FEDERALLY QUALIFIED HEALTH CENTER FEDERAL TORT CLAIMS ACT INSURANCE COVERAGE

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FTCA Background and History

The Federal Tort Claims Act ("FTCA"), established in 1948, is the legal mechanism for compensating people who have suffered personal injury due to the negligent or wrongful action of employees of the U.S. government.[1] The FTCA was passed following a 1945 crash of a a military plane into the Empire State Building. Eight months after the crash, the U.S. government offered money to families of the victims.[2] Some accepted, but others initiated a lawsuit that resulted in legislation that established the FTCA. The FTCA permits private parties to sue the United States in federal court for torts and negligence committed by persons acting on behalf of the United States, and provides compensation for personal injury, including death, resulting from the performance of medical, surgical, dental or related functions that constitute medical malpractice. Prior to the passage of the FTCA, lawsuits by private individuals and corporations against the federal government and federal employees were barred by sovereign immunity.[3]

Extension of FTCA Coverage to Federal Government Funded Entities

The FTCA originally only covered the federal government, federal government agencies, and federal government employees. In 1988 and again in 1990, Congress extended the FTCA to negligent acts of tribal contractors carrying out contracts, grants, or cooperative agreements pursuant to Public Law 93–638, the Indian Self-Determination and Education Assistance Act ("ISDEAA").[4] In general, the ISDEAA protects the following individuals/entities from personal liability under the FTCA when they are acting within their scope of official duty: federal employees, tribal employees, Public Health Service officers, and certain contractors, including Indian Health Centers.

In 1992, Federal Tort Claims Act coverage was extended to eligible Bureau of Primary Health Care ("BPHC") grantees funded through Section 330 of the Public Health Service Act, passed as the Federally Supported Health Centers Assistance Act ("FSHCAA") of 1992 (Public Law 102-501) through an amendment to Section 224 of the Public Health Service Act.[5] The general purpose of the FSHCAA was "to provide that doctors or other health care providers at a federally funded migrant health center, community health center, or health center providing services to homeless individuals or public housing residents (collectively referred to as "Health Centers"), would be deemed to be employees of the Public Health Service for civil liability purposes, and thus would be covered by the FTCA."[6]

Health Centers are community-based and patient-directed organizations that serve medically underserved communities and vulnerable populations with limited access to healthcare, including low income populations, the uninsured, those with limited English proficiency, migrant and seasonal farm workers, individuals and families experiencing homelessness, and those living in public housing.[7] Health Centers have been providing these comprehensive, culturally competent, quality primary healthcare services for more than 45 years. Currently, 1,200 Health Centers deliver care through over 9,000 service delivery sites across the United States.[8]

Health Centers were initially staffed by physicians who worked for the National Health Service Corps ("NHSC"); however, budget cuts and policy changes in the NHSC forced Health Centers to hire former NHSC physicians as their own employees and purchase professional malpractice insurance coverage. Then, during the medical malpractice insurance crisis that occurred from 1985 through 1995,[9] the cost of such insurance increased drastically. In addition, as set forth in the legislative history, Congress wanted to "eliminate the need for these Health Centers to purchase medical malpractice insurance, the costs of which [had] been found to far exceed the amount of claims paid by the Health Centers, and thus free up more resources to provide additional health care services."[10] Congress further sought to "strengthen the responsibility of grantees to check staff credentials, by conditional grants to applicants on their certification that they have reviewed and verified the professional credentials, references, claims history, fitness, professional review organization findings, and license status of their physicians and other licensed health care practitioners."[11]

The FHSCAA originally was a three year demonstration project to see if the coverage would lower a Health Center's medical malpractice costs and thus leave more money for providing services. Subsequent reviews of the costs savings concluded that the Health Centers benefited from the protections offered by the FTCA,[12] and Congress eventually approved a permanent extension of the coverage with the FSHCAA of 1995, which clarified the 1992 Act and confirmed that the FTCA covers any officer, governing board ("Board") member, or employee of a Health Center, as well as certain independent contractors, for actions within the scope of

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their employment or contract.[13] The FSHCAA also extended FTCA coverage to Veterans Administration Medical Centers and outpatient clinics, Military Hospitals, Indian Health Centers, the NHSC, the Public Health Service, and Free Clinics.

How FTCA Coverage for Health Centers Differs from FTCA Coverage for Government Agencies

FTCA Coverage for Health Centers is different from that provided directly to government agencies, and from insurance coverage provided by commercial medical malpractice insurers. Health Centers must meet very specific requirements in order to be covered by the FTCA, and many common activities engaged in by Health Centers and which might be covered by private malpractice insurance are not covered by the FTCA. Health Centers must meet rigid deeming requirements. Health Centers must operate within the parameters of the FTCA program rules to ensure that the Health Center does not jeopardize its FTCA coverage and to ensure that it does not exceed the limitations on the scope of coverage for certain staff members or services provided to certain patients.

The FTCA provides occurrence-based coverage for professional malpractice to a Health Center that is "deemed" eligible by the Health Resources and Services Administration ("HRSA") of the Department of Health and Human Services ("HHS"), but only for claims arising from acts or omissions by the Health Center, its qualified individual providers and/or other eligible individuals (i.e., Board members, officers, employees and certain individual contractors or the Health Center) that (1) occur on or after the effective date that HRSA determined the Health Center met the requirements for FTCA coverage; (2) are within that Health Center's approved scope of project and occur during the provision of services to Health Center patients (or non-patients in certain limited situations);[14] and (3) are within the requirements of the job description, contract for services, Health Center scope of employment, or duties as an officer or director of the Health Center.[15]

After a claim is filed against a Health Center, the Health Center must take deliberate steps to access coverage under the FTCA. Failure to perform the required steps may put the Health Center's FTCA coverage at risk.

Benefits of FTCA Coverage

Free Medical Malpractice Insurance Coverage

FTCA coverage provides significant benefits, including a reduction or elimination of professional liability insurance costs and unlimited coverage. There is no cost to participating Health Centers or their providers, and there is no personal liability for covered individuals. In addition, Health Centers are not limited to the traditional coverage limits of one million dollars per incident and three million dollars in the aggregate. Covered entities are not liable for any settlements or judgments that are made, as the federal government assumes responsibility for related costs. The Health Center and its officers, directors, employees and certain contractors covered by the FTCA are considered to be federal employees for the purpose of malpractice coverage under the FTCA, but are not considered federal employees for any other reason. Currently 956 Health Centers are deemed eligible by HRSA for FTCA medical malpractice coverage.[16]

Reduced Liability Risks

FTCA rules make it harder for a plaintiff to recover damages, thereby discouraging litigation. For example, there is a federal two year statute of limitations from the time a plaintiff discovered or should have discovered the injury (no competency or minor age tolling of statute of limitations), and the preliminary administrative review process serves as another statute of limitations if a lawsuit is not filed within six months after the claim was denied or failed to settle. In addition, there is no common law discovery rule, no jury and no punitive damages.

