

Partnerships between Federally Qualified Health Centers and Local Health Departments for Engaging in the Development of a Community-Based System of Care

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Acknowledgments / Disclaimer

Partnerships between Federally Qualified Health Centers and Local Health Departments for Engaging in the Development of a Community-Based System of Care familiarizes the reader with federally qualified health centers and local health departments and explores various collaborative models that optimize resources and promote improved health care access and quality improvement. While this guide does not describe the full scope of partnership options, it provides guidance to support the reader's efforts in evaluating, selecting, and implementing a partnership that is appropriate for a particular community.

This publication was prepared for the National Association of Community Health Centers (NACHC) by attorneys with the law firm of Feldesman Tucker Leifer Fidell LLP (FTLF). It is designed to provide accurate and authoritative information in regard to the subject matter covered. While incorporating certain principles of federal law, this guide is published with the understanding that it does not constitute, and is not a substitute for, legal, financial or other professional advice. Further, this guide does not purport to provide advice based on specific state law. Federally qualified health centers and local health departments should consult knowledgeable legal counsel and financial experts to structure and implement a partnership that is legally, financially, and operationally appropriate given the particular federally qualified health center's and local health department's respective goals, objectives, expectations, and resources.

National Association of Community Health Centers (NACHC)



Established in 1971, NACHC serves as the national voice for America’s Health Centers and as an advocate for health care access for the medically underserved and uninsured. NACHC’s mission is to promote the provision of high quality, comprehensive and affordable health care that is coordinated, culturally and linguistically competent, and community directed for all medically underserved populations.

National Association of County and City Health Officials (NACCHO)



NACCHO is the national nonprofit organization representing the approximately 2,860 local health departments (LHDs) nationwide, including members in all public health regions. NACCHO serves every LHD in the nation, without regard to the unit of government with which a department is associated. These include LHDs associated with counties; cities; combined county-city entities; towns; multi-town, multi-county, or other regional entities within a state; tribes; and states. NACCHO’s vision is health, equity, and well-being for all people in their communities through public health policies and services. NACCHO’s mission is to be a leader, catalyst, and voice for LHDs in order to ensure the conditions that promote health and equity, combat disease, and improve the quality and length of lives.

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Introduction

Federally qualified health centers (hereinafter “FQHCs” or Community Health Centers (“CHCs”)) and local health departments (hereinafter “LHDs”) share a common mission to improve community health, particularly among vulnerable and underserved populations. FQHCs and LHDs currently work collaboratively on behalf of their residents in many communities across the country.

Today, the reasons for partnership between FQHCs and LHDs are particularly compelling. The passage of the Patient Protection and Affordable Care Act (the “health reform law”) signals an overhaul of the health care system, with an important emphasis on primary care, prevention, and collaboration among a community’s health care providers. A core component of the health reform law is the expansion of the patient centered medical home model of care delivery, which calls for patient care to be coordinated and integrated across the health care system. Both the Patient Protection and Affordable Care Act and the expansion of the patient centered medical home model present fresh opportunities for health and community leaders to work together to design and implement local health delivery and care systems that:

- Address the health issues of underserved and vulnerable communities;
- Improve and document value;
- Generate positive patient and community experiences of care and engagement in health; and
- Improve the health of target populations with an emphasis on promoting health equity and eliminating health disparities.

FQHCs and LHDs differ in some substantive ways. FQHCs are charged with the delivery of a full continuum of primary and preventive care services, and enabling services. LHDs are charged with population health, which may or may not include health care delivery. Likewise, as federally-funded entities, FQHCs structure and regulations are relatively uniform compared to LHDs, whose governance and activities vary widely from state to state and from community to community. However, the two entities are well positioned to be strong partners and there is a long history of coming together to improve both individual and population health.

Partnerships between Federally Qualified Health Centers and Local Health Departments for Engaging in the Development of a Community-Based System of Care provides an overview of several partnership opportunities available to FQHCs and LHDs seeking to improve health outcomes in their community, while promoting cost-effective care. Through the lens of partnership, LHD readers will benefit from information presented about the key features of FQHCs and the various federal requirements applicable to the program. Likewise, FQHC readers will gain insight into LHDs.

