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Adding Specialty Services to a California FQHC: Legal and Regulatory Issues

Prepared for

CALIFORNIA HEALTHCARE FOUNDATION

by

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About the Author

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The author wishes to note that this paper is designed to provide accurate and authoritative information with respect to the subject matter covered but is offered with the understanding that neither the author nor the publisher is engaged in rendering legal or other professional services. If legal advice or other expert assistance is required, the services of a competent health care attorney should be obtained to address individual circumstances.

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About the Foundation

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I. Executive Summary

“A deeper frustration for health centers concerns their difficulty in securing follow-up appointments with specialists for patients who are uninsured or have Medicaid... ‘That’s when our doctors feel they’re practicing Third World medicine,’ she said. ‘You will die if you have cancer or a heart condition or bad asthma or horrible diabetes. If you need a specialist and specialty tests and specialty meds and specialty surgery, those things are totally out of your reach.’”

— KEVIN SACK, QUOTING UNITED NEIGHBORHOOD HEALTH SERVICES CEO MARY BUFWACK, IN “EXPANSION OF CLINICS SHAPES BUSH LEGACY,” *THE NEW YORK TIMES* (DECEMBER 26, 2008)

MANY FEDERALLY QUALIFIED HEALTH CENTERS (FQHCs) in California lack specialty care services for their patients. But FQHCs that want to add specialty services face significant legal and regulatory barriers. An FQHC seeking to include specialty care must make certain that those services will fit within federal regulations, that the health center will be fully reimbursed for them, and that its individual providers will have liability protection regarding those services.

This paper is intended for FQHCs and FQHC Look-Alikes that are expanding services to include specialty care. It outlines the federal laws and regulations that govern the provision of and reimbursement for specialty services by FQHCs. It also addresses the more limited role of California state law and agencies, most significantly involving Medi-Cal reimbursement but also facility, equipment, and professional licensing and permitting. The paper suggests how an FQHC can best comply with these complex federal and state rules, and includes practical checklists targeted to each set of important issues for a clinic adding specialty services.

Federal Law Regarding FQHC Scope of Services and Fees

Any significant change in a health center’s Scope of Project—including the addition of medical specialty services—requires approval by the Bureau of Primary Health Care (BPHC). An FQHC must submit a comprehensive narrative regarding federal requirements for specialty services, in particular addressing whether the services fall within “required primary health services” or “additional health services,” as defined by federal law.

Despite the possibility of retroactive approval and a grace period for implementation, it is crucial that an FQHC file its application for approval well in advance of its proposed implementation date. The consequences of failure to win timely approval can be so costly to a health center that premature commitment to new services should be assiduously avoided.

An FQHC must also determine how its fees for new services will comply with federal sliding scale requirements. With respect

to specialty services, FQHCs historically have had difficulty complying with these requirements and with the obligation to make their services equally available to all patients. These requirements should be fully appreciated by an FQHC and its governing board before the decision is made to add specialty care.

Medi-Cal and Medicare Reimbursement

Between them, Medi-Cal and Medicare provide coverage for 43 percent of California FQHC patients. Since another 45 percent of patients are uninsured and often able to pay little or nothing for services, these two government health insurance programs provide the largest source of remuneration to clinics. This paper explains how each program addresses the reimbursement of specialty services, including Medi-Cal's per-visit and individual provider rates, and its "four walls" policy that limits the sites where reimbursable services may be provided. The setting of rates under Medi-Cal reimbursement rules are so complex that this paper strongly urges FQHCs to consult an experienced health services auditor before attempting to establish rates for proposed specialty services.

Malpractice Insurance and the Federal Tort Claims Act

FQHCs must ensure that their individual providers are protected against malpractice liability claims. In general, FQHCs have access to malpractice coverage under the Federal Tort Claims Act (FTCA). But coverage for any particular specialist provider may depend on the exact contours of the work arrangement between the clinic and that provider. While most employees of an FQHC are covered by FTCA, independent contractors—the arrangement by which many specialist physicians provide services for a clinic—are covered only in very limited

circumstances. An FQHC must be aware of these complicated rules concerning FTCA coverage as it makes decisions about offering specialty care.

Referral and Compensation Arrangements for Professional Services

Federal anti-kickback and conflict-of-interest laws are complex terrains that FQHCs must negotiate to establish specialty services. The federal Anti-Kickback Statute (AKS) restricts the kinds of contractual arrangements health centers may make with specialist providers, but also provides "safe harbors" for certain employment and personal services agreements. Qualifying for these safe harbors can be extremely tricky, however, often requiring legal advice. AKS also provides a limited safe harbor specifically for FQHCs, but this can only protect payments *to* a health center, not *from* an FQHC to an individual.

Conflicts of interest are defined by the federal Stark Law, which covers Medicare and Medicaid related referrals. A physician (or family member) who has a financial relationship with an entity may not make a referral to that entity for the furnishing of designated health services billed to those programs. The reach of the prohibition is broad: "Referral" under the Stark Law includes a physician request for any item or service which can be reimbursed under Medicare, including consultation with another physician and even a request for establishment of a plan of care—all of which are common in specialty medicine. Like AKS, however, the Stark Law has exceptions for certain employment and personal services agreements.

California Licensing and Permitting Requirements

The majority of FQHCs in California are nonprofit "primary care clinics" licensed by the California Department of Public Health, Center for Health

Care Quality's Licensing and Certification program, as either community or free clinics. California law requires licensed clinics to give notice of any changes in services or physical plant.

Certain types of clinic activities may require additional state agency approvals. For example, the Clinic Licensing Law requires a special permit when a clinic offers one or more "special services" (although such a special permit has to date only been required for the provision of "birth services"). Additional approvals may be required in order to add certain specialty services that use particular equipment or present additional risks. An FQHC considering adding specialty services should analyze the facilities and equipment needed, and identify the required special state permits or licenses.

II. Introduction

ALTHOUGH THE SAFETY NET FOR PRIMARY care services is well-established in California, in many of the state’s communities the safety net for specialty care is far less developed. Patients who rely on Federally Qualified Health Centers (FQHCs)—a crucial component of the safety net—are acutely affected by the lack of specialty care services available there. As a consequence, FQHCs are increasingly interested in expanding the quality and range of specialty services they offer. Doing so, however, means facing a variety of significant regulatory barriers. An FQHC seeking to expand clinic services to include medical specialties must understand where such services might fit within controlling regulatory schemes. In particular, it must recognize and be able to articulate how the proposed new services will either fit into or parallel “required primary health services,” as that term is interpreted under sometimes ambiguous federal regulations. An FQHC must also ensure that it will be properly reimbursed for new specialist services, and that legal protection is provided to individual providers.

This paper is designed as a reference for FQHCs and consortia that are considering expanding services to include specialty care. It has two primary purposes:

- To outline federal and state laws and regulations that govern the provision of and reimbursement for specialty care services by FQHCs; and
- To suggest how FQHCs can best comply with these complex regulations, including specifically targeted checklists for clinics regarding each important set of issues.

The paper is directed at public and nonprofit entities that fall within the Medicaid or Medicare definitions of FQHCs, including FQHC Look-Alikes, and that are obligated to meet requirements applicable to health centers under 42 U.S.C. § 254b. (For basic information on FQHCs and other safety-net entities in California, see the recent California HealthCare Foundation report, *California’s Safety-Net Clinics: A Primer*.)¹

The sections that follow provide specific information for clinics about the following areas of federal law as they affect the provision of specialty services by FQHCs:

- Scope of Project modifications;
- Sliding scale fee requirements;
- Malpractice insurance and the FTCA;
- Medicaid and Medicare reimbursement; and
- Referral and compensation arrangements for professional service agreements.

A final section discusses state laws having to do with licensing and permitting of specific health care services.

III. Federal Law Regarding FQHC Scope of Services and Fees

FQHCs MUST COMPLY WITH SPECIFIC SETS of laws and regulations that address where and how they provide health care services, how they are paid for these services, and how they in turn pay their medical providers. Most of these laws and regulations are promulgated by the federal government. The Bureau of Primary Health Care (BPHC), within the Health Resources and Services Administration (HRSA), and the Center for Medicaid and Medicare Services (CMS) are the two federal agencies most directly involved with FQHC operations. The definitions of FQHC and FQHC services, for example, are contained in the federal statutes relating to the Medicare and Medicaid programs. Receiving FQHC designation depends on meeting the criteria for a health center grant under 42 U.S.C. § 254b (hereinafter referred to as Section 254b), as determined by HRSA (see Appendix A). Rules regarding FQHC qualification and operation are implemented and primarily enforced by BPHC, which regularly clarifies and elaborates on the legal requirements binding FQHCs in Policy Information Notices (PINs) and Program Assistance Letters (PALs), all of which are available on the BPHC Web site.²

California state law plays a more limited, but still critical, role in defining FQHC operations. Most significantly, the state Department of Health Care Services (DHCS) interprets federal Scope of Project rules for the purpose of Medi-Cal reimbursement, and develops and enforces other policies related to payment. In addition, state laws relating to facility, equipment, and professional licensing and permitting must be considered by an FQHC as it seeks to add specialty services. California state laws pertaining to

expansion of clinic services is discussed in Section VII, below.

The present section discusses federal regulations concerning changes to an FQHC's Scope of Project, and how a health center making such changes must at the same time address regulations regarding sliding scale fees.

Scope of Project Modifications

The threshold for an FQHC seeking to add medical specialty services is BPHC approval of the services as part of the clinic's Scope of Project.

An FQHC's Scope of Project stipulates what the project budget may support, and specifically defines the services, sites, providers, target population, and service area for which federal grant funds may be used, all of which is primarily directed toward ensuring that funds be expended for the benefit of the most vulnerable populations. The Scope of Project also drives, though it does not entirely coincide with, the scope of a health center's coverage under the 340B Discount Drug Program,³ the FTCA, and the reimbursement provisions of the Medicare and Medicaid programs.

Any significant changes to an FQHC's or FQHC Look-Alike's⁴ Scope of Project—including the addition of specialty care services—requires the prior approval of BPHC.⁵ (This process should not be confused with adjusting Medicaid prospective payment rates based on changes in the FQHC's scope of services, as discussed below.⁶)

In the last two years, BPHC has issued new guidance regarding both Scope of Project generally and the inclusion of specialty services in a clinic's Scope of Project in particular.