Claims, Scrutiny Expected to Increase

One of the central funding initiatives in the Patient Protection and Affordable Care Act is the expansion of Health Centers as a means of improving access to primary healthcare, and the number of Health Centers is increasing rapidly. Health Centers are likely to play a central role in the country's health system over the coming years, as Health Centers currently provide care to more than 22 million people, and an increasingly number of consumers will be obtaining healthcare services from Health Centers in the future.[17] As more Health Centers are established, the number of medical malpractice claims involving Health Centers will also likely increase. Plaintiffs' attorneys, their clients, and Health Center attorneys and compliance officers must be aware of FTCA requirements.

In addition, the 2015 Work Plan of HHS' Office of Inspector General ("OIG") indicates that the OIG will be auditing Health Center compliance,[18] and HRSA has recently begun to conduct random FTCA coverage compliance site visits of both Health Center initial applicants and deemed grantees to determine compliance with FTCA program requirements.[19]

The purpose of this article is to provide guidance to plaintiffs' counsel, Health Center legal counsel, and Health Center compliance officers on how to comply with the applicable FTCA requirements.

The Federal Tort Claims Act Health Center Policy Manual

The Federal Tort Claims Act Health Center Policy Manual (the "FTCA Manual") is the primary source for information on the FTCA program for Health Centers and related stakeholders.[20] HRSA recently issued an updated FTCA Manual which modifies and supersedes the prior manual (Policy Information Notice ("PIN") 2011-01), and reflects amendments to the FTCA Health Center regulations.[21] HRSA also issued a Program Assistance Letter ("PAL") that highlights the updates and modifications ("PAL 2014-09").[22] The revised FTCA Manual is intended to be the principal Health Center Program resource on FTCA matters; however if there are any conflicts between the Manual and the FTCA and regulations as interpreted by the courts, the FTCA, implementing regulations, and case law prevail.[23]

New changes reflected in the FTCA Manual include the following:

Individual Emergencies

The updated FTCA Manual includes an expansion of FTCA coverage for services rendered to non-Health Center patients in certain individual emergencies. To be covered by the FTCA when temporarily treating or assisting in treating a non-Health Center patient, the treatment must take place in or near the Health Center provider's location, the provider must be furnishing (or about to furnish) FTCA covered services within the Health Center's scope of project and must be asked, called upon or undertake to treat or assist in treating the non-Health Center patient. In addition to documentation of the original services, the Health Center must have documentation (such as an employee manual, provider contract or Health Center bylaws) that provides that a practitioner is required as a condition of employment to provide individual emergency treatment when the practitioner is already providing or undertaking to provide covered services.

Participation in Health Fairs

The updated FTCA Manual clarifies that Health Center staff that conduct or participate in health fairs are covered by the FTCA.

Immunization Campaigns

The updated FTCA Manual clarifies that Health Center staff that conduct or participate in an event to immunize individuals against infectious illnesses are covered by the FTCA. Covered immunization campaigns now include those provided to adults, in addition to those provided to children and adolescents.[24]

The FTCA Manual is generally updated infrequently and limited to significant updates, as minor changes are usually communicated in PINs or PALs.

The FTCA Coverage Application and Coverage Renewal Process

Each Health Center seeking FTCA coverage (including both Health Center grantees and sub-recipients) must submit an application in the form and manner prescribed by HRSA. All applications, whether initial or renewal applications, must be submitted through the FTCA deeming module within the HRSA Electronic Handbook ("EHB"). The application must document that the Health Center has successfully implemented all program requirements set forth in the FTCA and regulations and further described in HRSA guidance entitled "Calendar Year 2015 Requirements for Federal Tort Claims Act (FTCA) Medical Malpractice Coverage for Health Centers."[25] Program requirements include not only the submission of written documentation of appropriate policies, procedures, and practices, but also evidence of their implementation.[26]

In view of the importance of the application process, it is essential that all applicants for coverage or annual renewal:

- Submit FTCA application materials in a timely manner (including responding within specified time frames to all clarification and additional information requests from HRSA);
- Demonstrate implementation of the required policies, procedures, and requirements, as further outlined in PAL 2014-03; and
- Present and verify all material facts during the application process (including providing information during FTCA site visits).[27]

The FTCA Coverage Application

The FTCA coverage application must be complete and accurate and must demonstrate that the Health Center:

- Has implemented appropriate policies and procedures to reduce the risk of malpractice and the risk of lawsuits arising out of any health or health related functions performed by the covered entity;
- Has implemented a system whereby professional credentials, references, claims history, fitness, professional review organization findings, and licensure status of its physicians and other licensed or certified healthcare providers are reviewed and verified and, where necessary, has obtained the permission from these individuals to gain access to this information;
- Has no history of claims having been filed against the United States

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as a result of the application of the FSHCAA to the entity or its covered individuals, or, if such a history exists, has fully cooperated with the Department of Justice in defending any such claims and either has taken, or will take, any necessary corrective steps to assure against such claims in the future; and

- Will fully cooperate with the Attorney General and the federal government in providing the necessary information related to the claim.[28]

Documents to be Submitted with the Application

Health Centers must submit the following documents with the FTCA coverage application:

- A Quality Improvement/Quality Assurance ("QI/QA") Plan, signed, dated, and approved by the Health Center's Board within past three years (on or after April 5, 2011);
- Board-approved Credentialing and Privileging policies (signed and dated);
- Minutes from six QI/QA committee meetings. All minutes must be from meetings that took place between April 5, 2013 and the submission date of the application;
- Minutes from six Board meetings that reflect Board approval of QI/QA activities. All minutes must be dated between April 5, 2013 and the submission date of the application;
- Clinical policies and procedures for referral tracking, hospitalization tracking, and diagnostic tracking;
- A statement verifying whether or not there were any medical malpractice claims or allegations presented during the past five years, that any such claims or allegations were internally analyzed, and that appropriate actions were implemented as needed in response to such claims or allegations; and
- A credentialing list (in an excel spreadsheet) of all licensed and/or certified healthcare personnel employed and/or contracted by the Health Center, with information specified in PAL 2014-03.[29]

The HRSA FTCA Coverage Eligibility Deeming Process

Health Center FTCA coverage is contingent on approval of an annual deeming application by HRSA. Health Centers must demonstrate compliance with all applicable FTCA program requirements. The Health Center must demonstrate that it has implemented "appropriate policies and procedures to reduce the risk of malpractice and the risk of lawsuits arising out of any health or health-related functions performed by the entity."[30] It is not sufficient to develop policies and procedures; there must be evidence that such policies and procedures are implemented and in use. Similarly, the Health Center must show that it has reviewed and verified the professional credentials, references, claims history, fitness, professional review organization findings, and license status of its physicians and other licensed or certified healthcare practitioners and, where necessary, has obtained the permission from these individuals to gain access to this information.[31] In addition, the applicable statute mandates that any entity that has a history of any FTCA claims must demonstrate that it has "either has taken, or will take, any necessary corrective steps to assure against such claims in the future."[32]

The FTCA Deeming Application

Once a complete initial FTCA application is submitted, HRSA will complete its review within 30 days.[33] Grantees that do not submit complete applications in a timely manner may not receive deemed status (i.e. FTCA coverage) on the date desired. If additional information or clarification is needed, HRSA will notify the grantee, and the grantee will be given 10 business days from the date of the notification to provide the requested information to complete its application. Should requested information not be submitted within 10 business days of notification, the FTCA application may be determined to be incomplete and voided.

