Providing Care and the Federal Tort Claims Act Program: Introductory Guidance

Background

At the heart of a health center’s mission and its operations is the provision of preventive and primary health care services to patients. Consequently, health centers are subject to specific requirements in regard to providing care. Among the standards governing the provision of health care services are the requirements related to termination of the patient-provider relationship. In most businesses, the service provider can simply determine that it no longer wishes to sell services to its customers. In the case of the health care professional, however, medical ethics rules, as well as contractual obligations with payors and some state laws, limit the ability of the provider to terminate its relationship with patients.

Further, the health care services furnished by a health center, either directly through employed health professionals or under an established arrangement with other health care providers in the community, are regulated by a variety of professional and legal standards. These standards principally include the prevailing standards of care relevant to physicians and other health professionals set forth in a state’s professional licensing laws.

This document describes relevant legal requirements under Section 330 of the Public Health Service Act (“Section 330”) and the Federally Supported Health Centers Assistance Act (“FSHCAA”).

Section 330 Requirements

Section 330 implementing regulations describe the project elements with which health centers comply, including the following requirements relevant to patient care:

- a) Provide the health services of the center so that such services are available and accessible promptly, as appropriate, and in a manner which will assure continuity of service to the residents of the center’s catchment area.
- b) Implement a system for maintaining the confidentiality of patient records in accordance with the requirements of §51c.110 of subpart A.
- c) Have an ongoing quality assurance program.¹

In its Health Center Site Visit Guide (“Site Visit Guide”), the Health Resources and Services Administration (“HRSA”) has provided further guidance on these elements.² The Nineteen

¹ See 42 C.F.R. § 51c.303(a) - (c). For more information regarding quality assurance programs, see Quality assurance programs: Introductory guidance.
Requirements require health centers to have, among other things, “an ongoing Quality Improvement/Quality Assurance (QI/QA) program that includes clinical services and management, and that maintains the confidentiality of patient records.”

**Professional Liability Coverage under the Federal Tort Claims Act Program**

In order to assist health centers in providing care, Section 224 of the Public Health Service Act provides immunity from lawsuits to Section 330-funded health centers, and their officers, directors, employees, and certain full-time and part-time contracted clinicians when the health center successfully applies for and is deemed to be a Public Health Service (“PHS”) employee by the Health Resources and Services Administration (“HRSA”). These individuals and entities are treated as PHS employees for purposes of professional liability protection (i.e., medical malpractice).

If a health center patient decides to bring a malpractice lawsuit against the health center, its employee, covered contractor, etc., the patient cannot sue the health center or the provider, but must file an administrative claim against the United States according to the requirements of the Federal Tort Claims Act. Should the health center, its employee, covered contractor etc. be sued in state court for actions arising within the scope of this deemed employment, they should ensure prompt notification of the litigation to the U.S. Department of Health and Human Services (“DHHS”) Office of the General Counsel. The action may then be removed to federal district court and the United States substituted as the named defendant. The claims are reviewed by the DHHS Office of the General Counsel and litigated by the Department of Justice, according to FTCA requirements.

FTCA coverage does not extend to:

- Federally-Qualified Health Center Look-Alikes; health centers funded only with American Recovery and Reinvestment Act of 2009 (Stimulus) funds;
- Medical, dental or behavioral health students or residents providing care at the health center (unless otherwise employed by the health center);
- Otherwise covered professionals who are providing health care services for another entity, health center employees working for other organizations (“moonlighting”); and,
- Volunteers at the health center.

The Congressional intent behind extending the immunity enjoyed by PHS employees (FTCA protection) to health centers was to increase the availability of grant funds to support health centers’ provision of primary care services in medically underserved communities by allowing...

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3 Id. p. iv; see also, generally, pp. 15-17.
4 See also 42 C.F.R. Part 6.
5 Extensive discussion of the legal parameters of health center FTCA coverage, as well as the requirements and limitations to such coverage, can be found in the HRSA/BPHC Federal Tort Claims Act (FTCA) Health Center Policy Manual (July 2014).
6 Id.
health centers to substantially reduce their expenditures for medical malpractice insurance premiums.