Specifically, this guide addresses:

- The Patient Protection and Affordable Care Act, the patient centered medical home model of care, and the meaningful use of health information technology as drivers in FQHC-LHD partnerships;
- Benefits associated with FQHC-LHD partnerships;
- Key features of FQHCs and LHDs and their relevance to FQHC-LHD partnerships;
- Health information exchange and patient privacy considerations within the context of FQHC-LHD partnerships; and
- Various partnership models, including key terms for written agreements to implement an affiliation approach that is compliant with applicable FQHC federal rules and requirements.

1 | Federally Qualified Health Center-Local Health Department Partnerships: A Strategic Alliance

Partnerships are necessary to maximize resources, to reduce duplication of effort, and to improve quality, efficiency, and accessibility of health care services. The changing face of America's underserved population, the restricted resources under which FQHCs and LHDs operate, and the desire and need for more fully-functioning and better prepared public health and primary care systems all demand a health care system based in local partnerships.

Currently, FQHCs and LHDs successfully partner to address a variety of public health and primary care priorities, including but not limited to the following:

- HIV prevention and testing;
- STD testing, care and treatment;
- Dental health;
- Behavioral health;
- Chronic disease prevention;
- Maternal and child health; and
- Emergency preparedness.

NACHC and NACCHO: A Joint Mission to Promote Collaboration between FQHCs and LHDs

On June 1, 2010, the National Association of Community Health Centers (NACHC) and the National Association of County and City Health Officials (NACCHO) collectively wrote a letter to their respective members, stating "NACCHO and NACHC recognize that a new collaboration between our two organizations can help our respective members address the challenges of health system reform." The letter further noted that excellent models of local collaboration currently exist and that together the organizations plan to discover more models, to learn from them, and to encourage the development of such constructive relationships nationwide.

A. Patient Protection and Affordable Care Act

The passage of the Patient Protection and Affordable Care Act ("the health reform law") in 2010 provides for a significant financial investment in programs based in public health, primary care, and community collaboration. This investment reflects a national shift towards emphasizing wellness and prevention, clinical integration, and collaborative community based care. Indeed, it is well settled that reform will not be successful without such collaboration. Collaboration between FQHCs and LHDs is therefore not only desirable, it is necessary given the priorities set forth in health reform.

Health Reform and FQHC-LHD Collaboration

Through collaboration, FQHCs and LHDs may position themselves to participate in funding opportunities. There are several relevant funding opportunities described in the health reform law, including the following:

- Community health teams (Pub. L. 111-148 § 3502): The health reform law states that health teams composed of community-based, interdisciplinary medical professionals will be established to support primary care medical homes

that are within hospital areas served by those entities. This provision allows LHDs to receive funds to establish a community health team and collaborate with local primary care providers, including FQHCs.

- Community-based prevention and wellness programs (Pub. L. 111-148 § 4202): The health reform law establishes that there will be grants for LHDs to carry out 5-year pilot programs to provide public health community interventions. Among other requirements, LHDs are required to demonstrate the capacity to establish relationships with community-based clinical partners, such as FQHCs.
- Primary care extension programs (Pub. L. 111-148 § 5404): The health reform law authorizes grants to states to establish primary care extension programs. These programs rely on the collaboration of LHDs and FQHCs to identify community health priorities and participate in community-based efforts to address these primary care priorities.

In addition to these opportunities presented in the health reform law, both the Centers for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA) have made public health and primary care collaboration a priority, resulting in the availability of funding to support collaborative efforts.

From Fragmentation to a High Performance Health System

According to a Commonwealth Fund Commission on a High Performance Health System report, fragmentation in the health care delivery system fosters frustrating and dangerous patient experiences, especially for patients obtaining care from multiple providers in a variety of settings. Fragmentation also leads to waste and duplication, hindering providers' ability to deliver high-quality, efficient care.¹ The Commission identified the following six attributes of an ideal health care delivery system:

1. Patients' clinically relevant information is available to all providers at the point of care and to patients through electronic health record systems.
2. Patient care is coordinated among multiple providers, and transitions across care settings are actively managed.
3. Providers (including nurses and other members of care teams) both within and across settings have accountability to each other, review each other's work, and collaborate to reliably deliver high-quality, high-value care.
4. Patients have easy access to appropriate care and information, including after hours; there are multiple points of entry to the system; and providers are culturally competent and responsive to patients' needs.
5. There is clear accountability for the total care of patients.
6. The system is continuously innovating and learning in order to improve the quality, value, and patient experience of health care delivery.

