management assessments but rather a distinct report prepared as an annual summary of risk management activities and progress. Submission of previously prepared quarterly or monthly reports will not be acceptable.

CHANGE FROM CY2022

The CY 2023 Quality Assurance Section is now simply a series of affirmations that the health center has implemented the required policies and procedures. There are no documents to upload in this section.

CHANGE FROM CY2022

Credentialing and privileging spreadsheet returns!

The required components are:

- First Name
- Last Name
- Title
- Clinical Staff Type (*i.e.*, Licensed Independent Practitioner (LIP), Other Licensed or Certified Practitioners (OLCP), and Other Clinical Staff (OCS)
- Most recent Credentialing date

Other Issues Related to the FTCA Program

Medical Marijuana

MEDICAL MARIJUANA

- Federal Law on Marijuana – Controlled Substances Act prohibits
 - Possession
 - Manufacturing
 - Distribution
- As Federal grantees (health centers) are bound by the Controlled Substances Act regardless of state law

MEDICAL MARIJUANA (CONT.)

- Impact on FTCA coverage
 - Prescribing or distributing medical marijuana to a patient is not covered by the FTCA program.
 - Referrals to other providers: Unsettled legal issue – Does it “aid and abet” the distribution of marijuana. FTCA coverage can be jeopardized.

Telehealth/Telemedicine

TELEHEALTH/TELEMEDICINE

- Telehealth – use of technology to increase access without requiring patient and provider to be co-located.
- PAL 2022-01 *Telehealth and Scope of Project*.
 - Telehealth is not a service or service delivery method that needs to be shown on Form 5A
 - Prior approval from HRSA not necessary to implement telehealth
 - Considerations before implementing
 - Provider Licensure
 - Facility licensing
 - Equipment and training
 - Privacy and confidentiality
 - Medical records
 - Patient consent
 - Billing and third-party payments

TELEHEALTH/TELEMEDICINE (CONT.)

- Telehealth Scenarios:
 - Health Center Patient in health center site – health center employed physician in different health center site – service in scope:
 - Physician is covered
 - Health center is covered
 - Health Center Patient in health center site – contracted physician in non-health center site – service in scope:
 - Health center is covered
 - Physician may be covered
 - Health Center Patient in non-health center site – health center employed physician in health center site – service in scope:
 - Physician is covered
 - Health Center is covered

TELEHEALTH/TELEMEDICINE (CONT.)

- Other Scenarios:
 - Health Center Patient in health center site assisted by health center staff – non-health center physician in non-health center site – service not in scope of project.
 - Health center and staff covered???
 - Physician not covered.
 - Health Center Patient at home – Health center physician at home – service in scope:
 - Physician is covered?????
 - Health center is covered????
 - Non-Health center patient at non-health center site (school) – Physician at health center site – service in-scope.
 - Physician covered if health center has written agreement with the school.
 - Health center covered if there is written agreement with school.

Confidentiality

CONFIDENTIALITY

SAMHSA proposed changes to regs requiring additional confidentiality protections for certain substance abuse disorders.

- Applies to “Part 2” programs (42 CFR Part 2)
- Definition of Part 2 program does not change
- Changes to definition of “records” and applicability of Part 2
- See <https://www.feldesmantucker.com/samhsa-proposes-changes-to-42-cfr-part-2/> for more information
- HIPAA Violations
- No individual right to sue under HIPAA

CONFIDENTIALITY (CONT.)

- Cannot bring suit under FTCA for HIPAA violations.
- Is health center protected by the FTCA program for allegations of HIPAA violations or Part 2 violations?
- Is health center protected for allegations of breach of confidentiality under the FTCA program?

ADDITIONAL INFORMATION

- FTLF Learning Center
<https://learning.ftlf.com>
- Coronavirus Disease 2019 (COVID-19) Frequently Asked Questions
<https://bphc.hrsa.gov/emergency-response/coronavirus-frequently-asked-questions.html>
- Calendar Year 2023 Deeming Application Instruction
<https://bphc.hrsa.gov/sites/default/files/bphc/datareporting/pdf/pal-2022-01.pdf>
- Temporary Privileging of Clinical Providers by Federal Tort Claims Act (FTCA) Deemed Health Centers in Response to Certain Declared Emergency Situations
<https://bphc.hrsa.gov/sites/default/files/bphc/ftca/pdf/pal-2017-07.pdf>
- Federal Tort Claims Act Health Center Policy Manual
<https://bphc.hrsa.gov/sites/default/files/bphc/ftca/pdf/ftcahcpolicymanualpdf.pdf>
- Health Center Program Compliance Manual
<https://bphc.hrsa.gov/programrequirements/compliancemanual/introduction.html>

QUESTIONS?



CONTACT INFORMATION

Martin J. Bree

MBree@FTLF.com

202-466-8960

Feldesman Tucker Leifer Fidell LLP

1129 20th Street, NW, Suite 400

Washington, DC 20036

www.ftlf.com

ADDITIONAL TRAINING OPPORTUNITIES

Upcoming Live Webinars		
March 27 th @ 2 pm ET	Patient Confidentiality & COVID-19 <i>Complimentary Registration</i>	All webinars start @ 1 pm ET unless otherwise noted.
March 30 th	Post-Acute Care Series - Part IV: Emergency Preparedness Complimentary Registration	
April 9 th	Opioid Epidemic: Enforcement Updates	
May 14 th	PACE and Health Centers – Key Opportunities and Risk Areas	
April 22 nd	Procurement Standards	

Coronavirus (COVID-19) Webinars	
March 27 th @ 2 pm ET	Patient Confidentiality & COVID-19 <i>Complimentary Registration</i>
On-Demand	FTCA & COVID-19 <i>Complimentary Registration</i>
On-Demand	Coronavirus Appropriations Act of 2020 <i>Complimentary Registration</i>

learning.ftlf.com