**Deeming Process**

To be deemed to be a PHS employee (attain FTCA-covered status), health centers funded under Section 330 must complete a “deeming” application which demonstrates that the health center:

1. 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;
2. 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 health care providers are reviewed and verified and, where necessary, has obtained the permission from these individuals to gain access to this information;
3. Has no history of claims having been filed against the United States as a result of the application of 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,
4. Will fully cooperate with the Attorney General and the Federal Government in providing the necessary information related to the claim.7

Moreover, health centers are also required to have clinical protocols, tracking systems, medical record review procedures, and a quality assurance program to maintain eligibility. Health center grantees must submit a re-deeming application on an annual basis.8

In response to a full and complete deeming application, the health center will receive a “Notice of Deeming Action” from the Bureau of Primary Health Care confirming that the health center and its employees/certain eligible contractors are covered by FTCA.

**Scope of Coverage**

FTCA provides professional liability / medical malpractice coverage only for services provided within the health center’s Section 330-approved scope of the project9 and within the provider’s scope of employment.10 FTCA coverage for any new health center service or site is dependent

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7 Id.
8 Id.
9 A health center’s “scope of project” consists of five core elements -- sites, services, providers, service areas and target populations -- which are described in its grant application.
10 Accordingly, it is important to specify each health center site where a provider will serve patients, as well as the scope of services to be provided, in provider employment agreements and contracts. In addition, the employment agreements/contracts should clearly specify that the health care providers will provide services in accordance with
upon BPHC approval of a change in the health center’s scope of project. If certain activities are
treated by a health center as outside the Section 330-approved scope of project (e.g., providing
specialty services not approved by HRSA, selling excess capacity to other local providers),
commercial malpractice insurance coverage will be needed.

In addition to coverage for all health center employees (whether part-time or full-time), FTCA
coverage may extend to full-time and certain part-time contractors, provided that certain
conditions are met. First, the contract must be directly between the health center and the individual
licensed or certified health care practitioner. An agreement between a health center and a hospital
(or an incorporated physician group practice or any other entity that employs the clinician) will not
extend FTCA coverage to the individual health professionals who, as employees of another entity,
are assigned to provide clinical services at the health center through such an agreement.

Second, a health center must contract for the services of the licensed or certified health care
practitioner for at least 32 ½ hours a week (i.e., on a full time basis). An exception to this “full
time” requirement exists for contracted providers specializing in the fields of general internal
medicine, family practice, general pediatrics, and obstetrics and gynecology.

There will be no FTCA coverage if a deemed health center’s employed or contracted clinician bills
separately and individually for and collects reimbursement for services provided. There is an
exception to this rule whereby coverage can be maintained if all of the following conditions are
met:

- The provider’s employment contract authorizes the billing arrangements (…);
- The provider reports to the health center all such billings; and
- The funds received by the provider for the specific billing are transferred directly to the health
center within a reasonable period of time.11

The Authors recommend that this exception be avoided wherever possible.

Non-Health Center Patients

Generally, FTCA will not cover services provided to non-health center patients. DHHS, however,
has published regulatory exceptions, which establish coverage for certain health center activities
involving the provision of services to non-health center patients and/or at non-health center sites,
without the need to obtain specific clarification or a particularized determination (prior approval)
of coverage,12 provided that all requirements of the regulatory exception are met. The regulations

the health center’s policies and procedures, and subject to the ultimate oversight and direction of the health center’s
medical director and executive director. Moreover, the contract should provide that the contracted clinician will
participate in the health center’s quality assurance program and corporate compliance program.

12 Federal Tort Claims Act (FTCA) Medical Malpractice Program Regulations: Clarification of FTCA Coverage for
Services Provided to Non-Health Center Patients (Sept 23, 2013).
state that health centers should be “painstakingly exact” to make certain their situation “squarely
fits” the exception in the regulation.