HRSA FTCA Deeming Application Review Process

As part of the approval process, HRSA will review and verify all professional credentials, references, claims history, fitness, professional review organization findings, and license status of the Health Center's physicians and other licensed or certified healthcare practitioners.[34] HRSA may conduct a site visit at any point during the application review process and/or as part of its oversight responsibilities relative to the FTCA program to ensure that risk management, QI/QA policies and procedures, and credentialing have been appropriately implemented. HRSA may also conduct a random site visit to any initial applicant or deemed grantee to ensure implementation under 42 U.S.C. Section 233(h). If a site visit results in a finding that the Health Center has not met the FTCA program requirements, this finding may be grounds for a negative deeming determination.[35] Negative deeming determinations are common; however, most applicants are able to successfully address the deficiencies during the appeals process. Notwithstanding the above, nearly 100 Health Centers are rejected for deeming status on an annual basis.

HRSA Notification of a Deficient FTCA Deeming Applications

During the review process, if HRSA determines that the applicant

has not successfully demonstrated compliance with the FTCA deeming requirements and is in danger of being disapproved for FTCA initial or renewal coverage, HRSA will notify the Health Center of such non-compliance and provide the Health Center with a final opportunity to demonstrate compliance. The notice will outline: (1) the areas of non-compliance; (2) additional documentation that must be submitted to demonstrate evidence of compliance; (3) the time frame within which the documentation must be submitted; and the form and manner in which the submissions must be presented.[36] Once the additional information is submitted, HRSA will review the documentation and make a final determination within 30 days. After a final determination is made on the application, HRSA will notify the Health Center's contact person(s) identified in the application of whether or not the Health Center is deemed eligible for FTCA coverage.

The FTCA Deeming Coverage Letter

Each deemed Health Center will receive a general letter from HRSA explaining that it is covered by the FTCA and outlining the FTCA coverage (the "Deeming Letter"). The Deeming Letter serves as verification of coverage and must be renewed on an annual basis.[37] It is essential that that the Health Center keep annual Deeming Letters on file, since the Health Center will need to send the letters to HHS in the event that the Health Center is the subject of an FTCA lawsuit.

The FTCA Claims and Lawsuits Process

Exhaustion of Administrative Remedies

FTCA actions proceed in two steps. First, the claimant should contact the Health Center and subject healthcare providers and inquire if the Health Center and staff have been deemed Public Health Service employees. If a timely response is not received, the claimant may contact the BPHC to obtain a report on the Health Center's status as covered by the FTCA. If so, the claimant files an administrative complaint with the relevant federal agency or agencies.[38]

For example, in order to file a malpractice claim against a Health Center under the FTCA, the plaintiff must present his or her claim to the HHS Office of the General Counsel ("OGC"), General Law Division ("GLD"), Claims and Employment Branch ("CELB") ("OGC/GLD/CELB"). 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 ("SF")-95 or other written notification of an incident, accompanied by a claim for money. The claim must be filed in writing with the appropriate federal agency, using Form SF-95 or a letter.[39] The form or letter must provide written notification of the incident and the specific amount of monetary damages claimed.[40] Practitioners should carefully consider the damages demand, because the agency's liability generally cannot exceed the amount stated in the administrative complaint.[41] If an attorney prepares the claim, it must be presented in the claimant's name, be signed by the attorney, and show evidence of the attorney's authority to bring the claim on the claimant's behalf.[42]

Statute of Limitations

As noted above, an administrative claim must be presented in writing to the appropriate federal agency within two years after the claim accrues.[43] State law tolling rules such as those for infancy[44] or incompetency[45] do not apply to FTCA statutes of limitations.[46] A second FTCA statute of limitations requires that the lawsuit be filed within six months of the denial of the administrative claim.[47]

Federal Agency Review of the Administrative Claim

Upon receipt of a claim against a Health Center by the OGC, the Health Center is provided a litigation hold letter by the OGC and requested to provide the following information as soon as possible:

1. Three copies of the summons and complaint.
2. Three copies of the covered entity's initial deeming letter and all subsequent redeeming documentation including Notices of Grant Award ("NGAs") containing re-deeming language or re-deeming letters, as appropriate.
3. Three copies of the covered entity's Federal Section 330 grant application and Forms 5-A, 5-B and 5-C setting forth the approved scope of project, including delivery sites and services, for the period of time covered by the claim.
4. Three copies of a statement, on covered entity letterhead, identifying which providers are involved or named in the claim and their dates of employment at the covered entity (if not already provided for a premature lawsuit relating to the same incident).
5. Evidence that the named providers were licensed physicians or licensed or certified healthcare providers at the time of the incident, including documentation of the specialty of all named providers.
6. In the event the alleged incident arises from acts or omissions that occurred outside of the covered entity's approved service sites, the name and address of the outside facility and information as to the nature of the affiliation among the outside facility, Health Center and its personnel.
7. Three copies of the Wage and Tax statements (W-2) for each individual involved in the alleged incident for the period of time covered by the claim.
8. If the provider whose care is at issue was a licensed or certified healthcare provider contractor at the time of the alleged incident, three copies of the 1099 form; an employment contract covering the period of the alleged

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incident; and evidence that the healthcare provider contractor was working full time, an average of 32.5 hours per week, or if employed part time, that the healthcare provider contractor was providing services only in the fields of family practice, obstetrics and gynecology, general internal medicine or general pediatrics.