General Scope of Project Rules: PIN 2008-01

Policies regarding Scope of Project changes are provided in detail in PIN 2008-01; FQHC Look-Alikes follow the instructions in PIN 2003-21 (as modified by PIN 2005-17).⁷ These PINs describe and elaborate on how an FQHC is expected to comply with the basic requirements of Section 254b. (For a summary of these requirements, see Appendix A.)

The framework for an application to expand services, including medical specialist services, is set out in the five basic components of a Scope of Project, as defined by HRSA in the PIN, as follows:

- **Services.** An FQHC's services are listed (on Form 5, Part A) for the FQHC as a whole, not on a site-specific basis. Grantees must provide the "required primary health services" directly and/or through a formal written referral agreement under which the FQHC is responsible for providing and/or billing or paying for the direct care. If the service is both provided and billed for by another entity, it is not included in the FQHC's Scope of Project; informal referral arrangements are also excluded from an FQHC's Scope of Project. Services must be provided to all patients, regardless of ability to pay.
- **Sites.** An FQHC's sites (listed on Form 5, Part B) are defined as any location where a grantee, either directly or through a sub-recipient or established arrangement, provides primary health care services "to a defined service area or target population." Sites may be permanent or seasonal, and may include mobile van, migrant voucher, or intermittent sites, as defined more specifically in the PIN. Approved service sites must meet the following conditions:
 - Face-to-face contacts between patients and providers are documented as "encounters;"

- Providers exercise independent judgment in providing services to the patient;
- Services are provided directly by or on behalf of the grantee, whose governing board retains control and authority over provision of services at the location; and
- Services are provided on a regularly scheduled basis; however, there is no minimum number of hours per week that services must be available at an individual site.

In general, to the extent that an FQHC intends to seek reimbursement or claim costs for the operation of service sites or the provision of services under Medicare or Medicaid, or to seek coverage of services under the FTCA, the clinic will have to add the site to the Scope of Project.⁸ (FQHCs should contact their Project Officers if they are uncertain regarding these obligations.)

- **Providers.** Providers are defined as individual health care professionals who deliver services to health center patients on behalf of the FQHC, exercise independent judgment as to the services rendered to the patient during an encounter, and assume primary responsibility for assessing the patient and documenting services in the patient's record.
- **Target Population.** This is the health center-defined underserved population from within the established service area to which the FQHC directs its services, and which is "usually a subset of the entire service area population, but in some cases, may include all residents of the service area if it is determined that the entire population of the service area is underserved, and lacking access to adequate comprehensive, culturally competent quality primary health care services." The target

population is reported in the aggregate and not on a site-by-site basis.

- **Service Area.** Referred to in the statute as the “catchment area,” it is where the majority of the FQHC’s patients reside.

Addition of Specialty Services: PIN 2009-02

In December 2008, BPHC released PIN 2009-02, which describes the factors that it will consider in evaluating FQHC Scope of Project requests relating to specialty services.⁹ This PIN offers a general definition of “specialists,” describing them as “appropriately credentialed health care provider[s]... who [have] been granted appropriate specialty-specific privileges by the health center...” It warns, however, that “the full range of services within a specialist’s area of expertise may or may not be within the Federal scope of project.”

BPHC requires an FQHC to submit a comprehensive narrative regarding certain requirements for specialty services. In particular, clinics must address questions related to the distinction between “required primary health services” and “additional health services,” as such phrases are defined by federal law. (See Appendix D.)

If an FQHC is adding a medical specialist who will perform services within his or her specialty but who will not provide primary care services, that change is defined by the PIN as providing “additional health services” rather than “primary health services.” In this case, certain statutory requirements must be met; BPHC has identified the following four key areas it focuses on when determining whether a Scope of Project application to add specialty services has met these requirements:

1. An FQHC must establish that the services are “necessary for the adequate support of [the required] primary health services.”¹⁰ BPHC

has interpreted this to mean that the proposed services must “function as a logical extension of the required primary care services already provided by the health center.” The PIN gives the following examples of specialty services that support required primary care services:

- Pulmonary consultations and examinations, where the health center serves a substantial number of patients with asthma, COPD, Black Lung, or tuberculosis;
- Cardiology screenings and diagnoses, where the health center serves a substantial number of patients at risk for heart disease or high blood pressure;
- Minor podiatry outpatient examinations and procedures, where the health center serves a population with a high prevalence of diabetes;
- Psychiatric consultations, examinations, and diagnoses, where the health center serves a substantial number of patients with mental health and/or substance abuse diagnoses;
- Periodontic services, where the health center serves a significant population of children with poor oral health;
- Colonoscopies; and
- Appropriate oncological care of health center patients with cancer.

2. The FQHC must show that the target population needs the specialty services. The application must demonstrate this need in narrative format and with relevant data, and the FQHC must additionally “demonstrate its ability to maintain the level and quality of the required primary health services currently provided to the target population.”

3. The Scope of Project change must be accomplished without additional Section 330 grant support. The application must address whether the services that the FQHC proposes will meet Medicare and Medicaid definitions of “FQHC services,” and whether the site and/or services to be added will generate sufficient revenue to sustain the services and associated overhead costs. The application must also reflect an understanding by the FQHC that it must provide the services to all patients regardless of ability to pay.
4. The services must be provided at a site within the FQHC’s Scope of Project, such that the proposed new service will be accessible to the FQHC’s patients and the FQHC “will be able to maintain appropriate control over service delivery.”¹¹ FQHCs are required to provide the services:

- At an approved “service site” as defined by the PIN;
- Within the FQHC’s federal Scope of Project catchment area;
- At a new site that will be proximate to available FQHC services; or
- At a location where current in-scope services are provided but that does not meet the definition of a service site.

The first and second criteria above reflect BPHC’s intention that FQHCs provide an analysis of the specific health needs of the population being served, and the role of the specialty services in the continuum of care being offered. The PIN guidance does not list specific services that are eligible for inclusion in a Scope of Project, nor does it define specific eligible providers. It is prescriptive, however, regarding the application *process*: the health center

must “demonstrate and document the target population’s need for the proposed services” and that “[u]nmet need should be described both in narrative format and with data.”

The third criterion above—that the FQHC address whether the proposed services will meet Medicare and Medicaid definitions of “FQHC services”—typically does not present any problem if the services to be added are medical services and provided by an MD (though the rules are much less clear for services that are not provided by medical doctors). BPHC’s attention to this issue reflects concern about the vulnerability of certain services, particularly as states cut Medicaid “optional benefits” in a weak economic environment.

In sum, PIN 2009-02 offers useful guidance on how to submit an application for a Scope of Project change for the addition of specialty services. But it does not offer a clear picture of the limits on these services, or of HRSA’s priorities in this regard.

Importance of Prior Approval

BPHC repeatedly emphasizes the requirement to obtain *prior* approval for Scope of Project changes. This requirement takes on added importance for FQHCs planning to add specialty services.

An approved Scope of Project change may be effective retroactively to the date of receipt of a completed application. Looking forward, if a grantee cannot determine the exact date by which a change in scope will be fully implemented, the grantee is allowed up to 120 days following the date of the Notice of Grant Award, which indicates approval for the change in scope, to implement that change (e.g., open the site or begin providing a new service). Also, HRSA’s stated goal is to decide on requests within 30 days of a completed application.

These rules and policies may incline an FQHC to begin implementing changes at the time of

application; some clinics implement Scope of Project changes even before the application is complete. In light of the complex requirements of PIN 2009-02, however, FQHCs should be extremely cautious about entering into commitments to provide medical specialty services—including contracts with specialist providers—before actually receiving approval. Instead, health centers should submit their requests well in advance of committing to add services in order to limit the potential for avoidable losses should the application be significantly delayed or denied altogether.

The potential costs to clinics that implement Scope of Project changes in advance of BPHC approval are high. An FQHC that adds specialty services that are later deemed not to have been within its approved Scope of Project will be exposed to repayment obligations under Medicare and Medicaid. Malpractice claims for services provided outside of the FQHC's Scope of Project will not be covered by the FTCA and, to the extent not covered by other liability coverage, may subject the FQHC to significant defense, indemnification and associated costs.

Clinic Checklist: Scope of Project Modifications

- ✓ Can the services be provided, equally to all patients insured or uninsured, without additional Section 330 grant support, and does the application adequately support this fact?
- ✓ Are the services to be provided “FQHC services” as defined by Medicaid/Medi-Cal and Medicare, and “covered services” under other third-party payer agreements?
- ✓ Does the application demonstrate that the new services would improve or maintain access and quality of care for the target population?
- ✓ If there would be a change in service sites or populations served, would appropriate governing board representation and other requirements be met as set out in Section 254b and related regulations and policies?
- ✓ Will the FQHC appropriately credential and privilege the added providers?
- ✓ Does the application establish that the services are “necessary for the adequate support of the required primary health services” and would function as a “logical extension” of the primary care services already provided by the health center (such as by fitting within a BPHC example of what is supportive of primary care services)?
- ✓ Is the target population’s need for the specialty services adequately supported in the narrative and with relevant data?
- ✓ Is the site at which the services will be provided within the FQHC’s Scope of Project?
- ✓ Would the new services be sufficiently accessible to the FQHC’s patients, and permit the FQHC to exercise appropriate control and supervision of service delivery?
- ✓ Can the FQHC establish the availability of necessary enabling services, such as translation and transportation, associated with the proposed services?
- ✓ Has the application received the approval of the governing board?
- ✓ Will the application be submitted well in advance (at least 30 days) of the planned commencement of services?
- ✓ Does the proposed professional services agreement account for the possibility of delayed approval or the risk of BPHC’s denial of the Scope of Project application?