As long as the conditions discussed above are met, FTCA will cover deemed health centers and
their qualified providers for the services provided to non-health center patients under the following
regulatory exceptions, regardless of the fact that services are provided to non-health center
patients:13

• **Hospital or emergency room on-call arrangements.** The health center requires its
  physicians to obtain staff privileges at a hospital, and the hospital as a condition of
  obtaining such privileges (and thus being able to admit the center’s patients to the
  hospital), requires the health center and/or its physicians to agree to provide periodic
  hospital or hospital emergency room call. The physician’s employment agreement or
  contract for services must clearly require that such privileges are a condition of
  employment or required under the contract.

• **After-hours cross coverage arrangements with community providers.** The health
  center makes arrangements with local community providers for after-hours coverage of
  its patients, and agrees to provide the services of its providers for after-hours cross-
  coverage. The provider’s employment agreement or contract for services must require
  after-hours periodic cross-coverage for the patients of the community providers.

• **School-based clinics.** The health center’s staff provides primary and preventive health
  care services at a facility located in a school or on school grounds based on a written
  affiliation agreement with the school.

• **School-linked clinics.** The health center’s staff provides primary and preventive health
  care services at a site not located on school grounds, to students of one or more schools.
  The health center must have a written affiliation agreement with each school.

• **Immunizations campaigns.** On behalf of the health center, staff conduct or participate
  in an event to immunize individuals against infectious illnesses. Such events may be
  held in the health center, on its grounds, or elsewhere in the community served by the
  health center (such as community centers).

• **Health fairs.** On behalf of the health center, staff conduct or participate in an event to
  attract community members in order to perform health assessments. Health fairs may be
  held in the health center, outside on the health center’s grounds, or elsewhere in the
  community.

• **Homeless outreach.** The health center’s staff travels to a shelter for homeless persons
  or a street location where homeless persons congregate to conduct intake screening to

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13 Id.
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 at the same location).

- **Migrant camp outreach.** Health center staff travels to a migrant farm worker residence camp to conduct intake screening to determine those in need of clinic services. Health care services may be provided at the time of the intake activity or during subsequent clinic staff visits to the camp.

- **Individual emergencies.** A health center clinician is providing 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 the exceptions above, when the provider is asked, as the result of a non-health center patient’s emergency situation, to temporarily treat 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.

“**Particularized Determination**” of FTCA Coverage

To ensure coverage for activities provided pursuant to the exceptions described above, HRSA urges deemed entities to ensure that their proposed activities fit squarely within one of the examples provided.\(^\text{14}\) In cases where an activity does not clearly meet one of the exceptions, the deemed entity should seek a “particularized determination” of FTCA coverage.\(^\text{15}\) The regulations establish three criteria for approval of particularized determination requests, any one of which can be used to justify a determination of coverage:

- The provision of the services to non-health center patients benefits the health center’s patients as well as the general populations that could be served by the health center through community-wide intervention efforts conducted within the communities served by the health center.

- The provision of the services to non-health center patients facilitates the provision of services to the health center’s patients.

- The services rendered are otherwise required to be provided to the non-health center patients under an employment contract or similar arrangement between the health center and the covered provider.

\(^\text{14}\) See 42 C.F.R. § 6.6(e); regulatory notice published at 60 Fed. Reg. 49417 (Sept 25, 1995).

\(^\text{15}\) See 60 Fed. Reg. 49418 (Sept 25, 1995).
According to the Federal Tort Claims Act Health Center Policy Manual, an application for particularized determination of FTCA coverage for care to a non-health center patient must “include sufficient detail to determine” five things:

1. What services are provided;
2. Who provides the services;
3. Where the services are provided;
4. Why health center personnel are needed to provide such services; and,
5. How these services benefit the patients of the health center.

Additionally, such an application must have a narrative signed by the Chief Executive Officer of the health center explaining how the request meets the criteria described above.

Advice and Recommendations

The HRSA requirements regarding patient care policies and procedures are a minimal set of policies that a health center must have in place to comply with Section 330. As such, these policies provide a foundation upon which a health center should develop a more comprehensive set of policies relevant to its various clinical practice areas.