9. Three copies of a declaration verifying the employment of each individual involved in the alleged incident on the Health Center's letterhead, signed by each provider whose care is at issue. The declaration should state that to the best of his/her knowledge, the named provider was not billing privately, or, if the named provider was billing privately, he/she complied with the alternate billing arrangement requirements.
10. Three copies of any professional liability or gap insurance policy that provides coverage to the Health Center and the named provider. The policies must cover the dates of the alleged incident. If neither the covered entity nor the named provider involved in the alleged incident has medical malpractice coverage other than that provided under the FTCA, the covered entity should submit a statement on Health Center letterhead addressing that fact. However, if the named provider has purchased his/her own individual professional liability medical malpractice insurance coverage, which was in effect during the allegation time period, the covered entity must provide evidence of this coverage.
11. All correspondence received from the claimant pertaining to the claim.
12. The name and telephone number of a contact at the Health Center familiar with the certification information requested above.
13. Three copies of all of the plaintiff's medical records including x-rays, laboratory reports, and other results and treatments from the covered entity and any private facility that might be involved.[48]

The Administrative Agency Determination

The OGC will review the information received and make a recommendation with regard to coverage by the FTCA and defense of settlement of the claim. The agency has six months to assess the merits of the administrative tort claim, during which time no suit may be instituted.[49] If the agency does not elect to pay or settle the claim, and, instead, makes a "final denial" of the claim (i.e., denies the claim or fails to act on it within six months), the claimant then may file a complaint in federal district court.[50] In the alternative, the claimant may request an administrative reconsideration within six months of the denial. Once an administrative claim has been denied, the claimant must file suit within six months or request reconsideration. If neither is done, the action will be time barred.

Venue

Only federal district courts have subject matter jurisdiction over FTCA cases.[51] Venue is proper only in the federal district where the "plaintiff resides or wherein the act or omission complained of occurred."[52] However, the FTCA venue provision can be waived.[53] When a lawsuit is filed, the case is transferred to the Department of Justice ("DOJ"). The DOJ may attempt to settle the lawsuit; otherwise it goes into litigation. Cases are heard without a jury and are defended by the DOJ with help from the requisite federal agency (here, OGC).

Attorney's Fees

There is no provision in the FTCA for a separate award of attorney's fees. The FTCA specifically authorizes attorneys' fees and collection of contingent fee payments. If the claim is resolved administratively, recovery may not exceed 20 percent of the settlement. If the claim is settled after district court litigation is initiated, the attorney may recover up to 25 percent of the settlement or judgment.[54]

What the FTCA Covers

Scope of Project Limitation

FTCA coverage is limited to the performance of medical, surgical, dental, or related functions within the scope of the approved grant project, which includes sites, services, and other activities or locations, as listed in the grant application and any subsequent approved changes in scope requests.

Scope of Employment Limitation

FTCA coverage is further limited to those acts or omissions of a Health Center that are within the scope of employment of a covered individual (including acts of a qualified contractor that fall within an applicable contract) that cause personal injury, death or loss of property. The term "scope of employment" covers performance under an applicable individual contract. It is essential that all covered individuals including employees, contractors, officers and directors have: (1) current written job/position descriptions that delineate the duties they perform on behalf of the Health Center; (2) that these descriptions comply with the scope of employment, licensure and certification requirements and any contract or employment agreement; and (3) specify the type of services to be provided and the location where such services will be provided. These descriptions will be essential in determining if the person was acting within the scope of employment and is covered by the FTCA. For actions to be within the scope of employment, they must:

- Be within the approved scope of the project, including sites, services

and other activities and locations as defined in PIN 2008-01;[55]

- Be within the requirements of the job description, contract for services, and/or duties required by the Health Center;
- Occur during the provision of services to the Health Center's patients and in certain circumstances to non-Health Center patients.

Recordkeeping and Documentation

The Health Center is responsible for keeping records for covered individuals and any sites and schedules that may be relevant to FTCA coverage. In the event of a claim, HHS will verify that the individual was employed by or under contract with the Health Center at the time of the incident, that all statutory and program requirements have been met and that the Health Center and the covered individual complied with all FTCA requirements, such as providing healthcare services with the approved scope of project and within the scope of deemed employment.

FTCA Coverage Compliance Requirements

The QI/QA

In order to comply with FTCA coverage requirements, Health Centers must maintain a QI/QA program which has been approved by the Health Center Board and provides an organizational structure that supports the provision of high-quality patient care.[56] A QI/QA committee should oversee the QI/QA plan and hold monthly QI/QA committee meetings. The QI/QA committee should be a multidisciplinary team including administration, providers, and professional staff. The QI/QA program should describe the structure and purpose of the QI/QA committee; clinical, financial, or administrative areas addressed in quality improvement activities (e.g., continuity of care, disease management, credentialing, patient education, patient satisfaction); the process for implementing policies and procedures; how often the Board receives reports from the QI/QA committee on the QI plan and progress; and how recommendations from the QI/QA committee are presented to and approved by the Board.

QI/QA programs must provide for periodic assessments of utilization and quality of health services. These assessments must: (1) be conducted by physicians or other licensed professionals under the supervision of physicians; (2) be based on the systematic collection and evaluation of patient records;[57] and (3) identify and document needed changes and the results of such changes.[58] In addition, Health Centers must have a process for compiling information and reporting information to HRSA on costs, service utilization, and the availability, accessibility, and acceptability of the Health Center's services.[59]

Health Centers should compare data to benchmarks to determine what QA/QI areas need improvement and develop strategies or initiatives to address such areas. Thus, the QI/QA program should describe the process for assessing and identifying clinical quality and risk issues on a continuous basis, and include a list of tools used to systemically collect and analyze data. The QI/QA program should describe how the Health Center identifies potential problems, prevents adverse occurrences, and discusses how strategies for improvement are implemented, continually monitored, and measured.

Credentialing and Privileging

Health Centers must have a process for credentialing and privileging all licensed or certified healthcare practitioners, as reflected in a Health Center credentialing and privileging policy (with Board approval/signature/date on the document or Board minutes that show approval). HRSA provides the following general guidance:

- "All Health Centers shall assess the credentials of each licensed or certified health care practitioner."
- "A Health Center must verify that its licensed or certified health care practitioners possess the requisite skills and expertise to manage and treat patients and to perform the medical procedures that are required to provide the authorized services."[60]

Staff to be credentialed include staff who are licensed, registered, or certified by the state in which the Health Center is located to provide care and services without direction or supervision (Licensed Independent Practitioners ("LIPs"), such as physicians, dentists, physician assistants, nurse practitioners and nurse midwives); and staff who are licensed or certified to provide care and services, but must have direction or supervision (Other Licensed or Certified Practitioners ("OLCPs"), such as nurses, laboratory technicians, social workers, medical assistants, and dental hygienists). Health Center medical staff should not provide healthcare services prior to completion of the credentialing and privileging process.

Health Centers' policies and procedures should clarify required credentials for each position, which may include: current state license, certification, or registration; relevant education, training, or experience; current competence; health fitness, including immunization and PPD tuberculosis skin test status; government-issued picture identification; Drug Enforcement Administration ("DEA") registration (as applicable); hospital admitting privileges (as applicable); life support training (as applicable); and a query of the National Practitioner Data Bank.