Sliding Fee Scale Requirements

Both PIN 2008-01 and 2009-02 emphasize an FQHC's responsibility to provide all its services, including those by physician specialists, to all patients regardless of their ability to pay. Consistent with this requirement, an FQHC must have a sliding fee scale that is consistent with locally prevailing rates or charges, but also designed to cover the FQHC's reasonable cost of operation. The FQHC must apply a schedule of discounts to this fee scale, adjusted on the basis of the patient's ability to pay, with no patient denied services based on inability to pay.¹² Federal regulations implementing this sliding fee scale require:

- A full discount to patients with family incomes at or below 100 percent of the U.S. Department of Health & Human Services Federal Poverty Guidelines;
- No discount for patients with annual family incomes greater than 200 percent of such levels; and
- A sliding fee scale for patients with annual family incomes between these ranges.¹³

FQHCs are permitted to charge “nominal” fees “where imposition of such fees is consistent with project goals.” “Nominal” is not defined by the regulations, but is interpreted to mean a minimal charge in comparison to the actual cost of the services. While not directly applicable, FQHCs may look to Medicare reasonable cost principles—which define “nominal” as “a charge equal to 60 percent or less of the reasonable cost of a service”¹⁴—in determining these amounts. The FQHC's fee schedule must be consistent with locally prevailing rates, and charges must not act as a barrier to the patient's receipt of health care services.¹⁵

With respect to medical specialty services, FQHCs historically have had difficulty complying with the sliding fee scale requirements and the obligation to make their services equally available to all patients. These difficulties may arise from a failure to properly account for uncompensated care needs when negotiating professional services agreements with specialists. They may also result from misinterpretation of the statutory requirement that FQHCs ensure that uninsured patients not be denied the health care services that the FQHC provides to insured patients. The need to fulfill these requirements should be fully appreciated by an FQHC and its governing board before a decision is made to add these services. In particular, projected budgets should take into account the need to provide the services to all patients regardless of ability to pay.

Clinic Checklist: Sliding Fee Scale

- ✓ Does the FQHC have a sliding fee scale policy?
- ✓ Has the FQHC surveyed locally prevailing rates for the specialty services it seeks to add, and ensured that its charges would be consistent with such rates?
- ✓ Are “nominal” charges to be imposed on patients with incomes below 200 percent of the Federal Poverty Guidelines?
- ✓ Does the FQHC's schedule of fees ensure that the FQHC's reasonable costs of operation would be covered?
- ✓ Would the sliding fee scale policy be implemented to ensure that no person shall be denied services by reason of his or her inability to pay for the services?
- ✓ Has the FQHC's governing board approved the sliding fee scale and charges that would be applied to the added specialty services?

IV. Medicaid and Medicare Reimbursement

IN 2007, 37.8 PERCENT OF CALIFORNIA FQHC patients were covered by Medicaid (Medi-Cal) and 5.2 percent were Medicare beneficiaries (45.2 percent were uninsured).¹⁶ Thus, Medicaid and Medicare definitions of “FQHC services,” and the two programs’ reimbursement policies, play a significant role in a health center’s ability to sustain health services. An FQHC considering providing specialty services to its patients must therefore understand how each program addresses reimbursement of these services.

The definitions of “Federally Qualified Health Center” and “Federally Qualified Health Center services” are found in the laws relating to the Medicare and Medicaid programs. These definitions rely in turn on the statutory criteria for receiving a health center grant (see Appendix A). Although Medicaid provides far more reimbursement to most FQHCs, it is Medicare that defines coverage of FQHC “core” services, including those provided by physicians and other key professional staff.

Medicare

Medicare defines “FQHC services” as including the following:

- Physician services, and services and supplies provided “incident to” such services;
- Nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, and clinical social worker services, and other services and supplies provided “incident to” such services;
- Visiting nurse services in a CMS-designated home health shortage area;

- Otherwise covered drugs furnished by, and “incident to,” services of physicians and non-physician practitioners;
- Outpatient diabetes self-management training and medical nutrition therapy for beneficiaries with diabetes or renal disease; and
- “Preventive primary health services” that a center is required to provide under Section 254b.¹⁷

Medicare pays FQHCs in two different ways. It pays for certain services at the FQHC rate, and for other services on a fee-for-service basis. In order to be fully reimbursed under Medicare, the FQHC must be enrolled both with the appropriate Medicare administrative contractor as an FQHC, and with the local Medicare carrier as a clinic.¹⁸ Specialists who provide only defined FQHC services need not enroll individually in Medicare. If, however, they provide non-FQHC services—such as inpatient care—to FQHC patients, they need to enroll individually and familiarize themselves with the FQHC-specific billing requirements relating to such services.¹⁹

FQHCs that provide Medicare services through agreements with managed care plans should determine if these agreements cover specialty services; if not, they will need to be amended. Additionally, specialists will need to be credentialed by the plan in accordance with the terms of the FQHC’s agreements.

Before adding medical specialty services, FQHC clinical and administrative leadership, as well as billing staff, should thoroughly review the provisions of Chapter 13 of CMS Pub. 102, as well as the *Medicare Claims Processing Manual*, Chapter 9,

relating to “Rural Health Clinics/Federally Qualified Health Centers,” and thoroughly investigate any coverage of services that a specialist will provide on behalf of the FQHC.

Medicaid (Medi-Cal)

Federal law defines “FQHC services” more expansively for the Medicaid program than for Medicare. FQHC services are a mandatory Medicaid benefit and are defined to include not only the so-called Medicare “core providers”—the first four Medicare coverage bullets listed above—but also any other ambulatory service that is offered by the FQHC and is covered by the state’s Medicaid plan.²⁰ Therefore, in order to budget for the addition of new services, a California FQHC needs to understand the basic features of the Medi-Cal reimbursement system governing its services.²¹

Medi-Cal Reimbursement: Per-Visit Rate

Medi-Cal reimbursement is based on an all-inclusive, per-visit rate.²² This means that an FQHC clinic will be paid the same for specialty services as for all other visits. California law defines a “visit” as a face-to-face encounter with one of the following:

- Physician (defined by reference to the Medicare program as a medical doctor, osteopath, dentist, optometrist, podiatrist, or chiropractor);²³
- Physician assistant;
- Nurse practitioner;
- Nurse midwife;
- Clinical psychologist;
- Licensed clinical social worker;
- Visiting nurse (only in a CMS-designated home health shortage area);

- Comprehensive perinatal services practitioner;
- Adult day health center (four-hour session only); or
- Dental hygienist and registered dental assistant in alternative practice.²⁴

Under Medi-Cal, an FQHC receives an initial “prospective payment” rate that is, at its election, either based on the average of the per-visit rates of three FQHCs in the same or an adjacent service area with a comparable caseload, or on 100 percent of its actual, reasonable costs (determined in accordance with Medicare reasonable cost principles), for its first full fiscal year. Federal law requires that these rates be adjusted annually based on the Medicare Economic Index, to account for operational cost increases.

Additionally, rates may be adjusted where there are increases or decreases in costs arising from changes in the type, intensity, duration, or amount of “FQHC services” that a health center provides. California has implemented a process for this “scope of service” rate adjustment in Welfare & Institutions Code § 14132.100(e). The determination is a two-step process.

1. First, the change in services is assessed to ensure that it fits one of the categories of circumstances set out in Section 14132.100(e)(2)(A)–(I). A change in services generally is acceptable as a “scope change” if it is the result of a change of any “FQHC service” as defined by federal law or in the provider mix of an FQHC or one of its sites, or any changes in the scope of a project approved by HRSA.
2. Once it has been determined that there has been a change in the scope of “FQHC services” provided, the impact of the change is assessed under Medicare reasonable cost principles, using a cost report, to determine if the rate change

meets a minimum threshold. The net change in the FQHC's rate must equal or exceed 1.75 percent.

Professional Audit May Be Needed

It is almost always essential that an FQHC utilize an experienced auditor to prepare an application for rate changes based on a change in the FQHC's scope of services. There is wide variance in FQHC rates under Medi-Cal, with an average rate of \$150.80 for freestanding, nonprofit FQHCs, and \$235.61 for county FQHCs.²⁵ At least part of this variance can be attributed to an FQHC's failure, when setting or modifying rates, to obtain assistance from an experienced cost report auditor familiar with California's system of FQHC reimbursement. An FQHC that is planning to add new services should obtain such assistance, and base its projected budget on a well-grounded understanding of the impact of these services on the FQHC's rate and on aggregate reimbursement.

Medi-Cal Reimbursement: Individual Provider Payment

To the extent that the specialists whose part-time services are being added are physicians who operate independent practices, special attention should be paid to the fee-for-service rules governing services provided by individual physicians. Where some services are provided to a patient by the FQHC, which is reimbursed at an all-inclusive rate, and others are provided by the independent physician and reimbursed at a global or bundled rate, there is a risk of duplicative payment. For example, a physician billing Medi-Cal on the basis of a global rate may already have been reimbursed for services provided in the FQHC. The FQHC would not be aware of this unless staff made inquiries regarding the applicable billing rules relating to the fee-for-service environment, in addition to those relating to FQHC reimbursement. Failing to ensure that there

is no duplicative reimbursement for the same services increases program costs without additional benefit to patients, and in some cases may be considered fraudulent.

Medi-Cal Reimbursement: "Four Walls" Policy

Specialists often are unwilling to provide services through the Medi-Cal program in light of Medi-Cal's low reimbursement rates. As a result, many rural specialists propose providing FQHC services in their own offices, with those services treated as FQHC services for purposes of billing, reimbursement, and credentialing. Such an arrangement can be very beneficial as a means of eliminating duplicative costs, especially where the specialist uses significant space or costly equipment. Congress has recognized this fact by prohibiting state Medicaid agencies from preventing FQHCs from entering into contractual relationships with private practice dental providers in the provision of "FQHC services."²⁶ However, the DHCS "Four Walls" policy, which limits the place of service, would prevent such an arrangement for medical specialists.

This Four Walls rule is derived from a series of letters from CMS's predecessor agency, the Health Care Financing Administration. If a patient is treated outside the FQHC site but the service is billed as an FQHC service, DHCS has interpreted these letters to require the following:

1. The provider (physician, nurse practitioner, physician assistant, nurse-midwife, clinical psychologist, clinical social worker, or visiting nurse) has a written contract with the FQHC to provide the services;
2. The services are furnished only to FQHC patients at that location;

3. The patient must be treated at that location, rather than at the FQHC, for health or medical reasons; and
4. The services provided are of the type commonly furnished in the FQHC setting.²⁷

Where FQHCs have sought to treat patients at other locations for reasons of patient or provider convenience, to reduce costs, to expand access, or for some other reason, the second and third of these requirements have proven an obstacle. In 2003, DHCS generally acknowledged that this and other of its FQHC policies, including those in its state plan, were potentially invalid as a result of the department's failure to adopt them in compliance with the California Administrative Procedures Act.²⁸ Also, other states have interpreted the intention of the federal policies differently, and the situation remains in flux. However, until the stated DHCS policy is either changed, clarified, or invalidated, a California FQHC's professional services should be provided only on-site, or otherwise in compliance with the above-described policy.