¹ Commonwealth Fund, *Organizing the Health Care Delivery System for High Performance* (2008).

B. The Patient-Centered Medical Home Model of Care

The 2010 health reform law promotes delivery system innovation and improvement through systems of care such as patient-centered medical homes and accountable care delivery models. Health reform provides structure and incentives for providers to organize themselves and share savings under an accountable care organization (ACO), deliver care via the patient-centered medical home (PCMH) model, and receive bundled and global payments for acute and post-acute care.

The PCMH concept, originally introduced by the American Academy of Pediatrics (AAP) in 1967, received further endorsement in 2007 when AAP, together with the American Academy of Family Physicians (AAFP), American College of Physicians (ACP), and American Osteopathic Association (AOA), issued the Joint Principles of the Patient-Centered Medical Home. Now widely accepted among medical organizations and associations, the prevailing medical home concept is represented in the [Joint Principles](#), which emphasize a patient's ongoing relationship with a personal physician, a whole person orientation, team approaches to care, care integration and coordination, enhanced access, quality, safety, and payment for added value.

As one approach in a larger strategy to transform how health care is delivered in the United States, the PCMH illuminates the role of primary care in controlling costs, improving quality, and improving the patient experience of care. This framework aims to transform primary care practices in both the public and private sectors to ensure accessible, timely, comprehensive, patient-centered primary care and effective coordination with other providers.

Organizations such as the National Committee for Quality Assurance (NCQA) have created widely-supported standards for recognition as a PCMH. NCQA's [Physician Practice Connections®—Patient Centered Medical Home™](#) recognition program is based upon meeting specific elements in nine standard categories. The Primary Care Development Corporation (PCDC) offers a [How-To Manual](#) for safety net providers and organizations seeking to achieve NCQA medical home recognition. Similarly, the American College of Physicians (ACP) has developed a [Medical Home BuilderSM](#) tool that provides step-by-step instructions, tools, and resources.

NCQA Physician Practice Connections®—Patient Centered Medical Home™ Recognition Program²

PPC-PCMH Recognition is based on meeting specific elements included in nine standard categories:

1. Access and Communication
2. Patient Tracking and Registry Functions
3. Care Management
4. Patient Self-Management and Support
5. Electronic Prescribing
6. Test Tracking
7. Referral Tracking
8. Performance Reporting and Improvement
9. Advanced Electronic Communication

Note: NCQA standards were recently open for public comment; a proposal to collapse and reduce the categories from nine to six is under consideration.

² <http://www.ncqa.org/tabid/631/Default.aspx>.

“Yet as the United States seeks to optimize primary care, in part by advancing the concept of the ‘patient-centered medical home’ (PCMH), some of the key values of the CHC model—a whole-person orientation, accessibility, affordability, high quality, and accountability—could well inform tomorrow’s primary care paradigm for all Americans. Despite the challenges they face, the CHCs are already built on a premise resembling that of the PCMH, a holistic concept encompassing highly accessible, coordinated, and continuous team-driven delivery of primary care that relies on the use of decision-support tools and ongoing quality measurement and improvement.”³

Medical home initiatives within safety net populations are in abundance, and FQHC engagement is on the rise. Over 40 FQHCs have already achieved NCQA medical home recognition. According to the National Academy for State Health Policy, more than 35 state Medicaid agencies have **legislated medical home initiatives**, with many fully engaged in demonstrations, and the **Medicare-Medicaid Advanced Primary Demonstration Initiative** was announced in September 2009. The **Safety Net Medical Home Initiative**, a five-year demonstration launched in 2008 by the Commonwealth Fund, Qualis Health, and the MacColl Institute for Healthcare Innovation, relies heavily on FQHCs as it seeks to produce a replicable national model for implementing the PCMH in safety net primary care practices.