As Health Centers are required to maintain complete and organized documentation of credentialing and privileging records, Health Center policies should describe a format for organizing credentialing information and assuring appropriate confidentiality and security. Health Centers are permitted to use a Credentials Verification Organization ("CVO") to

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perform credentialing, however, if they do so, it is important for the Health Center to make sure that the documents maintained by the CVO are completed and organized and that the Health Center can access physical files or electronic databases in advance of a HRSA site visit.

The Credentialing Process

Credentialing is the process of assessing and confirming the qualifications of a licensed or certified healthcare practitioner to render specific healthcare service(s) based on a review of the practitioner's experience, credentials and other qualifications. Health Centers must develop and implement a consistent and systematic approach to assessing the credentials, training, competency, and practice history of each healthcare practitioner and the practitioner's ability to perform within her or her scope of practice. All Health Centers must assess the credentials of each licensed or certified healthcare practitioner, including employed, contracted, volunteers, and locum tenens (temporary) practitioners, at all Health Centers sites, and must review credentials on an ongoing basis with recredentialing at least every two years.[61]

Credentialing verification procedures should include primary and secondary source verification.[62] Health Center policies should define whether a credential must be verified using primary source verification or if secondary source verification is acceptable.[63] Credentialing of OLCPs requires primary source verification of license only. The credentialing process for LIPs is rigorous and includes two steps: (1) primary source verification of current license, relevant education, training and experience, current competence, health fitness or ability to perform the requested privileges; and (2) secondary source LIP verification, which requires proof of a government issued picture I.D., DEA registration (as applicable), hospital admitting privileges (as applicable), immunization and PPD tuberculosis skin test status, life support training (as applicable), and National Practitioner Data Bank queries every two years.

The Privileging Process

Each Health Center provider should be "privileged" specific to the services being provided at each of the Health Center's delivery settings. Privileging is the process whereby the Health Center determines the specific scope and type of patient care services that a healthcare practitioner may perform, based on an evaluation of the individual's credentials and performance. Health Center privileging and re-privileging policies should document: services for which privileges are granted; skills and expertise measures that must be achieved in order to demonstrate competency for each service to be granted privilege; standardized procedures to monitor proficiency of practice; periodicity of the review of privileges; and methods for disciplining a practitioner to assure compliance with credentialing and privileging policies. They should also describe a practitioner's rights to appeal if a decision is made to discontinue or deny privileges, and define the Health Center's approved appeal process, including information needed, format, and time limits for requesting the appeal.[64]

Health Center privileging verification should include primary source verification of a course of study from a recognized and certifying educational institution; direct, first hand one-on-one documentation by a supervising clinician who possesses the privilege of the particular procedure or management protocol; and direct proctoring by a qualified clinician possessing a degree of expertise in the particular procedure or protocol beyond the level of expertise of most primary care providers. Whatever verification procedures are used should be appropriate to the specialty of each practitioner, the breadth of clinical services offered by the Health Center, and the particular circumstances of the Health Center's accessibility to ancillary and tertiary medical practitioners.[65]

Governing Board Requirements

Health Center policies should define the role and responsibilities of the Board, including that the ultimate authority for credentialing and privileging of providers is vested in the Board,[66] which generally makes such determinations after reviewing recommendations from either the Clinical Director or a joint recommendation of the medical staff (including the Clinical Director) and the Chief Executive Officer. The credentialing and privileging policies and procedures must be reviewed and approved, signed, and dated by the Health Center Board of Directors.

Risk Management

Health Centers are required to use a portion of their savings to provide risk management services that identify, manage, control, and monitor all risks to the Health Center. Broadly defined, risk management includes any activity, process, or policy to reduce liability exposure, and includes processes for monitoring, anticipating, determining, minimizing and preventing accidental loss in a business. This review involves all aspects of a Health Center's infrastructure and services, including employee and staff training, financial matters, facility maintenance, fire safety, compliance with applicable laws and regulations, and clinical care. Complete risk management includes taking appropriate safety measures, having policies and procedures to anticipate risk and to address risks once a risk occurs, acting in a professional manner, and having appropriate insurance coverage.

After identifying risks, Health Centers must implement controls and

other techniques to manage the risks. The following risk management practices are recommended by HRSA:

- *Periodic Assessments of Malpractice Risk:* Safety culture surveys, event report reviews, claims reviews, root cause analysis, and patient complaints;
- *Supervision and Training of Staff on Risk Management:* Staff should receive supervision oversight and either onsite or offsite annual training on topics related to risk management;
- *Comprehensive patient medical records:* These records document the care provided to the patients at the Health Center. Health Centers should periodically review medical records for completeness, quality and legibility;
- *Appropriate use of clinical protocols:* Establishing guidelines for providing clinical care that healthcare practitioners use. Health Centers should develop and implement policies and procedures to minimize the risks associated with the provision of healthcare services, including but not limited to clinical protocols that define appropriate treatment and diagnostic procedures for selected medical conditions;
- *Diagnostic Tracking:* Health Centers should have policies and procedures and tracking systems for diagnostic tracking, and designate a staff member responsible for monitoring tracking logs and following up on compliance issues;
- *Hospitalization Tracking:* Health Centers should have policies and procedures and tracking systems for hospitalization tracking, and designate a staff member responsible for monitoring tracking logs and following up on compliance issues. Health Centers should educate patients to notify the Health Center of emergency room and hospital visits, and keep a log of patient hospital/emergency room visits;
- *Referral Tracking:* Health Centers should have policies and procedures and tracking systems for referrals, and designate a staff member responsible for monitoring tracking logs and following up on compliance issues. Health Centers should document all patient referrals, communicate to patients the importance of keeping referral appointments, ask specialists to contact the Health Center if a patient misses a referral appointment, and follow up with patients who miss appointments;
- *Patient Accessibility:* Health Centers should have policies and procedures that address triage, walk-in patients, telephone triage, and no-show appointments;
- *Formal grievance mechanism:* Health Centers should have a system to collect, analyze, and address complaints received from patients and/or staff;
- *Regular patient satisfaction surveys:* A survey to assess patient satisfaction with the level of service and clinical care that patients received should be done on a regular basis;
- *Up-to-date policies and procedures on risk management:* Health Centers should have written documents that are current and up-to-date and explicitly describe a Health Center's operations and processes related to risk management.[67]

A Health Center that fails to meet the risk management (or the QA/QI, credentialing, and privileging) compliance requirements may lose its existing FTCA coverage.

FTCA Compliance Oversight and Audits

HRSA has recently begun conducting random FTCA coverage compliance site visits of both initial applicants and deemed grantees to determine compliance with FTCA program requirements.[68] Factors that may prompt a site visit include, but are not limited to, the submission of an initial deeming application; submission of documentation which indicates non-compliance; follow-up on prior site visit findings/issues; history of repeated conditions on the Health Center's grant; and/or a history of medical malpractice claims.[69] Non-compliance with FTCA program requirements is grounds for a negative deeming determination.

