DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 6

RIN 0906-AA77

Federal Tort Claims Act (FTCA) Medical Malpractice Program Regulations: Clarification of FTCA Coverage for Services Provided to Non-Health Center Patients

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Final rule.

SUMMARY: This final rule amends the current regulatory text of the regulations for FTCA Coverage of Certain Grantees and Individuals with the key text and examples of activities that have been determined, consistent with provisions of the existing regulation, to be covered by the FTCA, as previously published in the September 25, 1995 Federal Register Notice (September 1995 Notice). Additionally, HRSA has added examples of services covered under the FTCA involving individual emergency care provided to a non-health center patient and updated the September 1995 Notice immunization example to include events to immunize individuals against infectious illnesses. The amended regulation will supersede the September 1995 Notice.

DATES: *Effective Date:* The amendments in this final rule are effective [**INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN FEDERAL REGISTER**].

FOR FURTHER INFORMATION CONTACT: Suma Nair, Director, Office of Quality and Data, Bureau of Primary Health Care, Health Resources and Services Administration, U.S. Department of Health and Human Services, 5600 Fishers Lane, Room 6A-55, Rockville, Maryland 20857; Phone: (301) 594-0818.

SUPPLEMENTARY INFORMATION:

A. Background

Section 224(a) of the Public Health Service (PHS) Act (42 U.S.C. 233(a)) provides that the remedy against the United States under the Federal Tort Claims Act (FTCA) for damage for personal injury, including death, resulting from the performance of medical, surgical, dental, or related functions by any commissioned officer or employee of the PHS while acting within the scope of his office or employment, shall be exclusive of any other related civil action or proceeding. The Federally Supported Health Centers Assistance Act of 1992 (Public Law 102-501), as amended in 1995 (FSHCAA) (42 U.S.C. 233(g)-(n)), provides that, subject to its provisions, certain entities receiving funds under section 330 of the PHS Act, as well as any officers, governing board members, employees, and certain contractors of these entities, may be deemed by the Secretary to be employees of the PHS for the purposes of this medical malpractice liability protection.

A final rule implementing Public Law 102-501 was published in the Federal Register (60 FR 22530) on May 8, 1995, and added a new part 6 to 42 CFR Chapter I, Subchapter A. This rule describes the eligible entities and the covered individuals who are or may be determined by the Secretary to be within the scope of the FTCA protection afforded by the Act.

Section 6.6, also published in the May 8, 1995 rule, describes acts and omissions that are covered by FSHCAA (covered activities or covered services). The language of subsection 6.6(d) matches the statutory criteria that may support a determination of coverage for services provided to individuals who are not patients of the covered entity.

Subsection 6.6(e) provides examples of situations within the scope of subsection 6.6(d). Questions were raised, however, about the specific situations encompassed by 6.6(d) and 6.6(e) and about the process for the Secretary to make the determinations provided by those subsections. In response, HRSA decided that it would be impractical and burdensome to require a separate application and determination of coverage for certain situations described in the examples set forth in 6.6(e), as further discussed in the September 1995 Notice (60 FR 49417). For those situations, it was determined that the activities described in the September 1995 Notice are covered under 42 CFR 6.6(d) without the need for a separate application, so long as other requirements for coverage are met, such as a determination that the entity is a covered entity, a determination that the individual is a covered individual, and a determination that the acts or omissions by those individuals occur within the scope of employment.

B. Notice of Proposed Rulemaking

HRSA published a Notice of Proposed Rulemaking (NPRM) on February 28, 2011. The NPRM proposed:

(1) To replace the current regulatory text at 42 CFR 6.6(e) of the regulations at 42 CFR part 6 ("FTCA Coverage of Certain Grantees and Individuals") with key text and examples of activities that have been determined, consistent with provisions of the existing regulation, to be covered by FTCA, as previously published in the September 1995 Notice, in 42 CFR 6.6(e);

(2) To update the "Immunization Campaign" example to clarify that this covered situation includes events to immunize individuals against infectious illnesses and does not limit coverage to childhood vaccinations; and

(3) To add the following new example as subsection 6.6(e)(4) to set forth its determination of FTCA coverage for services rendered to non-health center patients in certain individual emergency situations. This addition is expected to provide assurance of FTCA coverage in these situations and encourage reciprocal assistance by non-health center clinicians for health center patients in similar emergencies.