Other California state policies may also limit an FQHC's ability to provide specialty services. These include:

- DHCS offsetting of grant expenditures against grant proceeds;
- DHCS denial of certain costs where the services are not "physician type" services;
- DHCS denial of certain scope of service changes which are viewed as "insubstantial" according to standards developed by individual auditors;
- DHCS application of some fee-for-service utilization controls to FQHC services;

- The state plan amendment's evolving same-day visit rule; and
- The requirement (inconsistently applied) that mid-levels be separately enrolled in Medi-Cal while physicians need not be.

Ongoing confusion among FQHCs about even such basic issues as DHCS requirements relating to enrollment and which services are covered by the program can cause delays and present challenges for planning and budgeting. An FQHC, and its counsel, seeking to add specialty services in a manner not clearly defined in the Provider Manual or applicable law should request advance guidance from DHCS regarding all aspects of its proposed changes.

Clinic Checklist: Medicare and Medi-Cal

- ✓ Has the FQHC reviewed all applicable Medicare manuals and policies, and do all relevant staff as well as the governing board understand the implications of adding specialty services?
- ✓ Have experienced cost estimators been consulted regarding the addition of services and the impact on FQHC rates?
- ✓ Has the FQHC worked with experienced auditors to assess whether it may be entitled to a rate change as the result of the new services?
- ✓ Do contracts with individual specialist physicians specify a mechanism for addressing issues regarding fee-for-service provider payment?
- ✓ Are the services to be provided entirely on-site? If not, has legal counsel determined the availability of Medi-Cal reimbursement for services provided off-site?
- ✓ Has the FQHC worked with legal counsel and DHCS to obtain advance review of any proposed new services or new service sites?

V. Malpractice Coverage and the Federal Tort Claims Act

FQHCs BENEFIT SIGNIFICANTLY FROM ACCESS to medical malpractice coverage under FTCA. However, this coverage often is unavailable to medical specialists providing services on a contract basis, so clinics must be aware of the limits of FTCA as they make decisions about offering specialty care.²⁹

Overview of FTCA Coverage

The Federally Supported Health Centers Assistance Act of 1995 makes federally-funded community health centers, their employees, officers, and certain part-time contractors eligible for medical malpractice coverage under FTCA to the same extent as federal employees of the United States Public Health Service.³⁰

FTCA provides liability coverage for claims “for personal injury, including death, resulting from the performance of medical, surgical, dental, or related functions . . .”³¹ Once a physician has been deemed a federal employee, or a covered non-employee contractor, acting within the scope of his or her duties, the United States is substituted as the defendant and FTCA provides the exclusive remedy for the physician’s negligence.³² Personal injury claims asserted against an FQHC, its employee, or other covered representative must be asserted in the manner dictated by FTCA. Also, if a service is covered under FTCA when the event giving rise to the claim occurs, it will be covered regardless of when the claim is filed. Therefore, no continuation or “tail” coverage is needed. However, to the extent that services are not clearly covered by FTCA, an FQHC must obtain a policy covering professional errors and omissions.

FQHC Look-Alikes and other entities that are not receiving grant funds under Section 254b are not eligible for FTCA coverage.³³ Thus, FQHC Look-Alikes, as well as FQHCs that are Section 330 grantees but that have not been “deemed covered” by HRSA,³⁴ need to obtain commercial professional liability policies. It is usually preferable for the FQHC, as opposed to individual physicians, to obtain this coverage, since that reduces both overall cost and the likelihood that the FQHC will be exposed to unanticipated gaps in coverage. An FQHC’s agreement with a physician should address who will purchase both the policy and any continuation, or “tail coverage,” in the event of termination. The agreement should also address how the parties will timely be made aware of, and be able to address, any failures to obtain or pay for required coverage.

Limitations on FTCA Coverage

The key limitation of FTCA coverage in the context of specialty services is that many FQHCs staff their specialty practice with community physicians who work part-time under independent contracts, and FTCA coverage of contractors is extremely limited. For independent contractors to be covered by FTCA, they must either:

- Normally perform, on average, at least 32.5 hours of service per week for the entity, for the period of the contract; or
- Be a licensed or certified provider of services in the fields of family practice, general internal medicine, general pediatrics, or obstetrics and gynecology.³⁵

Thus, while employee physicians are eligible for FTCA coverage regardless of the number of hours they work, independent contractors outside of the traditional “primary care” training categories described above are not eligible unless their contract is for more than 32.5 hours weekly. Also, professional corporations and other forms of business entities are not eligible for coverage under FTCA, so some physicians who practice under such a rubric would need to be privately insured.³⁶

Direct Employment of Part-time MDs May Permit Coverage

Direct employment of part-time providers may help some clinics to achieve FTCA coverage for their specialty services. Under a 1975 opinion from the California Attorney General, nonprofit community clinics (in contrast to county clinics) are viewed as being entitled to directly employ physicians under California law.³⁷ Therefore, instead of entering into an independent contract agreement with a physician to become a part-time provider of specialty services for the clinic, an FQHC could hire the physician as an employee. This would obviate the problem of lack of FTCA coverage for contract providers who work for the clinic less than an average of 32.5 hours per week.

However, clinics must consider other issues relating to making treating physicians actual employees. For example, California Labor Code § 515.6(a) provides that a physician employee must be paid an hourly pay rate equal to or greater than a certain threshold amount (\$69.13 as of January 1, 2009), in order for the physician to be exempt from the employer's requirement to pay overtime. Other issues may include increased costs relating to FICA, unemployment, or other taxes, and eligibility for employee benefits such as health insurance, pension, and family leave.

Assuming that the FQHC and specialist physicians are otherwise eligible for FTCA coverage, an FQHC that is adding specialty care needs to carefully consider the exceptions to FTCA coverage in the context of the newly added services,

to minimize the risk of non-covered claims. As summarized by the FTCA Clinician's Handbook,³⁸ the following circumstances are *not* covered by FTCA:

- Activities that are either not associated with a deemed FQHC, not within the FQHC's Scope of Project, not within the physician's scope of employment, or not related to clinical malpractice;
- Activities related to supervision of non-FQHC employees and staff, such as actions undertaken as Medical Director for an FQHC-contracted nursing home or for a local emergency medical system;
- Supervision of care provided by students or residents to non-FQHC patients, unless the patient is part of the physician's required on-call scope of employment;
- Moonlighting or other activities outside the physician's scope of employment;
- Claims of a type customarily covered by general liability, directors' and officers' liability, automobile, fire, theft, or any other non-malpractice coverage; and
- Community activities, such as community call coverage, hospital calls, emergency room coverage, and services such as medical care for local events, may or may not be covered.

If an individual professional, rather than the FQHC, is directly reimbursed for certain off-site services and/or inpatient services, and the provider then remits the payment to the FQHC, the services may be covered if certain conditions (set out in PIN 2001-11) are met.³⁹

Job descriptions and professional services agreements with specialists should be drafted carefully to ensure that they do not create or overlook gaps in coverage. An individual provider's FTCA coverage is driven in part by his or her "scope of employment," defined by the duties contained in the job description, contract, and related documents, as well as by regular activities on the job. Also, an FQHC needs to ensure that new providers have been credentialed and that related due diligence has been performed. Wrap-around coverage is recommended for FQHCs, to avoid unanticipated exposure if a claim is found not to be within the physician's scope of employment or is otherwise excluded from coverage by FTCA.

Finally, the substance of the FTCA initial application and annual renewal have been recently modified, with requirements set out in a Program Assistance Letter (PAL) entitled "New Requirements for Deeming under the Federally Supported Health Centers Assistance Act for Calendar Year 2010."⁴⁰ Attachment 1 of this PAL includes a checklist to assist FQHCs in updating their risk management systems to reflect services provided by the health center.

Clinic Checklist: FTCA

- ✓ Have areas of coverage that are outside of FTCA been clearly identified and appropriate wrap-around insurance coverage obtained, prior to any services being delivered?
- ✓ Do contracts with specialists address their scope of employment in a manner that addresses concerns under FTCA?
- ✓ Are all professional services agreements with providers entered into with an individual, rather than a professional corporation, if FTCA coverage is relied upon?
- ✓ Has the FQHC reviewed the BPHC checklist in Sections II through V of Attachment 1 of PAL 2008-05, to ensure that requirements related to risk management systems and hospital and coverage issues, among others, have been met?

VI. Referral and Compensation Agreements Relating to Professional Services

AS A MATTER OF BASIC DUE DILIGENCE, AN FQHC should seek the assistance and advice of an experienced health law attorney in contracting for medical services, and at a minimum should ensure that all agreements are reviewed by counsel. Nevertheless, it is also essential that individuals conducting negotiations on behalf of an FQHC have a broad understanding of the main federal and state limitations on such arrangements. This is particularly so since the mere offer of improper compensation may constitute a kickback or improper self-referral arrangement in violation of federal law, exposing the FQHC to the risk of civil or criminal penalties.

The Anti-Kickback Statute

The federal Anti-Kickback Statute (AKS) makes it a crime to knowingly and willfully offer, pay, solicit, or receive any “remuneration,” directly or indirectly, for inducing or rewarding referrals of items or services reimbursable by Medicare, Medicaid, and other federal health care programs.⁴¹ Violation of the law is a felony punishable by a fine of up to \$25,000 and/or imprisonment for up to five years. Violations of AKS may also serve as the basis for imposition of civil money penalties, exclusion from all federal health care programs, and liability under the federal False Claims Act. Both sides of a transaction or proposed transaction—in the case of health centers adding a specialist, both the FQHC and the individual physician—are subject to criminal liability under AKS.