There are additional valuable sources of information pertaining to clinical standards. Health centers desiring to improve quality of care may seek to achieve compliance with the standards of pertinent national accrediting organizations, such as the Joint Commission or the Accreditation Association of Ambulatory Health Care (“AAAHC”). The National Committee for Quality Assurance (“NCQA”) sets forth accreditation standards for managed care organizations and the providers with whom they contract for the provision of patient care. These organizations set forth the standards that a provider must meet to be accredited and, although purely voluntary, provide guidance as to standards that generally exceed the prevailing “minimum” standards required by law.

Professional Liability Coverage under the Federal Tort Claims Act

To ensure compliance with all deeming requirements and to document the health center’s coverage, each health center should develop and maintain an “FTCA file” that includes:

1. A copy of the submitted deeming applications (including all attachments demonstrating appropriate systems and procedures for credentialing, risk management, clinical protocols, quality assurance, etc.);

16 The Authors of these materials include attorneys at the law firm of Feldesman Tucker Leifer Fidell LLP. The advice and recommendations consist of general guidance based on federal law and regulations and do not necessarily apply to all health centers under all facts and circumstances. Further, these materials do not replace, and are not a substitute for, legal advice from qualified legal counsel.
Areas of Concern that May Present FTCA Coverage Gaps

Health centers enter into a variety of service delivery arrangements, many of which are considered by the medical community to be part of the usual and customary practice of medicine (and, ultimately, result in high quality efficient health care for the health center’s patients). The Federal Tort Claims Act Health Center Policy Manual, however, has created doubt as to whether the provider activities under those arrangements are covered under FTCA. In particular, issues have been raised regarding coverage for services provided by health center providers to non-health center patients and/or at non-health center sites under arrangements that are similar to but do not fit squarely within the pre-approved regulatory exceptions.

Three common “gap-related” scenarios faced by many health centers include:

1. Hospital or emergency room on-call not required for privileges

If a health center requires its physicians to obtain admitting privileges at a community hospital and, as a condition of obtaining such privileges, the hospital requires that the physicians must agree to provide hospital or emergency room call, then the physicians are covered for services provided to non-health center patients while meeting on-call obligations provided that the other requirements for FTCA coverage are met.

In the years since the regulatory exceptions were first promulgated, changes have occurred in connection with the practice of medicine which in many cases have resulted in changes to the management of on-call rotations. For example:

- With increasing frequency, hospitals nationwide are eliminating the requirement that physicians participate in on-call in exchange for obtaining admitting or staff privileges.
- Many hospitals, to attract more physicians to their staff, are agreeing to pay physicians for the required emergency room call. This payment to the physician may jeopardize FTCA protections for the on-call work.

While HRSA has in the past indicated approval of certain of these types of arrangements, as of the date of this writing, HRSA’s position has yet to be formalized in written agency guidance. Thus, the Authors cannot state definitively that any specific arrangement that deviates from the pre-approved regulatory exceptions will be covered by the FTCA. To protect the health center and its qualified providers, in addition to complying with the advice provided herein, the Authors suggest that health centers follow the recommendations on establishing and documenting compliance with FTCA requirements in general, which are discussed in Federal Tort Claims Act: Health Center Policy Manual.
It is important to ensure that:

a. The on-call arrangement is included in the health center’s HRSA-approved scope of project by listing and describing the arrangement in the center’s grant application;

b. There is adequate and appropriate documentation to support performance of the on-call activities (i.e., a written agreement between the health center and the hospital); and,

c. The physician’s (or advanced practice nurse’s) job description/employment contract, requires the performance of the hospital on-call requirement.

Further description of these recommendations (along with model language, as appropriate) is provided below:

Health Center’s Grant Application: It is essential that the arrangement be documented in both the health center’s grant narrative and the applicable scope form. The health center should:

- List the arrangement on Form 5 – Part C (which lists “Other Activities / Locations”), along with the address of the facility (e.g., “hospital”) and the frequency with which the health center physicians furnish these services under the arrangement, as appropriate (e.g., as required for hospital and emergency room on-call); AND

- Indicate in the description portion of Form 5 – Part C the specific hospitals involved in such arrangement (including their specific locations) and whether non-health center patients are seen during such arrangements, as required by the hospital; and

- Describe the need for physicians to have hospital privileges with sufficient specificity in the application narrative, emphasizing how it contributes to the provision of comprehensive primary care services to the health center’s patients and the overall community.  