C. Comments in Response to the NPRM

HRSA received comments from 12 organizations and individuals in response to the NPRM. All of the comments submitted were in favor of the proposed rule. The major comments are summarized as follows:

(1) Clarify whether health centers that participate in health fairs are covered:

Several commentators requested that HRSA modify Paragraph 6.6(e)(1)(iii) to clarify that health centers that conduct or *participate* in health fairs are covered.

(2) Clarify whether health centers that participate in immunization campaigns are covered:

Several commentators requested that HRSA modify paragraph 6.6(e)(1)(iv), Immunization Campaigns, to clarify that health centers that conduct or *participate* in immunization campaigns are covered.

(3) Amend the proposed new paragraph 6.6(e)(4), addressing individual emergency situations, by adding the term “urgent situations,” and the phrase, “as determined by the health center provider at the scene of the incident:”

Several commentators requested that HRSA modify proposed paragraph 6.6(e)(4) to include urgent situations and to more clearly define what would constitute an emergency

or urgent situation. Additionally, commentators requested that the phrase, "as determined by the health center provider at the scene of the incident," also be added to 6.6 (e)(4).

(4) Clarify, define, and/or delete the term "after hours" in paragraph 6.6(e)(3):

Several commentators requested that HRSA provide clarification or define the term "after hours" utilized in paragraph 6.6(e)(3), "Coverage-Related Activities."

(5) Set forth a presumption of FTCA coverage for all services within an approved scope of project:

Several commentators requested that HRSA assert a presumption of coverage for all providers' services and activities included within the health center's federally approved scope of project.

D. Agency Analysis and Decision

(1) Clarify whether health centers that participate in health fairs are covered:

HRSA concurs with the comment and will add the phrase "or participate in" to paragraph 6.6(e)(1)(iii) of the final rule. The paragraph will therefore read "Health Fairs: On behalf of the health center, health center staff conduct or participate in an event to attract community members for purposes of performing health assessments. Such events may be held in the health center, outside on its grounds, or elsewhere in the community."

(2) Clarify whether health centers that participate in immunization campaigns are covered:

HRSA concurs with the comment and will add the phrase "or participate in" to example 6.6(e)(1)(iv) of the final rule. The paragraph will therefore read, "Immunization Campaign: On behalf of the health center, health center staff conduct or participate in an

event to immunize individuals against infectious illnesses. Such events may be held in the health center, outside on its grounds, or elsewhere in the community."

(3) Add to the proposed new paragraph 6.6(e)(4), addressing individual emergency situations, the term "urgent situations," and the phase, "as determined by the health center provider at the scene of the incident:"

HRSA has considered the statutory language, its regulatory implementation, and the legislative history of the FSHCAA and is declining to adopt additional recommendations at this time, as these additions appear to substantially change the scope of the proposed regulation and introduce novel legal issues that were not intended by, and have not been fully addressed by, this rulemaking process.

(4) Clarify, define, and/or delete the term "after hours" in paragraph 6.6(e)(3):

HRSA has considered the statutory language, its regulatory implementation, and the legislative history of the FSHCAA and is declining to adopt additional recommendations at this time, as these additions appear to substantially change the scope of the proposed regulation and introduce novel legal issues that were not intended by, and have not been fully addressed by, this rulemaking process. The original scope of this rule was to add an emergency situations example and to align the original immunization campaign example's language with HRSA's historical interpretation of that specific example. It is not within the scope of this rule, nor was it the intention of HRSA, to make substantial and material changes to other well-established examples that were congressionally approved. Moreover, it is not within the scope of this rule, nor was it HRSA's intention, to modify and expand the other examples beyond HRSA's historical interpretation of the established examples.

(5) Set forth a presumption of FTCA coverage for all services within the federally approved scope of project:

HRSA declines to incorporate the suggested language, as the authorizing legislation, the FSHCAA, section 224(g)-(n) of the Public Health Service Act (42 U.S.C. 233(g)-(n)), does not expressly confer authority on the Secretary to extend such a presumption, and the addition of such a presumption introduces novel legal issues that were not intended by, and have not been fully addressed by, this rulemaking process.