FTCA Coverage Compliance Risks

Health Centers should keep abreast of HRSA enforcement trends and key compliance risks. Recent FTCA compliance audits have focused on the adequacy of clinical policies and procedures for referral tracking, hospitalization tracking, x-ray tracking, lab result tracking, triage, walk-in patients, telephone triage, no-show appointments, HIPAA privacy and security, medical record reviews, risk management education and training, clinical protocols, credentialing, peer review, and QA/QI.[70]

HRSA FTCA Site Visits/Audits

Health Centers are usually given several weeks' notice before the compliance audit. The visits are conducted by an FTCA staff member along with private contractor(s). The site visits last two to three days, during which time the site visit team reviews risk management, quality improvement, quality assurance and credentialing policies and procedures and supporting documentation. The site visit team also meets with Health Center leadership and the Board. The site visit team provides findings and recommendations during an exit conference. If the site visit team finds that the Health Center has not met the FTCA program requirements, HRSA may determine that the Health Center should not be covered by the FTCA and deny the Center's deeming application.[71]

How To Prepare for an FTCA Coverage Compliance Audit

In order to prepare for a site visit, the Health Center should take the following steps:

1. Review the Health Center provider list to confirm that the Health Center does not have any part-time

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contracted providers who are not practicing in the fields of family practice, general internal medicine, general pediatrics, or obstetrics/gynecology.

2. Confirm that Health Center services are not provided to non-Health Center patients unless such services fall within an approved exception.
3. Ensure that the Health Center has written documentation that hospital call coverage or emergency room coverage is required for Health Center physicians to maintain medical staff privileges, if applicable.
4. Ensure that risk management/QA/QI programs include audits of the credentialing and privileging processes to ensure that policies and procedures are fully implemented and the Health Center is compliant with FTCA and Health Center requirements. Health Centers must have documentation and demonstrate oversight of employment agreements, cross-coverage activities, activities related to securing/maintaining hospital privileges, and independent contractor arrangements.

FTCA Coverage Gaps

Health Centers engage in numerous activities that are not covered by the FTCA, and those activities may present potential "gaps" in insurance coverage, resulting in exposure to unanticipated risk and liability for the Health Center. In order to address such potential gaps in coverage, the Health Center should be familiar with what the FTCA covers, identify potential risks and gaps in coverage, and purchase general liability, directors and officers liability, automobile coverage, fire coverage, theft coverage, and such other coverage as appropriate to cover gaps and potential risks. Obtaining comprehensive FTCA wrap-around gap insurance from a private insurer is an alternative solution. FTCA gap insurance is a professional liability insurance policy that covers activities not protected by the FTCA. Policies are generally written to cover all activities and services provided by the Health Center (*e.g.*, cross coverage, nursing home, and residency program activities) that would not be protected by the FTCA. Under such a policy, specific known gaps in FTCA coverage are protected, and unexpected gaps in coverage are protected, such as denial of FTCA coverage of a service that was expected to be considered within the Health Center's scope of project. Common Health Center activities that are not covered by the FTCA include the following:

Acts Outside the FTCA's Limited Scope of Coverage

FTCA coverage is restricted to tort/medical malpractice acts or omissions of a covered entity that are within the scope of employment of a covered individual. For actions to be within the scope of employment, and therefore to be covered activities, they must: (i) be within the approved scope of the project, including sites, services, and other activities and locations; (ii) be within the requirements of the job description, contract for services, and/or duties required by the covered entity; (ii) occur during the provision of services to the covered entity's patients and, in certain circumstances, to non-Health Center patients.

Health Center litigation defense or damages not covered by the FTCA include the following:

- Automobile/Patient Transportation
- Billing Errors and Omissions
- Civil Rights Violations
- Contract Indemnification
- Criminal Acts
- Data Security Cyber Liability
- Defamation
- Discrimination
- Employment Practices
- Fiduciary
- Fraud
- General Liability (slips and falls)
- HIPAA Privacy or Security Violations
- Medical Waste
- Property/Fire Damage
- Sexual Harassment or Abuse
- Theft
- Workers Compensation[72]

Health Care Providers Who Are Not Employed By or Are Not Under Contract With the Health Center

The FTCA does not cover providers who are not employed by or have not contracted directly with the Health Center. For the FTCA to cover an individual, there must be a documented contractual relationship between the Health Center and the individual provider. If the agreement is with the provider's medical group or professional medical corporation, the provider will not be covered by the FTCA. Compensation should be paid by the covered entity directly to the individual contract provider. In addition, the following healthcare providers and employees are not covered by the FTCA: volunteers; part-time contract dentists; part-time contract behavioral health providers; part-time contract specialists in most fields; Board members/officers for anything other than medical malpractice; medical residents who are not employed by the Health Center; medical students or other trainees; licensed or certified providers not included in the Health Center scope of service; and (with certain exceptions) individuals providing services outside the approved scope, services, and locations of the Health Center.[73]

Hospital-Related Activities

Inpatient hospital care to a covered patient is considered part of the continuity of care of the patient and covered

by the FTCA if the hospital services are within the Health Center's scope of project and the covered provider's scope of employment. However, hospital-related activities such as periodic hospital call or hospital emergency department coverage are only covered by the FTCA if required by the hospital as a condition for obtaining hospital admitting privileges. In order to be covered by the FTCA, the Health Center will have to provide HHS with documentation that the hospital call coverage and/or emergency department coverage in question was a condition of employment at the Health Center and required by the hospital as a condition of maintaining hospital privileges.[74]

Hold Harmless and Indemnification Clauses

Organizations that contract with the Health Center may require that hold harmless or indemnification clauses be incorporated into their contracts with the Health Center. As noted above, FTCA coverage does not include such indemnification coverage. To the extent that the Health Center is responsible for any losses incurred as a result of indemnification clauses in any of its contracts, the Health Center should obtain appropriate private insurance coverage for such claims.[75]

Coverage Determinations

If a Health Center is not sure whether or not a particular activity is covered by the FTCA, the Health Center may submit a request for a particularized determination of FTCA coverage. The coverage determination request should include sufficient detail for HRSA to determine: (1) what services are being provided; (2) who provides the services; (3) where the services will be provided; (4) why Health Center staff are needed to provide such services; and (5) how the services benefit Health Center patients.[76] The request for particularized determination must also provide a narrative explanation, signed by the Chief Executive Officer of the covered entity, setting forth how the request satisfies the criteria listed above. Job descriptions/positions and other relevant agreements or arrangements must be attached to the request to show how the covered entity will implement the activity for which FTCA coverage is sought. All particularized coverage determination applications or questions should be submitted in writing to ftcapd@hrsa.gov.