As explained by the Office of the Inspector General, “[b]ecause of the broad reach of the statute, concern was expressed that some relatively innocuous commercial arrangements were covered by the

statute, and therefore, potentially subject to criminal prosecution.”⁴² As a result, the federal government has created a number of “safe harbors” within which certain arrangements will not be viewed as running afoul of AKS. The two safe harbors most likely to be relied upon by FQHCs entering into agreements with medical specialists are those relating to “bona fide employees” and “personal services agreements” with independent contractors; a limited, FQHC-specific safe harbor also may apply. Given the significant penalties for violating the AKS law, an FQHC seeking to add medical specialist services must adhere closely to the requirements of these safe harbors.

AKS Safe Harbor for Bona Fide Employment Agreements

AKS excludes from the definition of impermissible remuneration “any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment” in the provision of items or services covered by the federal health care program.⁴³ Whether or not an employment arrangement is viewed as “bona fide” is determined in accordance with Internal Revenue Service rules.⁴⁴ The key elements of an employment arrangement that make it bona fide are described in the Internal Revenue Code as follows:

“The person for whom services are performed has the right to control and direct the individual who performs the services, not only as the result to be accomplished by the work, but also as to the details and means by which that result is accomplished. That is, an employee is subject to

the will and control of the employer not only as to what shall be done but how it shall be done.”⁴⁵

The IRS test to determine whether sufficient control is present for an individual to be viewed as an employee is set out in Appendix B.

A safe harbor-qualifying employment agreement gives an FQHC greater flexibility regarding compensation terms than does a personal service agreement (see immediately below). However, such an agreement must be drafted to meet the additional requirements for employment agreements set forth in the Stark Law,⁴⁶ as discussed later in this section.

AKS Safe Harbor for Personal Services Agreements

AKS also includes a safe harbor protecting certain independent contractor arrangements. An agreement with an independent contractor must fully meet each of the following seven requirements in order to be protected by this personal services safe harbor:

1. The agreement is set out in writing and signed by the parties.
2. The agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.
3. If the agreement is intended to provide for the services of the agent on a periodic, sporadic, or part-time basis, the agreement specifies the schedule, length, and charge for such intervals.
4. The term of the agreement is for not less than one year.
5. The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions, and is not determined in a manner

that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other federal health care programs.

6. The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law.
7. The aggregate services contracted for do not exceed those which are reasonably necessary for accomplishing the commercially reasonable business purpose of the services.

This personal services agreement safe harbor provides broad protection for an FQHC seeking to add medical specialist services: Whether the new physicians are part-time or full-time, to the extent the criteria set out in this safe harbor are otherwise met, the health center’s agreement with them will not violate AKS.

AKS Limited Safe Harbor Specifically for FQHCs

In 2007, a new safe harbor was added to AKS, protecting individuals or entities “providing goods, items, services, donations, loans, or a combination thereof” to health centers “pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center entity.”⁴⁷ An example of the kind of payment that might fall within the protection of this safe harbor (if its nine standards are fully satisfied) is a donated or below-cost service provided by a medical specialist to a Section 330-funded health

center. However, the crucial limitation of this safe harbor is that it only protects payments *to* a Section 330-funded health center, not *from* an FQHC to an individual.⁴⁸ Also, this FQHC safe harbor provides no protection for FQHC Look-Alikes, and no protection for above fair market value payments. To the extent that an FQHC is leasing space and/or equipment to the physician, additional safe harbors relating to space and equipment rental arrangements are available.

The Stark Law

Beginning in the 1980's, concerns about excessive, medically unjustified referrals by physicians to entities in which they had financial interests prompted Congress to restrict self-referral arrangements. Named after Congressman Fortney "Pete" Stark, the Stark Law applies to referrals by physicians for "designated health services." This law applies directly to Medicare, and indirectly to Medicaid; that is, a Medicaid federal match, or FFP, may not be paid for a designated health service on the basis of a referral that would result in the denial of payment for the service under Medicare.⁴⁹

In general, the Stark Law provides that, unless an exception applies, if a physician⁵⁰ (or physician's immediate family member) has a financial relationship with an entity, the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under Medicare. The entity may not present or cause to be presented a claim to Medicare or a bill to any individual, third party payer, or other entity for designated health services furnished pursuant to a prohibited referral.

The definition of "referral" under the Stark Law is extremely broad and includes a physician request for an item or service which can be reimbursed under Medicare Part B. This term therefore

encompasses, for example, a request by a physician for a consultation with another physician, and any test or procedure ordered by, to be performed by, or under the supervision of, that other physician. It also includes a request for or establishment of a plan of care by a physician for a designated health service.⁵¹

The "designated health services" covered by the Stark Law are:

- Clinical laboratory services;
- Physical therapy services;
- Occupational therapy services;
- Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services;
- Radiation therapy services and supplies;
- Durable medical equipment and supplies;
- Parenteral and enteral nutrients, equipment, and supplies;
- Prosthetics, orthotics, and prosthetic devices and supplies;
- Home health services;
- Outpatient prescription drugs;
- Inpatient and outpatient hospital services; and
- Outpatient speech-language pathology services (for services furnished on or after July 1, 2009).

An item or service that is paid as a part of a "composite" rate is not a "designated health service" and the referral is not subject to the Stark Law.⁵² Initially, this limitation would appear to exempt many clinic services, since most FQHC services are reimbursed under Medicare and Medicaid on the basis of an all-inclusive, or composite, rate. However,

the benefit of this limitation is largely illusory. FQHCs are reimbursed by Medicare on a fee-for-service basis for most of the designated health services that are the primary focus of the Stark Law, including clinical laboratory services, radiology, and hospital inpatient services. As a result, FQHCs must ensure that their agreements with physicians, as that term is defined by Medicare, comply fully with one or more of the exceptions identified in either the Stark statute itself or its implementing regulations.

Some of the Stark exceptions that FQHCs might rely upon are similar to AKS safe harbors. In particular, the Stark Law contains exceptions for bona fide employment agreements and for personal services agreements (independent contracts). As with AKS, the Stark Law's complexity and the significance of the penalties associated with failing to meet its requirements suggest the wisdom of an FQHC fully and unstintingly conforming with the letter and spirit of the Stark exceptions for either bona fide employees or personal services agreements.

Stark Exception for Bona Fide Employment Agreements

The Stark Law contains an exception, from its definition of "compensation arrangements," for bona fide employment agreements which satisfy certain requirements.⁵³ Under Stark, an individual is considered "employed by" or an "employee" of an FQHC if the individual would be considered to be an employee of the entity under analogous Internal Revenue Service rules. This Stark employment exception would protect an agreement between a physician who has a bona fide employment relationship with the FQHC if each of the following requirements is satisfied:

1. The employment is for identifiable services;
2. The amount of the remuneration under the employment is consistent with the fair market value of the services;
3. The amount of the remuneration is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician;
4. The remuneration is provided pursuant to an agreement which would be commercially reasonable even if no referrals were made to the employer; and
5. The employment meets such other requirements as the Secretary of HHS may impose by regulation as needed to protect against program or patient abuse.⁵⁴

At the heart of the Stark Law's prohibition on self-referral is an effort to eliminate unearned compensation. Thus, a determination that the payments are at fair market value is critical to establishing that the arrangement qualifies under the exception. The Stark Law defines the fair market value of services as follows:

"Fair market value means the value in arm's-length transactions, consistent with the general market value. 'General market value' means... the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, ... at the time of the service agreement. Usually, the fair market price is... the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, where the... compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals."⁵⁵

Because of the limitations on access to health care services in areas served by FQHCs, many health centers use physicians on a part-time basis to provide specialty services. These clinics need to balance greater flexibility under the Stark exceptions for bona fide employment agreements against the added cost of directly employing such physicians.

Stark Exception for Personal Services Agreements

The Stark Law also exempts agreements for personal services between FQHCs and physicians (and their immediate family members), where the agreements meet requirements similar to those in the AKS personal services safe harbor. Specifically, an agreement must satisfy each of the following criteria:

1. The agreement must be set out in writing, signed by each of the parties, specifying the services covered by the agreement.
2. The agreement must cover all of the services to be furnished by the physician to the entity.
3. The aggregate services contracted for must be reasonable and necessary for the legitimate business purposes of the arrangement(s).
4. The term of each arrangement must be for at least one year. If an arrangement is terminated during the term (with or without cause), the parties may not enter into the same or substantially same arrangement during the first year of the original term of the arrangement.
5. Compensation to be paid over the term of each arrangement must be set in advance, must not exceed fair market value, and—except for a physician incentive plan that has been reviewed by legal counsel and determined to be in compliance with applicable law relating to referral and compensation—must not take into account

the volume or value of any referrals or other business generated between the parties.

6. The services to be furnished under each arrangement must not involve the counseling or promotion of a business arrangement or other activity that violates any federal or state law.

Clinic Checklist: Referral and Compensation Agreements

- ✓ Is there a written contract with the specialist that covers all services that are provided on behalf of the FQHC, whether the specialist is an employee or independent contractor?
- ✓ If the arrangement with the specialist is an independent contractor relationship, does it meet each of the requirements of the AKS personal services safe harbor and the requirements of the personal services arrangements exception from the Stark Law?
- ✓ If the arrangement with the specialist is an employment relationship, does it meet each of the requirements of the AKS bona fide employee safe harbor and the bona fide employee exception from the Stark Law?
- ✓ If a productivity bonus is to be paid to either the physician or an immediate family member of the physician, has the arrangement been reviewed by legal counsel and determined to meet the requirements of all applicable law relating to referral and compensation?
- ✓ Has the determination that the compensation does not exceed fair market value been adequately documented for AKS and Stark purposes?
- ✓ If the compensation arrangement is based on part-time services, or if reimbursement is on a per-encounter basis, has legal counsel reviewed the agreement to ensure that concerns regarding potential violations of state and federal law relating to kickbacks have been fully addressed?