Provider Employment Agreement, Job Description or Employee Handbook: To minimize or avoid potential confusion regarding whether participation in hospital and/or emergency room on-call by the health center’s clinicians is a condition of their employment, the Authors recommend including in the employment agreement, job description and/or employee handbook language similar to the following:

All health care services shall be provided by Provider in accordance with this Employment Agreement, Provider’s job description, Health Center’s Principles of Practice, and Health Center’s Scope of Project as it is defined for purposes of coverage under the Federal Tort Claims Act (“FTCA”) pursuant to Section 224(g) of the Public Health Service Act.

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18 Provisions of this type may be applicable to providers other than physicians based on state law.
For all hospitals where Provider has privileges, Provider shall participate in hospital and emergency room on-call rotations for hospital care and emergency coverage as required by said hospital(s). Provider shall promptly prepare and file accurate and complete time records and reports of hours worked when required. All services provided by Provider pursuant to a hospital or emergency room on-call arrangement shall be provided in accordance with Provider’s Job Description and Health Center’s Scope of Project as it is defined for purposes of FTCA coverage.

2. Cross coverage arrangements with community providers not limited to after-hours

If a health center makes arrangements with local community providers for after-hours coverage of its patients, and agrees to provide the services of its own providers for after-hours cross-coverage, the services furnished by the health center provider while participating in cross coverage (or reciprocal call coverage) will be covered by FTCA provided that the other requirements for FTCA coverage are met.

Similar to hospital or emergency room on-call, however, changes have occurred in the manner by which health centers and their local community providers collaborate on coverage arrangements. In particular, many cross coverage (or reciprocal call coverage) arrangements are no longer limited solely to “after-hours” coverage. Health centers often enter into cross coverage arrangements with community partners (such as community call or coverage groups) that include coverage for intermittent capacity shortages when, among other things:

1. The health center’s or the community partner’s providers are on vacation or personal leave (or are otherwise unavailable); or,
2. The health center experiences a relatively unanticipated temporary increase in patients beyond its current capabilities.

Given the significant increases in the costs of securing locum tenens arrangements or other arrangements for additional capacity on a temporary basis, many community providers, including health centers, are forming these community call or coverage groups with increasing regularity, thus ensuring that their patients have access to necessary services.

There is no specific definition of “after-hours” and how it relates to health center operations. Thus, the Authors cannot state definitively that any specific arrangement that deviates from the pre-approved regulatory exceptions will be covered by FTCA.

It is important to ensure that:

1. The cross coverage arrangement is included in the health center’s HRSA-approved scope of project by listing and describing the arrangement in the health center’s grant application; and;
2. There is adequate and appropriate documentation to support performance of the cross-coverage activities.
Further description of each of these recommendations (along with model language, as appropriate) is provided below:

Health Center’s Grant Application: It is essential that the cross coverage arrangement be documented in both the health center’s grant narrative and the applicable scope form. Similar to hospital or emergency on-call, PIN 2008-01 indicates that the health center should:

- List the arrangement on Form 5 – Part C, along with the general location / facility (as applicable) and the estimated frequency with which the health center providers’ furnish services under the arrangement, as appropriate; AND
- Provide a brief description of the arrangement in the description portion of Form 5 – Part C; AND
- Describe the arrangement with sufficient specificity in the application narrative, emphasizing how it contributes to the provision of comprehensive primary care services to the health center’s patients and the overall community.

This is reiterated in the FTCA Health Center Policy Manual.