A 2009 study by the Commonwealth Fund examined FQHC capacity to function as a medical home based on the presence or absence of five indicators developed from the National Committee for Quality Assurance’s medical home measures: Patient Tracking and Registry Functions; Test Tracking; Referral Tracking; Enhanced Access and Communication; and Performance Reporting and Improvement. Twenty-nine percent of FQHCs had capacity in all five domains; 55% in 3-4 domains; and 16% in 0-2 domains. A key opportunity for improvement is in care coordination across different settings of care.⁴

A National Demonstration Project by the American Academy of Family Physicians (AAFP) randomized 36 family practice sites to facilitated versus self-directed groups in implementation of the PCMH model. They found that transformation of practices required a tremendous amount of resources and external support. And while greater adoption of medical home components was associated with improvement in measures of quality, prevention and chronic disease care, patient ratings declined in both the facilitated and self-directed groups during this transformation process. This evaluation reports that the “jury is still out on the actual impact on quality of care and patient outcomes....Realistically, it may require reform of the larger delivery system, integrating primary care with the larger health care system, for the full impact of a PCMH implementation to result in statistically significant enhancements to most patient quality-of-care outcomes.”⁵

³ Health Care Reform and Primary Care — The Growing Importance of the Community Health Center, Eli Y. Adashi, MD, H. Jack Geiger, MD, and Michael D. Fine, MD. *New England Journal of Medicine* 362:2047-2050 (2010).

⁴ Enhancing the Capacity of Community Health Centers to Achieve High Performance, *Findings from the 2009 Commonwealth Fund National Survey of Federally Qualified Health Centers*, Michelle M. Doty, Melinda K. Abrams, Susan E. Hernandez, Kristof Stremikis, and Anne C. Beal, May 2010.

⁵ Summary of the National Demonstration Project and Recommendations for the Patient-Centered Medical Home, Benjamin F. Crabtree, PhD, Paul A. Nutting, MD, MSPH, William L. Miller, MD, MA, Kurt C. Stange, MD, PhD, Elizabeth E. Stewart, PhD and Carlos Roberto Jaén, MD, PhD *Annals of Family Medicine* 8:S80-S90 (2010) doi: 10.1370/afm.1107.

While the health reform law is national in scope, the task of implementing it and ultimately transforming the way health care is delivered in this country will fall on state and local public health and primary care systems. Meaningful transformation will require an unprecedented level of cooperation and integration among various systems of health care delivery—both public and private. Furthermore, the PCMH or health care home for underserved and vulnerable populations must support and build individual efficacy to maintain or improve health while providing a structure for community participation in the operation of the health care home. Safety net practices should be engaged partners in a community health system that ensures access and coordination with specialty care, diagnostic services, public health services, health information exchanges, hospitals, and other care settings as well as agencies and community organizations providing social, education, housing, and other services necessary to maintain and improve health. For underserved and vulnerable patients, the health care home should function as more of a village, requiring the transformation of the local primary care and public health systems and strong leadership from within each.

C. Meaningful Use of Health Information Technology

It is essential that FQHCs and LHDs establish the ability to exchange information for the purposes of coordinating care for their shared patients and to provide the ability to improve population health. The Centers for Medicare and Medicaid Services released its Final Rule on the Medicare and Medicaid Electronic Health Record Incentive Program on July 28, 2010 in the Federal Register.⁶ These rules require that eligible professionals use health information

technologies, particularly electronic health records, that have the “capability to exchange key clinical information (for example, problem list, medication list, medication allergies, diagnostic test results), among providers of care and patient authorized entities electronically” to improve care coordination.⁷ Eligible professionals working in FQHCs and meeting the “30% needy individuals” patient volume threshold will be required to demonstrate successful exchange of clinical information by their second year of participation in the Medicaid Incentive Program to receive an incentive payment for that year. In subsequent years they will be required to have the ability to exchange this data on a regular basis.

The rules also specify that eligible professionals may choose to have the “capability to submit electronic syndromic surveillance data to public health agencies and actual submission in accordance with applicable law and practice” and/or the “capability to submit electronic data to immunization registries or immunization information systems and actual submission according to applicable law and practice” as an element of meaningful use for purposes of qualifying for an incentive payment under the Incentive Program.⁸ These two options, along with the capacity to submit electronic data on reportable lab results to public health agencies (applicable only to hospitals), comprise the objectives aimed at improving population and public health.