VII. California Licensing and Permitting Requirements

CALIFORNIA LAW RELATED TO LICENSING and certification provides the primary state-level regulatory framework affecting the provision of health care services by FQHCs. The majority of FQHCs in California are nonprofit clinics as defined in the California Health & Safety Code.⁵⁶ As such, they fall within the definition of “primary care clinics” for which a license must be obtained from the California Department of Public Health, Center for Health Care Quality’s Licensing and Certification program. Community and free clinics, as defined by Health & Safety Code § 1204(a), must also be licensed. All such entities licensed by the California Department of Health Care Services (DHCS) are by definition “primary care clinics.” Surgical clinics, chronic dialysis clinics, and rehabilitation clinics as defined by Health & Safety Code §1204(b), on the other hand, are defined as “specialty clinics.” However, the fact that an entity is designated as a “primary care clinic” under California law does not restrict it from providing specialty care services as they are commonly understood.

California’s clinic licensing law requires clinics to provide written notice of changes in services or physical plant no less than 60 days prior to adding the services or remodeling or modifying an existing primary care clinic site.⁵⁷ Clinics making such changes should base the descriptions in their notifications on the types of services as described in the relevant statute, including medical, surgical, dental, optometric, or podiatric advice, services, or treatment.⁵⁸

Certain types of activities in an outpatient setting require additional approvals from either DHCS or a professional licensing board. For example, the Clinic

Licensing Law requires a “Special Permit” in addition to a clinic license when a clinic offers one or more “special services,”⁵⁹ although such a special permit has to date only been required for the provision of “birth services.”

Additional approvals may be required in order to add certain specialty services, to use particular equipment, or to provide additional services that present unique risks. For example, if a nonprofit primary care clinic were to provide ambulatory surgery services, it would be required to obtain a separate license for the relevant space, and comply with the applicable building code standards for such facilities, including seismic safety standards.⁶⁰ Or, a clinic in which a dentist places patients under general anesthesia would be required to obtain a general anesthesia permit from the Dental Board of California. Other commonly required permits or licenses include the following:

- Air tank permit;
- Board of Pharmacy drug dispensary permit;
- Optometrist diagnostic or therapeutic pharmaceutical agent certification;
- Medical waste generator registration and treatment/transfer station permit;
- Radiation source registration;
- X-ray certification; and
- Controlled substances registration.

Any FQHC considering adding specialty services should analyze the particular facilities and equipment that will be needed, and should consult the relevant licensing and permitting bodies in order to determine the need for special permits or licenses. Agencies involved in licensing and permitting in California FQHCs are identified in Appendix C. Additional information regarding required permits and licenses can be found at www.calgold.ca.gov, under the category “physician.”

Clinic Checklist: Licensing and Permitting

- ✓ Has notice been provided to the California Department of Public Health, Center for Health Care Quality’s Licensing and Certification program regarding the addition of the services at least 60 days prior to the addition of the new services?
- ✓ Are any additional licenses or permits required in order to provide the services, or with respect to equipment to be used by the specialist?

VIII. Conclusion

AS CALIFORNIA'S SAFETY NET PROVIDERS face increasing demand for primary care, they also see increased need to provide specialty care services. The analysis required of an FQHC seeking to add specialty services to its scope of project presents both a challenge and an opportunity. BPHC requires that the FQHC review the community's need for the proposed services, as well as the FQHC's ability to successfully implement, integrate, and sustain those services. The health center must examine third-party payer coverage policies, insurance and FTCA coverage issues, potential conflicts of interest, and licensure and permitting obligations. While these tasks require complicated assessments, perhaps with the assistance of outside professional legal and accounting professionals, they also provide an excellent opportunity for an FQHC to conduct a fundamental review of its patients' need for specialty services, and can position the health center to serve as a consistent and reliable source of precisely those specialty services most appropriate for the community it serves.

Appendix A: Summary of Statutory Requirements for Maintaining Federally Qualified Health Center Status

The definitions of “Federally Qualified Health Center” and “Federally Qualified Health Center services” are contained in the laws relating to the Medicare and Medicaid programs. The Medicare and Medicaid definitions of entities qualifying as FQHCs rely in turn on satisfaction of the criteria for receiving a health center grant under 42 U.S.C. § 254b, as determined by the federal Health Resources & Services Administration (HRSA). These criteria address all aspects of health center operations. An FQHC applying to add specialty services should establish that the health center’s administration understands this framework and intends to comply with all of these requirements.⁶¹ They include the following:

- The FQHC must be located in a medically underserved area, or serve a special medically underserved population.⁶²
- The FQHC must be a public or nonprofit entity.⁶³
- The FQHC must provide certain “required primary health services,” made up of “basic health services” related to traditionally defined primary care services, diagnostic laboratory and radiology services, preventative health treatment, immunization and screening services, emergency medical services, appropriate pharmaceutical services, referrals to providers of medical services, including “specialty referral when medically indicated” and for other health-related services (including substance abuse and mental health services), case management, various enabling services such as outreach, translation and transportation, and patient health education.⁶⁴
- The FQHC may also provide such “additional health services” as may be appropriate for particular centers, where the services are “necessary for the adequate support of the ‘required primary health services’.”⁶⁵
- The FQHC must make the “required primary health services” available promptly in its service area (referred to as its “catchment area”).⁶⁶
- The FQHC must establish and maintain collaborative relationships with other health care providers in its catchment area.⁶⁷
- The FQHC must have an ongoing quality improvement system that includes clinical services and management, and that maintains the confidentiality of patient records.⁶⁸
- The FQHC must demonstrate its financial responsibility by use of required accounting procedures.⁶⁹
- The FQHC must have or intend to contract or otherwise provide Medicare, Medicaid and State Children’s Health Insurance Program (SCHIP) services, and must make every reasonable effort to collect appropriate reimbursement for its costs in providing services to patients covered by these or other public assistance or private insurance programs.⁷⁰
- The FQHC must prepare a fee schedule that is consistent with locally prevailing rates, designed to cover its reasonable costs of operation, and that is accompanied by a schedule of discounts based on the patient’s ability to pay.⁷¹
- The FQHC must make every reasonable effort to collect payments for services in accordance with its fee schedules, and to collect full and undiscounted fees from beneficiaries or enrollees in Medicaid, Medicare, or other public assistance program or private health insurance program.⁷²
- The FQHC must ensure that no patient will be denied health care services due to the individual’s inability to pay for such services, and that any fees or payments required by the health center be waived in order to fulfill this obligation.⁷³
- A majority of the FQHC’s governing board must be users of the health center’s services, and as a group the board must represent the individuals being served by the health centers. The governing board must meet at least monthly, select the services to be provided by the FQHC, approve

the selection of the center's director, and establish the general policies of the health center.⁷⁴

- The FQHC must have developed a business plan and budget that meet specified requirements, and an effective procedure for compiling and reporting the cost of its operations, the pattern of use of its services, the availability, accessibility, and acceptability of its services, and other operational matters.⁷⁵
- The FQHC must periodically review its catchment area to ensure that its size is such that the services provided by the FQHC are available and accessible to its residents, that the boundaries of the catchment area, to the extent practicable, conform to the relevant boundaries of political subdivisions, school districts, and federal and state health and social service programs; and that the boundaries of such area eliminate, to the extent possible, barriers of access to the services of the center, including those resulting from the area's physical characteristics, its residential patterns, its economic and social grouping, and available transportation.⁷⁶
- FQHCs that serve a population including a substantial proportion of individuals of limited English-speaking ability must develop a plan and make arrangements responsive to the needs of this population for providing services to the extent practicable in the language and cultural context most appropriate to such individuals.⁷⁷
- The FQHC must develop an ongoing referral relationship with one or more hospital.⁷⁸
- The FQHC must encourage persons receiving or seeking health services from the center to participate in any public or private health program or plan for which they are eligible, while ensuring that they are not denied care based on an inability to pay.⁷⁹

Appendix B: Employee Relationship Guidelines for Federal Employment Tax: The Twenty Factor Assessment (IRS Revenue Ruling #87-41, June 8, 1987)

The twenty factors the IRS uses in assessing the employment status of an individual for federal employment tax purposes are:

1. *Instructions.* A worker who is required to comply with other persons' instructions about when, where, and how he or she is to work is ordinarily an employee. This control factor is present if the person or persons for whom the services are performed have the right to require compliance with instructions.
2. *Training.* Training a worker by requiring an experienced employee to work with the worker, by corresponding with the worker, by requiring the worker to attend meetings, or by using other methods, indicates that the person or persons for whom the services are performed want the services performed in a particular method or manner.
3. *Integration.* Integration of the worker's services into the business operations generally shows that the worker is subject to direction and control. When the success or continuation of a business depends to an appreciable degree upon the performance of certain services, the workers who perform those services must necessarily be subject to a certain amount of control by the owner of the business.
4. *Services Rendered Personally.* If the services must be rendered personally, presumably the person or persons for whom the services are performed are interested in the methods used to accomplish the work as well as in the results.
5. *Hiring, Supervising, and Paying Assistants.* If the person or persons for whom the services are performed hire, supervise, and pay assistants, that factor generally shows control over the workers on the job. However, if one worker hires, supervises, and pays the other assistants pursuant to a contract under which the worker agrees to provide materials and labor and under which the worker is responsible only for the attainment of a result, this factor indicates an independent contractor status.
6. *Continuing Relationship.* A continuing relationship between the worker and the person or persons for whom the services are performed indicates that an employer-employee relationship exists. A continuing relationship may exist where work is performed at frequently recurring although irregular intervals.
7. *Set Hours of Work.* The establishment of set hours of work by the person or persons for whom the services are performed is a factor indicating control.
8. *Full Time Required.* If the worker must devote substantially full time to the business of the person or persons for whom the services are performed, such person or persons have control over the amount of time the worker spends working and impliedly restrict the worker from doing other gainful work. An independent contractor, on the other hand, is free to work when and for whom he or she chooses.
9. *Doing Work on Employer's Premises.* If the work is performed on the premises of the person or persons for whom the services are performed, that factor suggests control over the worker, especially if the work could be done elsewhere. Work done off the premises of the person or persons receiving the services, such as at the office of the worker, indicates some freedom from control. However, this fact by itself does not mean that the worker is not an employee. The importance of this factor depends on the nature of the service involved and the extent to which an employer generally would require that employees perform such services on the employer's premises. Control over the place of work is indicated when the person or persons for whom the services are performed have the right to compel the worker to travel a designated route, to canvass a territory within a certain time, or to work at specific places as required.
10. *Order or Sequence Set.* If a worker must perform services in the order or sequence set by the person or persons for whom the services are performed, that factor shows that the worker is not free to follow the worker's own

pattern of work but must follow the established routines and schedules of the person or persons for whom the services are performed. Often, because of the nature of an occupation, the person or persons for whom the services are performed do not set the order of the services or set the order infrequently. It is sufficient to show control, however, if such person or persons retain the right to do so.