Adequate and appropriate documentation to support performance of the cross-coverage activities:

To minimize or avoid potential confusion regarding whether participation in the health center’s cross coverage arrangement is a condition of employment, the Authors recommend including in the employment agreement, job description, and/or employee handbook language similar to the following:

Provider shall participate in Health Center’s cross coverage arrangements with local community providers for medical care furnished to Health Center and non-Health Center patients in accordance with all requirements of applicable cross-coverage arrangement(s) executed by Health Center, Health Center’s policies and procedures and clinical standards of care, and the clinical work schedule developed by Health Center. Health Center shall make reasonable efforts to ensure that cross coverage obligations are reasonably allocated among the medical staff. Provider shall promptly prepare and file accurate and complete time records and reports of hours worked pursuant to such agreements. All services provided by Provider pursuant to a cross coverage arrangement shall be provided in accordance with Provider’s Job Description and Health Center’s Scope of Project as it is defined for purposes of FTCA coverage.

Written agreement between the health center and the cross coverage partner: To further document the cross coverage arrangement, the health center and its cross coverage partner should enter into a written agreement, describing the arrangement and any specific services provided. This is particularly important given that, after a malpractice claim is filed, the FTCA coverage determination process conducted by the Federal Government includes a review of all applicable documentation to establish compliance with the required terms of the arrangement in question. The
Authors recommend including in the cross coverage agreement language similar to the following but modified to suit the particular circumstances:

*Each Party, through their employed or contracted health care professionals, shall furnish [add field / type of service] cross-coverage services, as set forth below [or “as set forth in Exhibit A, attached hereto and incorporated herein by reference”], to such other Party’s patients who are under the care of, and to supplement the services provided by, the other Party’s health care professionals, in accordance with a schedule to be mutually developed and arranged between the Parties, or as otherwise required as back-up or in an emergency. Services shall be furnished in the same professional manner and pursuant to the same professional standards as are generally provided to a Party’s own patients, and in accordance with each Party’s applicable policies and procedures, based upon the mutual agreement of the Parties as to the specific terms thereof that shall be applicable hereunder. Each Party shall see the other Party’s patients in a timely manner, and without questioning the need for a consult or a request for transfer of a patient from a first-call provider (or first responder) to the care of a Party. Reciprocal cross-coverage shall include, but is not limited to:*

a) **Formal and informal telephone coverage of the Parties’ patients, as needed and in accordance with relevant policies;**

b) **Consultation regarding high risk patients, as needed and in accordance with relevant policies; and**

c) **Reciprocal on-call coverage to supplement the call coverage provided by each Party’s respective health care professionals.**

3. **Certain individual emergencies**

Increasingly, health center providers find themselves in the situations where a health center provider is on-site at a hospital for the purpose of caring for a health center patient who has been hospitalized (i.e., rounding) or to fulfill his or her on-call obligations. Assuming that rounding and/or on-call activities are included within both the health center’s approved scope of project and the provider’s scope of employment, they are covered by FTCA without question. However, while caring for his or her patient, hospital staff requests that because of an emergency the health center provider treat, or assist in treatment of, an inpatient who is not a health center patient (i.e., hospital reciprocity care).

In regulations published in September 2013, HRSA added a new approved example of FTCA-covered care to non-health center patients, referred to as “Coverage in Certain Individual Emergencies.” In this new example, if a health center provider is providing or undertaking to

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19 Since both parties are agreeing to provide services under a cross-coverage arrangement, it is also important to clarify that FTCA coverage will apply solely to the health center and its clinicians and not to the other provider(s), who will secure and maintain its own professional liability insurance.

20 Federal Tort Claims Act (FTCA) Medical Malpractice Program Regulations: Clarification of FTCA Coverage for Services Provided to Non-Health Center Patients (Sept 23, 2013).
provide care to a health center patient, or other individuals (as specified in the rule), and is asked to provide care to a non-health center patient nearby as a result of the non-health center patient’s emergency situation, FTCA coverage may be available to cover that care. For FTCA coverage to apply, the health center must document (employee manual, health center bylaws, employment agreement) that the provision of this type of individual emergency treatment is a requirement of the provider’s position at the health center.

Health centers who have staff that may be asked to respond in hospital emergencies should:

- Require that the provision of individual emergency treatment, when the practitioner is already providing or undertaking to provide covered services, is a condition of employment as documented in the employment agreement, job description, and/or employee handbook.
- Ensure that there is adequate and appropriate documentation to support performance (i.e., documentation on Form 5C listing specific hospitals where health center staff admit and follow health center patients).