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Are You Beyond the Red Line? Mastering Your FQHC's Scope of Project to Avoid Noncompliance

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By: Michael A. Dowell

Ensuring compliance with Scope of Project requirements is one of the most critical—and frequently misunderstood—obligations for Federally Qualified Health Centers (FQHCs).

The approved scope defines the legal and operational boundaries of a health center's federal award, directly governing eligibility for Section 330 grant funding, official FQHC designation, Prospective Payment System (PPS) reimbursement, and Federal Tort Claims Act (FTCA) malpractice coverage.

When health centers misstep, the consequences can be severe, including recoupment of funds, loss of deemed status, imposition of corrective action plans, heightened oversight, and, in extreme cases, termination of federal funding.

Defining Your FQHC's Scope of Project

"Scope of Project" is a formal legal and regulatory framework that governs FQHC operations under Section 330 of the Public Health Service Act (42 U.S.C. § 254b; and 42 C.F.R. Part 51), defined and enforced by the Health Resources and Services Administration (HRSA).

It constitutes the legally approved set of activities an FQHC is authorized to perform using federal grant funds, and encompasses specific service sites, services, provider types, geographic service areas, and target populations. HRSA's Bureau of Primary Health Care (BPHC) identifies five key components that collectively define this scope:

1. **Target Population:** The specific medically underserved population or population group the project is approved to serve.
2. **Service Area:** The geographic area from which the health center draws its patients.

3. **Services:** The required (e.g., primary medical, behavioral health) and additional (e.g., dental, vision) services the center is approved to provide, which may vary by grant type.
4. **Service Sites:** The physical locations where the health center delivers services.
5. **Providers:** The types of clinical professionals (e.g., physicians, nurse practitioners, dentists) who deliver the services.

This framework is further detailed in the HRSA *Health Center Compliance Manual*, Chapter 4 (*Required and Additional Health Services*), which provides the operative compliance standards and should be consulted alongside statutory and regulatory authorities when interpreting scope requirements.

Generally, only activities and locations documented in HRSA's approved forms—including **Form 5A** (services), **Form 5B** (sites), and **Form 5C** (other activities/locations) — are considered "in-scope."

This distinction carries significant practical and financial consequences: activities conducted within the approved scope qualify for Prospective Payment System (PPS) reimbursement, Federal Tort Claims Act (FTCA) medical malpractice coverage, and participation in the 340B Drug Pricing Program. Activities outside the approved scope do not.

The Right Way vs. The Risk: Change-in-Scope (CIS) or Scope Creep?

Change In Scope

A **"change in scope"** (CIS) is a formal regulatory process through which an FQHC must seek and obtain HRSA approval before implementing certain operational changes.

HRSA recognizes that not all changes to a health center's operations are equal: some changes are significant enough to alter the nature, location, or reach of the federally funded project, while others are routine operational adjustments that fall within the existing approved scope.

Changes that affect any of the five key Scope of Project components—target population, service area, services, service sites, or providers—generally require advance CIS approval before implementation.

Table of Change in Scope Types

Change Type	**Examples**	**HRSA Action Required**	**Results in New NoA?**	**Timeline/Notes** *(Implementation window after approval)*

Formal Changes	New service site, new required service, new target population	Prior approval via CIS in EHBs	Yes	Up to 60-day review; 120-day
Scope Adjustment Changes	Site address/phone/NPI change, minor mods	Submit via EHBs for approval	No	Faster review
Self-Updates	Administrative (e.g., minor updates not altering operations)	Direct in EHBs, no prior approval	Yes	Immediate

Scope Creep

"Scope creep" occurs when operational changes that require HRSA approval are implemented without it—often not through a single deliberate decision, but through incremental choices that accumulate over time. Common examples include:

- gradually expanding the range of services offered
- adding hours or locations
- piloting new programs, or
- shifting the target population served

Because these changes can appear routine from an operational standpoint, they are frequently made without a threshold determination of whether CIS approval is required.

The consequences are significant. Activities that fall outside the federally approved Scope of Project do not qualify for Prospective Payment System (PPS) reimbursement or Federal Tort Claims Act (FTCA) coverage, or participation in the 340B Drug Pricing Program.

Unauthorized changes may also constitute findings of noncompliance during HRSA reviews, and in serious cases can trigger grant conditions, corrective action requirements, or recoupment of funds. Scope creep is therefore not merely an administrative irregularity—it is a legal and financial exposure that requires active monitoring and prevention.

The Change in Scope Compass: A Compliance Checklist

Not every operational change requires a formal CIS submission, but every proposed change should trigger a threshold review to determine whether HRSA approval is needed. For changes that do require formal CIS approval, the following process applies:

Phase 1: Pre-Submission and Internal Review

Before submitting anything to HRSA, the health center must perform due diligence to ensure the change is necessary and sustainable.