For more information regarding electronic health records and meaningful use, readers may refer to the [Department of Health and Human Services \(DHHS\) website](#).

⁶ 42 Fed. Reg. 44314, July 28, 2010.

⁷ 42 Fed. Reg. 44360, July 28, 2010.

⁸ 42 Fed. Reg. 44367, July 28, 2010.

D. Partnership Benefits

The potential benefits of FQHC-LHD partnerships extend beyond the four walls of the exam room and into the greater community. Partnerships put the well-being of a community into greater focus with overall goals to improve access to care, improve health outcomes, and decrease health disparities. Specifically, an FQHC-LHD partnership may:

Systems of Care

- Enhance the capacity of community providers to provide value, high quality, cost-effective medical homes for vulnerable populations.
- Assist low-income individuals to access the full range of safety net services and public benefits available in the community (e.g., food stamps, substance abuse counseling, Medicaid eligibility, and other social services).
- Generate more positive patient and community experiences of care and engagement in health.

Resources

- Help to avoid the unnecessary duplication of services, lowering the costs of providing care and ultimately strengthening the existing safety net delivery system.
- Reduce the need for more expensive in-patient and specialty care services as well as emergency room visits, resulting in significant savings to a community's health care system.
- Allow limited federal, state and local resources to be targeted and allocated to areas that most require them.

Clinical Outcomes

- Reduce chronic disease through the reduction of risk factors, such as smoking.
- Reduce the spread of infectious disease in the community.
- Improve immunization rates against vaccine-preventable diseases.
- Improve access to prenatal care; educate women about well-baby care, childhood immunizations, and nutrition; prevent mother-to-baby transmission of HIV; and decrease premature birth and morbidity.

Public Health Monitoring

- Support comprehensive community public health assessments through collaboration and sharing of surveillance and other population-based data.
- Allow providers to gather vital patient level data through disease registries.
- Facilitate the partner notification process for HIV and other sexually transmitted diseases.

2 | Defining Safety Net Providers: Federally Qualified Health Centers and Local Health Departments

A. Federally Qualified Health Center Fundamentals

1. Defining a Federally Qualified Health Center

An FQHC is a public or private non-profit, charitable, tax-exempt organization that receives funding under Section 330 of the Public Health Service Act (Section 330), or is determined by the Department of Health and Human Services (DHHS) to meet requirements to receive funding without actually receiving a grant (i.e., an FQHC “lookalike”).⁹

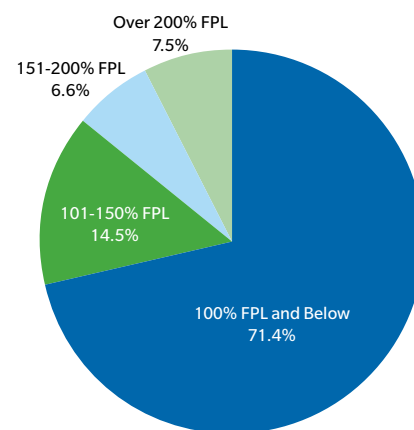
FQHCs serve as the health care home for 20 million people nationally through over 7,500 service delivery sites.¹⁰ It is estimated that FQHCs save the national health care system up to \$24 billion a year. This includes \$6.7 billion in savings for the federal share of the Medicaid program, and is driven by lower utilization of costly specialty care, emergency departments, and hospitals.¹¹

FQHCs successfully overcome barriers to care because they are located in high-need areas; are open to all residents of their service areas; offer services that facilitate access to care, such as outreach and transportation; and tailor their services to their patients’ and their communities’ unique cultural and health needs.¹²

FQHC patients are some of the nation’s most vulnerable individuals. Recent surveys indicate:¹³

- 71% of patients have family incomes at or below the Federal Poverty Level (FPL).
- 38% of patients are uninsured.
- 36% of patients depend on Medicaid.
- Roughly half of FQHC patients live in economically depressed inner city communities with the other half residing in rural areas.

FQHC Patients by Income Level, 2009



Note: Federal Poverty Level (FPL) for a family of three in 2009 was \$18,310. (See <http://aspe.hhs.gov/poverty/08poverty.shtml>.) Based on percent known. Percents may not total 100% due to rounding.

Source: Bureau of Primary Health Care, HRSA, DHHS, 2009 Uniform Data System.