11. *Oral or Written Reports.* A requirement that the worker submit regular or written reports to the person or persons for whom the services are performed indicates a degree of control.
12. *Payment by Hour, Week, Month.* Payment by the hour, week, or month generally points to an employer-employee relationship, provided that this method of payment is not just a convenient way of paying a lump sum agreed upon as the cost of a job. Payment made by the job or on a straight commission generally indicates that the worker is an independent contractor.
13. *Payment of Business and/or Traveling Expenses.* If the person or persons for whom the services are performed ordinarily pay the worker's business and/or traveling expenses, the worker is ordinarily an employee. An employer, to be able to control expenses, generally retains the right to regulate and direct the worker's business activities.
14. *Furnishing of Tools and Materials.* The fact that the person or persons for whom the services are performed furnish significant tools, materials, and other equipment tends to show the existence of an employer-employee relationship.
15. *Significant Investment.* If the worker invests in facilities that are used by the worker in performing services and are not typically maintained by employees (such as the maintenance of an office rented at fair value from an unrelated party), that factor tends to indicate that the worker is an independent contractor. On the other hand, lack of investment in facilities indicates dependence on the person or persons for whom the services are performed for such facilities and, accordingly, the existence of an employer-employee relationship. Special scrutiny is required with respect to certain types of facilities, such as home offices.
16. *Realization of Profit or Loss.* A worker who can realize a profit or suffer a loss as a result of the worker's services (in addition to the profit or loss ordinarily realized by employees) is generally an independent contractor, but the worker who cannot is an employee. For example, if the worker is subject to a real risk of economic loss due to significant investments or a bona fide liability for expenses, such as salary payments to unrelated employees, that factor indicates that the worker is an independent contractor. The risk that a worker will not receive payment for his or her services, however, is common to both independent contractors and employees and thus does not constitute a sufficient economic risk to support treatment as an independent contractor.
17. *Working for More Than One Firm at a Time.* If a worker performs more than de minimis services for a multiple of unrelated persons or firms at the same time, that factor generally indicates that the worker is an independent contractor. However, a worker who performs services for more than one person may be an employee of each of the persons, especially where such persons are part of the same service arrangement.
18. *Making Service Available to General Public.* The fact that a worker makes his or her services available to the general public on a regular and consistent basis indicates an independent contractor relationship.
19. *Right to Discharge.* The right to discharge a worker is a factor indicating that the worker is an employee and the person possessing the right is an employer. An employer exercises control through the threat of dismissal, which causes the worker to obey the employer's instructions. An independent contractor, on the other hand, cannot be fired so long as the independent contractor produces a result that meets the contract specifications.
20. *Right to Terminate.* If the worker has the right to end his or her relationship with the person for whom the services are performed at any time he or she wishes without incurring liability, that factor indicates an employer-employee relationship.

Appendix C: Principal California State Agencies Regulating Services or Equipment in FOHCs

SERVICE/EQUIPMENT	AGENCY
Air Tanks	Department of Industrial Relations, Pressure Vessel Unit
Certification for Optometrists—primary open angle glaucoma, lachrymal irrigation and dilation, and therapeutic pharmaceutical agents	Department of Consumer Affairs, Board of Optometry
Clinic Drug Dispensing Permit	Department of Consumer Affairs, Board of Pharmacy
Community/Free Clinic Licensure	California Department of Public Health, Licensing and Certification Program
<ul style="list-style-type: none"> • Dentists • Registered Dental Hygienist (including those with extended functions and/or in alternative practice) • Registered Dental Assistant (including those with extended functions) 	Department of Consumer Affairs, California Dental Board
<ul style="list-style-type: none"> • Physicians • Licensed Midwives • Medical Assistants • Registered Dispensing Opticians • Research Psychoanalysts (including students) 	Department of Consumer Affairs, Medical Board of California
<ul style="list-style-type: none"> • Registered Nurse • Clinical Nurse Specialist • Nurse Anesthetist • Nurse-Midwife (including those furnishing number) • Nurse Practitioner (including those furnishing number) • Psychiatric/Mental Health Nurse • Public Health Nurse 	Department of Consumer Affairs, California Board of Registered Nursing
Physician Assistants	Department of Consumer Affairs, Physician Assistant Committee
Radiation Source Registration—radiation-emitting machines or devices containing radioactive material; X-ray certification	Department of Public Health, Radiologic Health Branch
Request for Business & Professions Code § 805 Report (required before licensed clinic may grant or renew staff privileges for physician, dentist or psychologist)	<ul style="list-style-type: none"> • Department of Consumer Affairs, Medical Board of California • California Board of Psychology • California Dental Board • Osteopathic Medical Board of California

Appendix D: Required Primary Health Services and Additional Health Services for FQHCs

REQUIRED PRIMARY HEALTH SERVICES

[42 U.S.C. Section 254b(b)(1)]

The term “required primary health services” means:

- (i) Basic health services which, for purposes of this section, shall consist of:
 - (I) health services related to family medicine, internal medicine, pediatrics, obstetrics, or gynecology that are furnished by physicians and, where appropriate, physician assistants, nurse practitioners, and nurse midwives;
 - (II) diagnostic laboratory and radiologic services;
 - (III) preventive health services, including:
 - (aa) prenatal and perinatal services;
 - (bb) appropriate cancer screenings;
 - (cc) well-child services;
 - (dd) immunizations against vaccine-preventable diseases;
 - (ee) screenings for elevated blood lead levels, communicable diseases, and cholesterol;
 - (ff) pediatric eye, ear, and dental screenings to determine the need for vision and hearing correction and dental care;
 - (gg) voluntary family planning services; and
 - (hh) preventive dental services;
 - (IV) emergency medical services; and
 - (V) pharmaceutical services as may be appropriate for particular centers.

(ii) Referrals to providers of medical services (including specialty referrals when medically indicated) and other health-related services (including substance abuse and mental health services).

(iii) Patient case management services (including counseling, referral, and follow-up services) and other services designed to assist health center patients in establishing eligibility for and gaining access to Federal, State, and local programs that provide or financially support the provision of medical, social, housing, educational, or other related services.

ADDITIONAL HEALTH SERVICES

[42 U.S.C. Section 254b(b)(2)]

The term “additional health services” means:

Services that are not included as required primary health services and that are appropriate to meet the health needs of the population served by the health center involved. Such term may include:

(A) Behavioral and mental health and substance abuse services.

(B) Recuperative care services.

(C) Environmental health services, including-

- (i) the detection and alleviation of unhealthful conditions associated with:
 - (I) water supply;
 - (II) chemical and pesticide exposures;
 - (III) air quality; or
 - (IV) exposure to lead;
- (ii) sewage treatment;
- (iii) solid waste disposal;
- (iv) rodent and parasitic infestation;
- (v) field sanitation;
- (vi) housing; and
- (vii) other environmental factors related to health.

REQUIRED PRIMARY HEALTH SERVICES

[42 U.S.C. Section 254b(b)(1)]

The term “required primary health services” means:

(iv) Services that enable individuals to use the services of the health center (including outreach and transportation services and, if a substantial number of the individuals in the population served by a center are of limited English-speaking ability, the services of appropriate personnel fluent in the language spoken by a predominant number of such individuals).

(v) Education of patients and the general population served by the health center regarding the availability and proper use of health services.

Exception. With respect to a health center that receives a grant only under subsection (g), the Secretary, upon a showing of good cause, shall—

- (i) waive the requirement that the center provide all required primary health services under this paragraph; and
- (ii) approve, as appropriate, the provision of certain required primary health services only during certain periods of the year.

ADDITIONAL HEALTH SERVICES

[42 U.S.C. Section 254b(b)(2)]

The term “additional health services” means:

In the case of health centers receiving grants under § 254b(g), special occupation-related health services for migratory and seasonal agricultural workers, including—

- (i) screening for and control of infectious diseases, including parasitic diseases; and
- (ii) injury prevention programs, including prevention of exposure to unsafe levels of agricultural chemicals including pesticides.

Endnotes

1. California HealthCare Foundation, *California's Safety-Net Clinics: A Primer*, March 2009 (www.chcf.org/topics/view.cfm?itemID=115960).
2. The PINs are available on HRSA's Web site (bphc.hrsa.gov/policy). The applicable regulations are set out in Parts 51c and 56c of Title 42 of the Code of Federal Regulations (www.access.gpo.gov/nara/cfr/waisidx_08/42cfrv1_08.html).
3. 42 U.S.C. § 256b.
4. This requirement of prior BPHC approval applies to all FQHCs, including Look-Alikes. FQHC Look-Alikes follow a different, more streamlined process for applying for changes to their sites and services. Nevertheless, the general principles derived from the basic requirements of 42 U.S.C. § 254b are applicable to all FQHC Scope of Project modification requests.
5. 42 C.F.R. 51c.107(c) states that “[p]rior approval by the Secretary of revisions of the budget and project plan is required whenever there is to be a significant change in the scope or nature of project activities.” See also “Changes in Scope.” *HHS Grants Policy Statement*. January 1, 2007; II:55–56 (www.hhs.gov/grantsnet/docs/HHSGPS_107.doc).
6. 42 U.S.C. § 1396a(bb)(3)(B) requires state Medicaid plans to provide for an annual adjustment to PPS rates in order to take into account any increase or decrease in the scope of FQHC services furnished by the center.
7. Grantees are required to submit Scope of Project modification requests on behalf of any sub-grantees.
8. Only “service sites” as defined in the PIN must be added to the FQHC's Scope of Project. Administrative offices or locations that do not provide direct health care services are not service sites. PIN 2009-02: 6.
9. See “Defining Scope of Project and Policy for Requesting Changes,” HRSA PIN 2008-01, and the associated technical correction PIN 2009-03. See also “Specialty Services and Health Centers' Scope of Project,” PIN 2009-02.
10. 42 U.S.C. § 254b(a)(1)(B). See also PIN 2009-02: 8.
11. PIN 2009-02: 9.
12. 42 U.S.C. § 254b(k)(3)(G).
13. 42 C.F.R. § 51c.303(f) and (u). While the regulation ties the sliding fee scale to the now-obsolete CSA Poverty Income Guidelines (formerly in 45 C.F.R. § 1060.2), HRSA has consistently interpreted the applicable income scale to be the Federal Poverty Guidelines (aspe.hhs.gov/poverty).
14. 42 C.F.R. § 413.13.
15. FQHCs must also be certain that they comply with the requirements of any sliding fee scale obligations in grant programs such as the Ryan White CARE Act, which also has an annual payment cap, and California's Expanded Access to Primary Care program.
16. HRSA Uniform Data System. 2007 California data, Table 4, lines 7–9 (excludes FQHC Look-Alikes) (bphc.hrsa.gov/uds/2007data/california/table2.htm).
17. See 42 U.S.C. § 1395x(aa)(3) for the Medicare definition of FQHC services. While the statutory Medicare definition of covered FQHC services includes those “preventive primary health services” that a center is required to provide under 42 USC § 254b, this phrase has been further refined in regulation to exclude some of these required health-related services (42 C.F.R. § 405.2448). Most notably, Medicare-covered FQHC services do not include the provision of outreach, translation, transportation, and certain other services that FQHCs are required to provide.
18. For more information regarding Medicare billing and enrollment policies, see www.cms.hhs.gov/center/fqhc.asp.