- **Identify the Change Type:** Determine if the modification involves a new service site (Form 5B), a new service (Form 5A), a new target population, or a geographic service area change.
- **Categorize the Action:** Use HRSA's Compliance Manual and PIN 2008-01 to determine if the change is a Formal CIS (requires prior approval), a Scope Adjustment (address changes), or a Self-Update.
- **Conduct Impact Analysis:** Assess how the change will affect staffing, finances, clinical operations, and overall compliance risk.
- **Verify Service Delivery Method:** Confirm if the service will be provided directly, via formal contract, or through a formal referral arrangement.
- **Obtain Board Approval:** Ensure the Board of Directors has reviewed the impact analysis and formally approved the submission.
- **Review for Form 5C Eligibility:** If the activity is irregular (e.g., health fairs, street medicine, or home visits), determine if it should be listed on Form 5C instead of added as a full-service site.

Phase 2: HRSA Submission Process

Timing is critical. Implementation of formal changes cannot begin until HRSA approval is granted.

- **Prepare Required Forms:** Update Form 5A (Services), 5B (Sites), or 5C (Other Activities) as appropriate.
- **Utilize HRSA Checklists:** Consult the "Form 5B Scope Accuracy Worksheet" or other BPHC resources to ensure the submission is complete.
- **Submit via EHBs:** Upload the CIS request through the HRSA Electronic Handbooks (EHBs) at least **60 days** prior to the planned start date.
- **Monitor the Review Clock:** Be prepared for a 60-day review period; note that any required corrections will reset this clock.

Phase 3: Implementation and Verification

Once approval is received, the health center has a specific window to make the change "official."

- **Confirm Approval:** Do not begin operations until you receive a new Notice of Award (NoA) or Notice of Look-Alike Designation (NLD).
- **Execute Within 120 Days:** Formal changes must be implemented within 120 days of the HRSA approval date.
- **Complete Scope Verification:** Once the change is live, submit the Scope Verification task in the EHBs to finalize the record.

- **Update Billing & Compliance**: Ensure all billing systems, NPI registries, and FTCA records reflect the newly approved scope.
- **Required attachments for Formal CIS**: Form 5A/5B/5C as applicable; board resolution; one-page impact analysis; provider roster; description of new or modified service or billing and claims plan; site address; hours of operation; executed lease; and executed contracts/referral agreements.

Charting Your Territory: Properly Documenting Off-Site and Outreach Care

Not all health center activities occur at a formal service site. HRSA provides a mechanism—Form 5C—to document certain off-site activities within the approved Scope of Project without requiring a full-service site designation. This documentation matters: activities not reflected in the approved scope fall outside FTCA coverage and may create scope creep exposure.

Form 5C: Other Activities and Locations

Use Form 5C to document activities that do not meet the threshold criteria for a formal service site (Form 5B). Typical Form 5C activities include the following:

Category	Service Type	Brief Description
Offsite direct clinical care	Home and residential visits	Clinician visits in homes, assisted living, group homes, shelters, SNFs, and rehab.
	Mobile and satellite clinics	Care via mobile units or part-time sites in churches, CBOs, and housing complexes.
	School and workplace services	On-campus or employer-site, primary, behavioral, and preventive care.
	Street medicine	Care provided directly in encampments, parks, and similar locations.
Offsite specialty and enabling services	Care coordination/case management	Coordination and case management in homes, shelters, schools, and community sites.
	Behavioral and dental offsite care	Behavioral health, SUD, and dental services in schools, LTSS, and community sites.
	Pharmacy and health outreach	Medication management plus environmental and occupational health outreach.
Telehealth / virtual offsite care	Telehealth visits	Video or audio-only visits for primary care, behavioral health, and chronic disease.

	Remote monitoring & CCM	Remote patient monitoring, chronic care management, and other non-face-to-face care.
	Virtual specialty support	e-consults and virtual specialty services coordinated by the FQHC.
Offsite outreach and enabling services	Health education outreach	Engagement and health promotion at homes, schools, shelters, and events.
	Enrollment and support services	Offsite eligibility/enrollment help, transportation, and maternal-child outreach.
	Vulnerable population outreach	Outreach to homeless and justice-involved individuals in community and justice settings.
Referral-based offsite services	Specialty and hospital follow-up	Referrals to specialists plus hospital/ED/post-discharge follow-up in the community.
	Social service linkages	Connections to housing, food, employment, legal aid, and other social supports.

Form 5C is generally appropriate when the activity is non-routine, occurs at a location that is not regularly staffed on a scheduled basis, or offers only a limited subset of in-scope services. When a location begins operating on a regular, scheduled basis—particularly if it generates a substantial volume of patient visits—it may cross the threshold requiring a formal Form 5B service site designation and a CIS submission.

This threshold question should be revisited periodically as off-site activities evolve. Form 5C entries must be submitted to and approved by HRSA as part of the Scope of Project; internal documentation alone is not sufficient to bring an activity within scope or preserve FTCA coverage.