⁹ Section 1861(aa)(4) of the Social Security Act.

¹⁰ *Fact Sheet- America’s Health Centers*. NACHC, August 2010. Available at www.nachc.com/research.

¹¹ *Fact Sheet- America’s Health Centers*. NACHC, August 2010. Available at www.nachc.com/research.

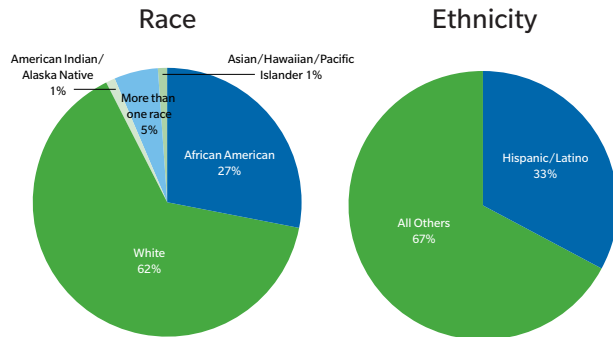
¹² Section 330 of the Public Health Service Act (42 U.S.C. § 254b) and its implementing regulations (42 C.F.R. Part 51c).

¹³ *Fact Sheet- America’s Health Centers*. NACHC, August 2010. Available at www.nachc.com/research.

“[Community Health Centers] provide quality care at prices that people can afford, with the dignity and respect they deserve, and in a way that takes into account the challenges that they face in their lives.”

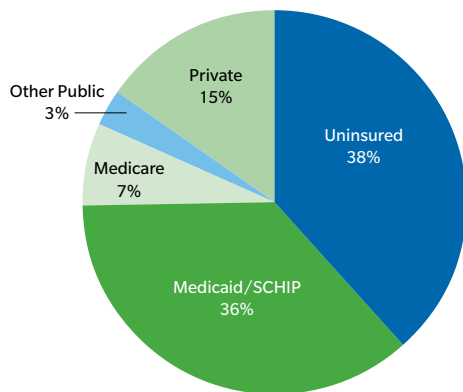
—President Barack Obama, Remarks by the President on Community Health Centers, December 2009

FQHC Patients by Race/Ethnicity, 2009



Note: Based on percent known. Percents may not total 100% due to rounding.
 Source: Bureau of Primary Health Care, HRSA, DHHS, 2009 Uniform Data System.

FQHC Patients by Insurance Status, 2009



Note: Other Public may include non-Medicaid SCHIP. Percents may not total 100% due to rounding.
 Source: Bureau of Primary Health Care, HRSA, DHHS, 2009 Uniform Data System.

America’s Health Centers owe their existence to a remarkable turn of events in U.S. history, and to a few determined community health and civil rights activists working in low-income communities during the 1960s. Millions of Americans, living in inner-city neighborhoods and rural areas throughout the country, suffered from deep poverty and a desperate need for health care. Among those determined to seek change was H. Jack Geiger, then a young doctor and civil rights activist. Geiger had studied in South Africa and witnessed how a pioneering community health model had wrought astonishing improvements in public health. In the 1960s, as President Johnson’s declared “War on Poverty” began to ripple through America, the first proposal for the U.S. version of a community health center sprung to life at the Office of Economic Opportunity. Funding was approved in 1965 for the first two neighborhood health center demonstration projects, one in Boston, Massachusetts, and the other in Mound Bayou, Mississippi. You can read more about the history of the health center movement, and learn about the pioneers who helped make it happen, at an [online exhibit](#) on global health launched by the National Library of Medicine. More information about FQHCs is also available at the [Faces of Hope Campaign](#), which was launched to raise awareness about Community Health Centers.¹⁵

“For more than 40 years, health centers in the United States have delivered comprehensive, high-quality primary health care to patients regardless of their ability to pay.”¹⁴

¹⁴ *Health Centers: America’s Primary Care Safety Net, Reflections on Success, 2002-2007*. DHHS, HRSA, BPHC, June 2008, p. 1.

¹⁵ NACHC’s press kit is available at <http://www.nachc.com/press-kit.cfm>.

What is a Public Health Center?