The Impact of Mergers and Acquisitions on FTCA Deeming

When covered entities merge to form a new corporate entity, the new corporation must apply for FTCA coverage. No employee, contractor, or officer of the new corporation will have FTCA coverage until a deeming application from the new corporation is approved by HRSA/BPHC. If a covered entity is absorbed by a non-deemed Health Center, the staff from the deemed corporation will no longer be covered under FTCA. If a covered entity absorbs a non-deemed Health Center, the staff from the non-deemed Health Center will be covered under FTCA if they meet all deeming requirements.[77]

Conclusion

Whether advising a claimant or medical care provider in tort/medical malpractice litigation, attorneys should have a good understanding of the FTCA. Health Centers that wish to qualify for FTCA coverage should be prepared for FTCA coverage compliance audits and on an ongoing basis should ensure that they meet the FTCA program requirements. Health Centers should adopt, implement, review and update appropriate policies and procedures related to risk management, medical record documentation, credentialing, quality improvement and quality assurance. Health Centers should also maintain documentation of monitoring and audits of policies and procedures, and should maintain quality of care review committee minutes and reports to demonstrate that the Health Center has reduced the risk of medical malpractice and the risk of lawsuits. If the Health Center has had any lawsuits, it should document how it has addressed the issues raised in the lawsuit(s) and the systemic changes it has made to reduce the risk of re-occurrence.

The FTCA provides important malpractice coverage for qualifying Health Centers. The intent of the FTCA Medical Malpractice Program is to increase the availability of funds to Health Centers to provide primary healthcare services through savings of approximately $209 million per year in premiums.[78] By reducing or eliminating the Health Center's malpractice insurance premiums, Health Centers have more money to increase the number of patients served, increase the scope of services such as health education and case management, reduce barriers to care and implement expanded programs for quality assurance and risk management that benefits patients and the community. It is in the best interest of each Health Center to ensure that its program complies with the FTCA so that it can be eligible for FTCA coverage.

As of March 2009, the most recent data available specific to Health Centers, a total of 2,594 administrative claims and 800 federal lawsuits had been filed against Health Centers with FTCA coverage. Of those filed claims and lawsuits, HHS settled 185 claims during the administrative process, and the DOJ settled or tried 454 lawsuits in federal court, for a total of approximately $298 million paid to resolve the settlements and lawsuits. Of the remaining 1,955 claims, 646 were disallowed during the administrative review process, and 1,309 claims/lawsuits were outstanding as of March 2009.[79] Having FTCA coverage can indeed be very helpful.

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Federally Qualified Health Center Federal Tort Claims Act Insurance Coverage

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Endnotes

1 28 U.S.C. § 2671 et seq.

2 *Commissioners of the State Ins. Fund v. United States*, 72 F. Supp. 549 (S.D.N.Y. 1947).

3 *Id.*

4 25 U.S.C. § 450f (d) and 25 U.S.C. § 458aaa–15.

5 FSCHAA extended FTCA protections under 28 U.S.C. § § 1346(b), 2401(b), and 2679-81 to eligible Health Centers funded under Section 330 of the Public Health Service Act so that Health Centers did not have to spend grant dollars purchasing costly medical malpractice insurance. See Public Law 102-501 (1992) and Public Law 104-73 (1995).

6 H.R.Rep.No. 102-823(1), 102nd Cong., 2nd Sess. (1992). Health Center Program grantees are organizations that receive grants under the Health Center Program as Authorized under section 330 of the Public Health Center Act, as amended. Grantees are sometimes referred to as federally funded Health Centers.

7 Health Centers are regulated by the Bureau of Primary Health Care ("BPHC") under the Health Resources and Services Administration ("HRSA") of the U.S. Department of Health and Human Services ("HHS"). The term "Health Centers" includes Health Centers supported by federal grants, Health Centers that have been determined to meet the definition of a Health Center but do not receive Section 330 funds under the Health Center program, and outpatient health programs and facilities operated by tribal organizations. However, FTCA coverage is only available to Health Centers funded under Section 330.

8 *See America's Health Centers*, NAT'L ASS'N OF COMMUNITY HEALTH CENTERS FACT SHEET (National Association of Community Health Centers, Bethesda, MD), March 2014 www.allhealth.org/briefingmaterials/AMERICASHEALTHCENTERSMARCH2014_4G.PDF.

9 John T. Hammerlund, "Community Health Centers and Rising Malpractice Premiums: An Overview of the Community Health Center Program and Proposed Solutions to the Malpractice Insurance Rate Crisis," 1 Cornell Journal of Law and Public Policy 135-174 (1992).

10 *Id.*

11 *Id.*

12 "Cost to the Government for Providing Medical Malpractice Coverage to Community and Migrant Health Centers," Office of the Inspector General, Department of Health and Human Services, March 25, 1996, P. 3.

13 42. U.S.C. § 233.

14 HRSA has approved FTCA coverage for Health Center treatment of non-patients in the following situations: school based clinics, health fairs, immunization campaigns, migrant outreach, homeless outreach, hospital call and emergency room coverage, after-hours cross coverage, continuity of care, clinical research, teaching activities, emergency events, and activities under other grant funding.

15 42 C.F.R. § 6.6.

16 http://bphc.hrsa.gov/ftca/about/index.html.

17 Jacqueline C. Leifer, Molly S. Evans, Robert A. Graham, and Emilie T. Pinkham, *Federally-Qualified Health Centers: From Safety Net Provider to Cornerstone of Health Reform?* J. Health & Life Scr. L., Oct. 2014, American Health Lawyers Association, www.healtlawyers.org/JHLSL.

18 See, HHS OIG 2015 Work Plan, which can be found at http://oig.hhs.gov/reports-and-publications/archives/workplan/2015/FY15-Work-Plan.pdf.

19 Martin J. Bree, "HRSA Initiates Random FTCA Audits; Malpractice Coverage At Stake," Feldesman Tucker Health Care Blog, September 18, 2014, www.feldesmantucker.com/hrsa-initiates-random-ftca-audits-malpractice-coverage-stake.

20 United States Department of Health and Human Services Health Resources Services Administration Federal Tort Claims Act Health Center Policy Manual (Supersedes PIN 2011-01), July 21, 2014, http://bphc.hrsa.gov/policiesregulations/policies/ftcahcpolicymanualpdf.pdf.

21 Title 42, part 6 (42 C.F.R. part 6).

22 HRSA policies are generally reflected in Policy Information Notices and Program Assistance Letters. Policy Information Notices ("PINs") define and clarify policies and procedures that grantees funded under Section 330 must follow. Program Assistance Letters ("PALs") summarize and explain items of significance for health centers, including,

for example, HRSA program implementation activities, recently enacted laws, final regulations, and/or new HHS initiatives.

23 United States Department of Health and Human Services, Health Resources Services Administration Program Assistance Letter 2014-09, Notice of Federal Tort Claims Act (FTCA) Health Center Policy Manual Update, page 1 (July 21, 2014). http://bphc.hrsa.gov/policiesregulations/policies/pal201409pdf.pdf.