Top HRSA Audit Findings: Where FQHCs Trip Up

Based on HRSA's FQHC compliance reports, audit guidance, and OIG reports, the most commonly cited CIS violations fall into the following categories:

- **Undocumented or Unapproved Service Sites:** Satellite offices, co-location arrangements, or mobile unit stops are opened and begin seeing patients before—or instead of—obtaining Form 5B approval.
- **Services Provided Outside Approved Scope:** Clinical services—most commonly behavioral health, dental, or specialty services—are added before obtaining the required Form 5A amendment.
- **Target Population Drift:** Expansion of FQHC patient base to include populations not reflected in the approved scope without obtaining CIS approval.

- **Telehealth Service Area Violations:** Providing telehealth services to patients located outside the approved geographic service area without CIS approval.
- **Unapproved Contractual Arrangements:** Contracts or arrangements with outside providers, hospitals, or community organizations that expand services or shift clinical control are entered into without CIS approval.
- **Form 5C Locations Operating as De Facto Service Sites:** Off-site activities that began as occasional outreach gradually become regularly scheduled, staffed locations without the required upgrade to Form 5B status.
- **PPS Billing for Non-Qualifying Sites:** Billing at the PPS rate for services delivered at locations not approved as Form 5B service sites—including Form 5C locations, provider offices, and contracted sites.
- **Board Approval Deficiencies:** CIS submissions submitted to HRSA without a prior formal board resolution, or with only generic board authorization not specific to the proposed change.
- **Outdated or Inaccurate Form 5A/5B Information:** Approved scope documentation is not updated to reflect operational changes—including site relocations, hour changes, or service reconfigurations.

The Cost of Getting It Wrong: Regulatory, Financial and Legal Risks

Non-compliance with CIS requirements carries cumulative regulatory, financial, and legal consequences that can escalate significantly if not promptly remediated. Taken together, these consequences reflect that scope compliance is not an administrative formality—it is a governance and compliance obligation with material legal, financial, and operational stakes.

Regulatory Consequences

Scope violations identified during HRSA Operational Site Visits or other reviews typically result in formal audit findings, corrective action plan requirements, and conditions placed on the federal award.

Persistent or significant non-compliance can result in heightened oversight, suspension of grant funding, or—in the most serious cases—loss of FQHC designation. Because FQHC designation is the foundation for PPS reimbursement, 340B Drug Pricing Program eligibility, NHSC assignment eligibility, and CMS FQHC certification, its loss constitutes an existential financial and operational event for most health centers.

Financial Consequences

Services determined to be out of scope may result in the disallowance of associated federal grant costs and repayment obligations. Out-of-scope PPS billing—where services were billed at the PPS rate from locations or for services not within the approved scope—exposes the health center to Medicaid and Medicare recoupment applied retroactively to all claims submitted during the period of non-compliance.

Where out-of-scope PPS billing constitutes actual knowledge, deliberate ignorance, or reckless disregard, it may give rise to False Claims Act liability, including qui tam actions brought by whistleblowers, with potential treble damages and civil monetary penalties.

Scope misalignment may also impact 340B Drug Pricing Program eligibility, as only registered sites that are included in the approved Scope of Project qualify; discrepancies can result in repayment obligations, audit findings, or removal from the program.

Tort Liability Consequences

FTCA malpractice coverage applies only to activities performed within the approved Scope of Project. Activities conducted outside that scope—whether at unapproved sites, by unapproved provider types, or for unapproved services—are not covered by FTCA.

This exposes both the organization and the individual providers involved to personal malpractice liability without the benefit of federal deemed coverage, requiring private malpractice coverage for those activities at the organization's or provider's own expense.

Importantly, HRSA assesses the Scope of Project accuracy during the FTCA deeming and annual redeeming process, and discrepancies between actual operations and approved scope may result in denial, restriction, or loss of deemed coverage.

Operational Integrity: Managing Your Scope as a Strategic Asset

The Scope of Project, when viewed through both a project management and regulatory lens, defines the boundaries within which an FQHC is authorized to operate. FQHCs should treat their scope of project as a controlled and actively managed asset. This includes maintaining a centralized, up-to-date inventory of all approved sites, services, providers, and populations, and ensuring it is consistently referenced in operational decision-making.

Governance plays a critical role in CIS compliance. Boards must have control and authority over all in-scope services, regardless of location or delivery method. They should actively oversee scope-related decisions, approve all CIS submissions, approve contracts and formal referral agreements that affect scope, and ensure leadership is accountable for maintaining compliance. By aligning operational growth with formal CIS processes, FQHCs can meet community needs while preserving their funding, compliance status, and legal protections.

We are Here to Help

Hinshaw's healthcare law attorneys have extensive experience advising FQHCs, FQHC Look-Alikes, and other licensed community clinics on regulatory and compliance matters. For further information, **please contact Michael Dowell, Hinshaw's healthcare law team, or your Hinshaw attorney.**

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Michael A. Dowell

Partner

213 614-7341

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