In order to qualify for Section 330 funding, an organization must, among other requirements, be a nonprofit private or **public entity** and must have a consumer-directed board of directors that meets specific requirements with respect to board member selection, composition, and the exercise of broad policy and oversight authorities.¹⁶ Recognizing that most public entities¹⁷ are not, and legally could not, be governed by a consumer-directed board, Congress revised Section 330 in 1978 to authorize the DHHS to expend up to 5 percent of the annual Section 330 appropriation in support of “public health centers” with governing boards that do not fully exercise all of the required authorities.¹⁸ Public health centers may receive Section 330 funding or may be designated as an FQHC look-alike.

Guidance issued by HRSA, set forth in *Policy Information Notice (PIN) 99-09: Implementation of the Balanced Budget Act Amendment*, explains that there are two models of public health centers. One is a direct model, in which the public entity meets all of the Section 330 FQHC program requirements. The direct model is extraordinarily uncommon due to the fact that seemingly few public entities have, or legally could have, a board that meets Section 330 selection and composition requirements. The other model is a co-applicant arrangement, which consists of a public entity and a co-applicant entity that collectively meet all Section 330 requirements. The public entity receives the grant funds or look-

alike designation, and the co-applicant entity serves as the FQHC’s governing board. Together, the two jointly function as the public health center.

HRSA PIN 99-09 stipulates that under the co-applicant model, the co-applicant board for the public health center must meet the Section 330 composition and responsibility requirements as described on pages 18–19 of this guide, except for the requirement that the board establish personnel and financial management policies for the public health center. HRSA PIN 99-09 also allows for certain joint decision-making between the public entity and the co-applicant board, although the board must maintain certain autonomous authorities.

LHDs are eligible to apply for designation as a public health center if they meet the applicable Section 330 requirements, many of which are highlighted on pages 16–20 of this guide, and qualify as a “public agency,” defined as follows:

- The organization is a state or a political subdivision of a state with one or more sovereign powers.
- The organization is an instrumentality of government, such as those exempt under Internal Revenue Code Section 115.
- The organization is a subdivision, municipality, or instrumentality of a U.S. affiliated sovereign state that is formally associated with the United States.
- The organization is operated by an Indian tribe or tribal or Indian organization under the Indian Self-Determination Act or urban Indian organization under the Indian Health Care Improvement Act.

For more information on establishing a public health center, see NACCHO’s issue brief, *Developing Quality Applications for Community Health Center Funding*.

¹⁶ 42 U.S.C. § 254b(k)(3)(H); 42 C.F.R. § 51c.304.

¹⁷ Public entities may include, but are not limited to, public hospitals and municipal health departments. Public entities are specifically defined in HRSA PIN 2010-01: *Confirming Public Agency Status under the Health Center Program and FQHC Look-Alike Program* available at <http://bphc.hrsa.gov/policy/pin1001/>.

¹⁸ 42 U.S.C. § 254b(r)(2)(A).

2. Key Federally Qualified Health Center Requirements

HRSA encourages FQHCs to affiliate with other entities, but expects them to remain diligent in complying with all Section 330-related requirements.¹⁹ It is of utmost importance that FQHCs and their partnering LHDs consider Section 330 statutory, regulatory, and policy requirements throughout the evaluation and implementation of any affiliation. A thorough review of legal considerations helps ensure that the partnership is appropriately structured, reduces exposure to liability, and protects an FQHC's designation.

Cornerstones of the FQHC Model

There are four cornerstones of the FQHC model, all of which must continue to be satisfied under any collaboration. Specifically, the FQHC must:

1. Be located in a federally-designated medically underserved area or serve a federally-designated medically underserved population;
2. Serve all residents of the FQHC's service area or all residents who belong to a targeted "special population" (i.e., migrant and seasonal farmworkers, homeless individuals, and residents of public housing) if the FQHC receives funding to serve such special population, regardless of an individual's or family's ability to pay;
3. Provide a full continuum of primary and preventive care services; and
4. Be governed by an independent community-based board of directors that complies with all Section 330-related size, composition, and selection requirements and maintains and autonomously exercises all authorities and responsibilities required of an FQHC governing board.

Organizational Requirements

FQHC organizational requirements are set forth in various sources, most notably Section 330 of the Public Health Service Act,²⁰ the DHHS FQHC implementing regulations,²¹ and [HRSA PIN 98-23: Health Center Program Expectations](#).