24 FTCA Manual Subsection I.C.4.

25 PAL 2014-03, "Calendar Year 2015 Requirements for Federal Tort Claims Act (FTCA) Medical Malpractice Coverage for Health Centers," February 3, 2014 (PAL 2014-03). PAL 2014-03 describes the process for Health Center Program grantees to submit FTCA deeming applications for CY 2015.

26 *Id*.

27 *Id*.

28 Federal Tort Claims Act Health Center Policy Manual, Section I(A.2), July 21, 2014. See also PAL 2014-9, which explains recent amendments to the FTCA Health Center regulations.

29 Note 5, *supra*.

30 Section 224(h)(1) of the Public Health Service Act.

31 Section 224(h)(2) of the Public Health Service Act.

32 Section 224(h)(3) of the Public Health Service Act.

33 Please note that an FTCA deeming application is not considered complete until all required documentation has been completed and submitted through the EHB, and if required by HRSA, a site visit has been completed.

34 42 U.S.C. § 233(h)(2); See also HRSA PINs PIN 2001-16 and 2002-22.

35 Note 5, *supra*.

36 *Id*.

37 *Id*.

38 28 U.S.C. §§ 2672, 2675; 28 C.F.R. §§ 14.2-14.4.

39 28 U.S.C. § 2401(b) and 2675(a); 28 C.F.R. § 14.2(a). Form SF-95 is available at: www.gsa.gov/portal/forms/download/116418. See, e.g. *Hart v. Dep't of Labor ex rel. United States* 116 F.3d 1338 (10th Cir. 1997) (affirming dismissal of plaintiff's claim because the completed administrative claim was filed with the attorney general rather than the Department of Labor).

40 *Id. See also Adams v. United States*, 615 F.2d 284 (5th Cir. 1980) (finding presentation of claim satisfied provided the agency has sufficient notice of the incident to investigate and the claim states a sum of certain damages).

41 28 U.S.C. § 2675(b). A Westlaw guide on using jury verdicts to assess damages can be found at: http://west.thomson.com/documentation/westlaw/wlawdoc/wlres/verdqr06.pdf.

42 28 C.F.R. § 14.2(a).

43 28 U.S.C. § 2401(b).

44 *McMillan v. United States*, 46 F.3d 377, 381 (5th Cir. 1995) ("under the FTCA, the limitations period is not tolled during the minority of the putative plaintiff; rather his parents' knowledge of the injuries is imputed to him").

45 *Chomis v. United States*, 377 F.3d 607, 615 (6th Cir. 2004) ("courts have uniformly held that mental incompetency, standing alone, will not toll the running of the statute of limitations under the FTCA").

46 *Gonzales v. United States*, 284 F.3d 281 (2002) – a Health Center case where a plaintiff filed a suit within the Massachusetts three year statute of limitations. The court held that the claim is time barred, dismissing plaintiff arguments re: discovery rule, equitable tolling and fraudulent concealment.

47 28 U.S.C. § 2401(b). See, e.g., *Willis v. United States*, 719 F.2d 608.

48 Note 7, *supra* at 21-22.

49 28 U.S.C. § 2675(a); See e.g., *McNeil v. United States*, 508 U.S. 106, 113 (1993), where a pro se plaintiff filed suit four months before filing his administrative claim, the Supreme Court unanimously held that "the FTCA bars claimants from bringing suit until they have exhausted their administrative remedies."

50 28 U.S.C. § 2675; 28 C.F.R § 14.9.

51 28 U.S.C. § 1346(b).

52 28 U.S.C. § 1402(b).

53 See *Upchurch v. Piper Aircraft Corp.*, 736 P.2d 439, 440 (8th Cir. 1984) (holding United States waived venue objection by not including it in answer).

54 28 U.S.C. § 2678.

55 "Scope of project," generally refers to activities for which the Health Center has been approved by HRSA to engage in.

56 42 C.F.R. § 51c.303(c), 42 C.F.R. § 56.303(c), and 42 U.S.C. § 254b(k)(3)C).

57 Pursuant to 42 U.S.C. § 254b(n), Health Centers are required to establish and maintain such records as the Secretary of HHS shall require.

58 42 C.F.R. § 51c.303(c), 42 C.F.R. § 56.303(c), and 42 U.S.C. § 254b(k)(3)C).

59 42 U.S.C. § 254b(k)(3)(I)(ii).

60 PIN 2001-16.

61 *See* PIN 2002-22.

62 Primary source verification is verification by the original source of a specific credential to determine the accuracy of a qualification reported by a practitioner. Secondary source verification is verification by sources other than primary sources.

63 *See* PIN 2002-22 Table: Comparative Summary of Requirements for Credentialing and Privileging "Licensed or Certified Health Care Practitioners."

64 "Human Resources Insights: Tips for Health Center Credentialing and Privileging, National Association of Community Health Centers, May 2013.

65 *Id*.

66 Alternatively, the Board may delegate this responsibility (via resolution or bylaws) to an appropriate individual or committee, to be implemented based on policies and procedures approved by the Board (including methods to assess compliance with these policies and procedures).

67 Martin J. Bree, "Managing FTCA Risk, a Key Component of an Enterprise Risk Management Program," Bi-State Primary Care Association Meeting, May 14, 2013.

68 Martin J. Bree, "HRSA Initiates Random FTCA Audits; Malpractice Coverage At Stake," Feldesman Tucker Health Care Blog, September 18, 2014, www.feldesmantucker.com/hrsa-initiates-random-ftca-audits-malpractice-coverage-stake.

69 PAL 2014-03, February 3, 2014.

70 Stephen J. Frew, JD, "Avoiding the Traps that Lead to Liability," Johnson Insurance Services, LLC, http://c.ymcdn.com/sites/www.nvpca.org/resource/resmgr/Website_PDFs/04_Frew_-_FQHC_Risk_9-8-14.pdf.

71 Note 5, *supra*.

72 National Association of Community Health Center Analysis: Federal Tort Claims Act Coverage: Reducing Exposure for Common "Gap" Areas, September 2009.

73 *Id*. See 78 Fed. Reg. 58202, September 23, 2013. 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, and cross-coverage activities.

74 *Id*.

75 *Id*.

76 FTCA Manual, Section C.4.

77 Note 7 *supra*.

78 Only 190 claims were filed in 2011. Diagnosis and treatment related incidents were the largest amount of claims, closely followed by obstetrics-related incidents. Christopher W. Gibbs, JD, MPH, "FTCA Medical Malpractice Basics and Program Updates", Department of Health and Human Services, Health Resources and Services Administration, Bureau of Primary Health Care, Office of Quality and Data (2014).

79 "*Federal Tort Claims Act: Information Related to Implications of Extending Coverage to Volunteers at HRSA Funded Health Centers*," United States Government Accountability Office Report GAO-09-693R (June 24, 2009).