Federalism

HRSA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. HRSA has determined that the final rule does not contain policies that have substantial direct effects on the states, the relationship between the national government and the states, or the distribution of power and responsibilities among the various levels of government. Accordingly, HRSA has concluded that the final rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

Other Impacts

HRSA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental,

public health and safety, and other advantages; distributive impacts; and equity). This rule is not economically significant under section 3(f) of Executive Order 12866 and is not being treated as a "significant regulatory action" under section 3(f). Accordingly, the rule has not been reviewed by the Office of Management and Budget.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule simply updates an existing regulation to add further details to the description of certain situations that are covered by the FTCA, and because such coverage is provided for under federal law, HRSA certifies that the rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." HRSA does not expect this final rule to result in any one-year expenditure that would meet or exceed this amount.

Paperwork Reduction Act

There are no new requirements for information collection associated with this amendment.

List of Subjects in 42 CFR Part 6

Emergency medical services, Health care, Health facilities, Tort claims.

Dated: September 12, 2013.

Mary K. Wakefield,

Administrator,

Health Resources and Services Administration.

Approved: September 16, 2013.

Kathleen Sebelius,

Secretary.

In consideration of the foregoing, the Department Health and Human Services (HHS), Health Resources and Services Administration (HRSA) amends 42 CFR part 6 as follows:

PART 6 - FEDERAL TORT CLAIMS ACT COVERAGE OF CERTAIN GRANTEES AND INDIVIDUALS

1. The authority citation for part 6 continues to read as follows:

Authority: Sections 215 and 224 of the Public Health Service Act, 42 U.S.C. 216 and 233.

2. Amend § 6.6 by adding paragraph (e)(4) to read as follows:

§ 6.6 Covered acts and omissions.

* * * * *

(e) * * *

(4) For the specific activities described in this paragraph (e)(4), when carried out by an entity (and its eligible personnel) that has been covered under paragraph (c) of this section, the Department has determined that coverage is provided under paragraph (d) of this section, without the need for specific application for an additional coverage determination under paragraph (d) of this section, if the activity or arrangement in question fits squarely within these descriptions; otherwise, the health center should seek a particularized determination of coverage.

(i) Community-Wide Interventions. (A) School-Based Clinics: Health center staff provide primary and preventive health care services at a

facility located in a school or on school grounds. The health center has a written affiliation agreement with the school.

(B) School-Linked Clinics: Health center staff provide primary and preventive health care services, at a site not located on school grounds, to students of one or more schools. The health center has a written affiliation agreement with each school.

(C) Health Fairs: On behalf of the health center, health center staff conduct or participate in an event to attract community members for purposes of performing health assessments. Such events may be held in the health center, outside on its grounds, or elsewhere in the community.

(D) Immunization Campaigns: On behalf of the health center, health center staff conduct or participate in an event to immunize individuals against infectious illnesses. The event may be held at the health center, schools, or elsewhere in the community.

(E) Migrant Camp Outreach: Health center staff travel to a migrant farmworker residence camp to conduct intake screening to determine those in need of clinic services (which may mean health care is provided at the time of such intake activity or during subsequent clinic staff visits to the camp).

(F) Homeless Outreach: Health center staff travel to a shelter for homeless persons, or a street location where homeless persons congregate, to conduct intake screening to determine those in need of clinic services

(which may mean health care is provided at the time of such intake activity or during subsequent clinic staff visits to that location).

(ii) Hospital-Related Activities. Periodic hospital call or hospital emergency room coverage is required by the hospital as a condition for obtaining hospital admitting privileges. There must also be documentation for the particular health care provider that this coverage is a condition of employment at the health center.

(iii) Coverage-Related Activities. As part of a health center's arrangement with local community providers for after-hours coverage of its patients, the health center's providers are required by their employment contract to provide periodic or occasional cross-coverage for patients of these providers.

(iv) Coverage in Certain Individual Emergencies. A health center provider is providing or undertaking to provide covered services to a health center patient within the approved scope of project of the center, or to an individual who is not a patient of the health center under the conditions set forth in this rule, when the provider is then asked, called upon, or undertakes, at or near that location and as the result of a non-health center patient’s emergency situation, to temporarily treat or assist in treating that non-health center patient. In addition to any other documentation required for the original services, the health center must have documentation (such as employee manual provisions, health center bylaws, or an employee contract) that the provision of individual

emergency treatment, when the practitioner is already providing or undertaking to provide covered services, is a condition of employment at the health center.

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