19. See § 30.3 of 2008-05, May 5, 2008, relating to non-FQHC services that are covered by Medicare and reimbursed on a fee-for-service basis. CMS Pub. 102, Ch. 13.
20. 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(2)(C), 1396d(l)(2), 1395x(aa)(1)(A)–(C) and 1396a(bb). The Medicare “core providers” are those described in §1395x(aa)(1)(A)–(C).
21. Administrative and clinical leadership should be familiar with the full provisions of California law defining the manner of reimbursement for FQHC services as set out in California Welf. & Inst. Code §§ 14087.325 and 14132.100–14132.108, and expanded upon in the Medi-Cal Provider Manual, Inpatient/Outpatient—Clinics and Hospitals—Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (files.medi-cal.ca.gov/pubdoco/Manuals_menu.asp).
22. 42 U.S.C. §1396a(bb) and California Welf. & Inst. Code § 14132.100.
23. Effective July 1, 2009, California Welf. & Inst. Code §14131.10(b) eliminated Medi-Cal coverage of optional adult dental services, including dental hygienist and RDHAP services, acupuncture, audiology, speech therapy, chiropractic, optometry and optician services, podiatry, and psychology, with certain exceptions. This statute overrides any other Medi-Cal law describing these services to the extent that it reflects coverage of an “optional” Medicaid benefit. Psychology services are clearly recognized as part of the “mandatory” FQHC benefit which states are required to reimburse in FQHCs/RHCs even if eliminated as an “optional” Medicaid benefit.
24. California Welf. & Inst. Code § 14132.100(g).
25. Listing of FQHC/RHC rates obtained from California Department of Health Care Services. February, 2009.
26. 42 U.S.C. § 1396a(a)(72).
27. DHCS Audits & Investigations, *Policy and Procedure Questions and Answers*, June 26, 2000, retracted by DHCS by letter to all providers dated July 14, 2000, and not subsequently reissued. While these policies have never in fact been adopted as regulations, they have been relied upon to retroactively disallow reimbursement for FQHC services, at times in the millions of dollars.
28. Letter from Diana M. Bonta, Director, California Department of Health Care Services, to John D. Smith, Interim Director, Office of Administrative Law, in response to Executive Order S-2-03, requiring a report of potential violations of California Government Code § 11340.5(a).
29. For extensive information concerning FQHCs and FTCA coverage, see “New Requirements for Deeming under the Federally Supported Health Centers Assistance Act for Calendar Year 2009,” PIN 08-05; “Health Centers and The Federal Tort Claims Act,” PIN 99-08; “Clarification of Policy for Health Centers Deemed Covered Under the Federal Tort Claims Act for Medical Malpractice,” PIN 2001-11; and “Questions and Answers on the Federal Tort Claims Act Coverage for Section 330, Deemed Grantees,” Program Assistance Letter (PAL), 99-15.
30. See 28 U.S.C. §§ 1346 and 2672-2680 for the Federal Tort Claims Act, and 42 U.S.C. § 233(g) for the provisions of the Public Health Service Act relating to coverage of FQHCs under FTCA.
31. 42 U.S.C. § 233(a).
32. See 42 U.S.C. § 233(c), (g). Moreover, once the Secretary of HHS deems a physician to be an employee of the Public Health Service, “the determination shall be final and binding upon the Secretary and the Attorney General and other parties to any civil action or proceeding.” 42 U.S.C. § 233(g)(1)(F).
33. 42 U.S.C. § 233(g)(4).
34. In order for an FQHC to be “deemed covered” by FTCA, it must receive approval from HRSA pursuant to the requirements set out in Program Assistance Letter 2009-05.
35. 42 U.S.C. § 233(g)(1) and (4).

36. Some courts have recently held that professional corporations solely owned by a single professional are covered by FTCA despite language to the contrary in PIN 99-08 (April 12, 1999). See *El Rio Santa Cruz Neighborhood Health Center v. HHS*, 396 F.3d 1265 (2005). See also *Ismie Mut. Ins. Co. v. HHS*, 413 F. Supp.2d 954 (N.D. Ill. 2006). Before contracting with an individually owned professional corporation, an FQHC must verify FTCA coverage directly with the Bureau of Primary Health Care.
37. 58 Ops. Cal. Atty. Gen. 291. May 20, 1975.
38. *Clinician's Handbook on the Federal Tort Claims Act*, 2nd edition; 2002 ([ftp://ftp.hrsa.gov/bphc/pdf/quality/2002clinicianhandbook.pdf](http://ftp.hrsa.gov/bphc/pdf/quality/2002clinicianhandbook.pdf)).
39. PIN 2001-11 addresses circumstances where providers bill for the services and remit the funds received for that service to the health center. It is the policy of the BPHC that such an arrangement will not *by itself* remove the provider of that service from coverage under FTCA. Instead, FTCA coverage will apply to the provider and the center so long as all of the following apply: (1) the provider reports to the health center all such billings; (2) the funds received by the provider for the specific billings are transferred directly to the health center within a reasonable period of time; and (3) the provider's employment contract authorizes the billing arrangement as described. Care should be taken to ensure that no services are provided without either FTCA or wrap-around coverage. Where Medicare or Medicaid funds are involved, the health center should make certain that the arrangement is permitted under the reassignment of benefits rules applicable to such programs.
40. PAL 2009-05. May 1, 2009.
41. 42 U.S.C. § 1320a-7b(b).
42. 72 Fed. Reg. 56632. October 4, 2007.
43. 42 U.S.C. § 1320a-7b(b)(3)(B).
44. 42 C.F.R. § 1001.952(i) and 26 U.S.C. § 3121(d)(2).
45. 26 U.S.C. § 3121(d)(2).
46. 42 U.S.C. § 1395nn(e)(2) and 42 C.F.R. § 411.357(c).
47. 42 U.S.C. § 1320a-7b(b)(3)(I).
48. 42 C.F.R. § 1001.952(w).
49. 42 U.S.C. § 1396b(s).
50. "Physician" means a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor. 42 C.F.R. § 411.351 and 42 U.S.C. § 1395x(r). "Referring physician" means a physician who makes a referral for designated health services, directs another person or entity to make a referral, or controls referrals made by another person or entity. A physician and the professional corporation of which he or she is a sole owner are the same for purposes of the Stark Law. 42 C.F.R. § 411.351.
51. 42 U.S.C. § 1395nn(h)(5)(A); 42 C.F.R. § 411.351.
52. 42 C.F.R. § 411.351. If the service itself is payable through a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services), it would still be considered a "designated health service" subject to the Stark Law's referral prohibition.
53. 42 U.S.C. § 1395nn(h)(2).
54. 42 C.F.R. § 411.357(c).
55. 42 C.F.R. § 411.351. Prior efforts by CMS to define fair market value by reference to particular salary surveys have been eliminated from the implementing regulations.
56. California Health & Safety Code § 1204(a).
57. California Health & Safety Code § 1212(b)(1).
58. California Health & Safety Code § 1200.
59. California Health & Safety Code §§ 1202 and 1203.
60. It is not clear that BPHC would approve a Scope of Project application permitting the addition of ambulatory care center services, but such approval would be a prerequisite for reimbursement of the services as FQHC services.

61. Additional conditions that FQHCs must meet in order to be certified to participate in Medicare are set out in Part 491 of Title 42 of the Code of Federal Regulations.
62. 42 U.S.C. § 254b(a)(1) and (b)(3).
63. 42 U.S.C. § 254b(c)(1) and (e)(1).
64. 42 U.S.C. § 254b(a)(1). Health centers that are only receiving migrant farm-worker grants may obtain full or partial waivers of the obligation to provide these “required primary health services.” Recipients of homeless grants must also provide substance abuse services.
65. 42 U.S.C. § 254b(b)(1)(B) and (b)(2).
66. 42 U.S.C. § 254b(a)(1) and (k)(3)(A). This requirement does not apply to FQHCs that are only recipients of grants relating to migrant farm-worker, homeless, or public housing health care services under § 254b(g), (h) or (i).
67. 42 U.S.C. § 254b(k)(3)(B).
68. 42 U.S.C. § 254b(k)(3)(C).
69. 42 U.S.C. § 254b(k)(3)(D).
70. 42 U.S.C. § 254b(k)(3)(E)–(F).
71. 42 U.S.C. § 254b(k)(3)(G)(i).
72. 42 U.S.C. § 254b(k)(3)(G)(ii).
73. 42 U.S.C. § 254b(k)(3)(G)(iii).
74. 42 U.S.C. § 254b(k)(3)(H).
75. 42 U.S.C. § 254b(k)(3)(I).
76. 42 U.S.C. § 254b(k)(3)(J).
77. 42 U.S.C. § 254b(k)(3)(K).
78. 42 U.S.C. § 254b(k)(3)(L).
79. 42 U.S.C. § 254b(k)(3)(M).



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