Medically Underserved Area / Medically Underserved Population

An organization must serve a federally-designated Medically Underserved Area (MUA) or Medically Underserved Population (MUP) to qualify as an FQHC. MUAs and MUPs are federal designations made by HRSA for defined geographic areas/ population groups with insufficient health resources.

Scope of Services

FQHCs are required to provide, either directly or through an established arrangement, health services related to family medicine, internal medicine, pediatrics, obstetrics and gynecology, diagnostic laboratory and radiological services, pharmaceutical services as appropriate, and defined preventive health services.²²

FQHCs are also required to provide (among other things):²³

- Patient case management services;

¹⁹ Throughout the guide, the terms "affiliation," "collaboration," and "partnership" may be used interchangeably to indicate collaborative models of providing care; the use of one term over the other does not reflect a particular legal structure.

²⁰ 42 U.S.C. 254b.

²¹ 42 C.F.R. § 51c.

²² For the complete list of required services, see 42 U.S.C. 254b(b)(1)(A).

²³ 42 U.S.C. 254b(2)(b)(1)(A).

- Services that “enable” patients to utilize the FQHC’s medical services, including outreach and transportation services; and
- Education of patients and the general population served by the FQHC regarding the availability and proper use of health services.

According to *HRSA PIN 2009-02: Specialty Services and Health Centers’ Scope of Project*, health services related to mental health and substance abuse treatment are considered by HRSA to be “primary health care services” and are included among the health services that FQHCs are required to provide directly or through contracts or established arrangements under Section 330.²⁴

FQHCs may also provide “additional health services” that are not included as required primary health services, yet are appropriate to meet the health needs of the population served by the FQHC.²⁵

FQHCs may include specialty services in their scope of project, upon approval by HRSA, if they can demonstrate that the service is a logical extension of or related to the primary care services provided and that there is a need for the service among the FQHC’s patients. For example, if an FQHC has a large diabetic population, services such as ophthalmology, podiatry, and endocrinology may be necessary components of treatment plans and, thus, extensions of or related to the primary care furnished to this population.

All of an FQHC’s patients must have “reasonable access” to the FQHC’s full scope of services, either directly or through formal established arrangements. Therefore, the FQHC does not have to make its full scope of services available at each of its sites, provided that all patients can reasonably access all services offered by the FQHC, either at the FQHC’s other site(s) or through an established formal arrangement (e.g., referral) with another provider.

There is no formula for determining “reasonable access.” To assess if access is reasonable, it is recommended that FQHCs evaluate the distance between sites and transportation barriers. As described in the *Scope of Project* section beginning on page 23 of this guide, this requirement must be carefully considered if an FQHC seeks to add a new site and/or service to its scope of project.

Schedule of Charges and Discounts

FQHCs must serve all residents of their respective service area, regardless of an individual’s or family’s ability to pay.

With respect to reimbursement for such services, FQHCs must have a schedule of charges consistent with locally prevailing rates and designed to cover the FQHC’s reasonable costs of operation. FQHCs also must provide discounts based on ability to pay.²⁶ Specifically, FQHCs must:

- Charge patients whose annual income is above 200% of the Federal Poverty Level and third-party payors without applying any discounts; and
- Apply discounts based on ability to pay for uninsured and underinsured patients whose annual income is above 100% and at or below 200% of the Federal Poverty Level.

FQHCs may collect, at most, a nominal fee from uninsured and underinsured patients whose annual income is at or below 100% of the Federal Poverty Level.²⁷

²⁴ HRSA PIN 2009-02: *Specialty Services and Health Centers’ Scope of Project*, p. 5 available at <http://bphc.hrsa.gov/policy/pin0902/default.htm>.

²⁵ Health Care for the Homeless grantees are required to provide substance abuse services (42 U.S.C. § 254b (h)(2)).

²⁶ 42 U.S.C. § 254b(k)(3)(G)(i); see also 42 C.F.R. § 51c.303(f).

²⁷ 42 U.S.C. § 254b(k)(3)(G)(i); see also 42 C.F.R. § 51c.303(f).

Section 330 also requires FQHCs to assure that no patient will be denied health care services due to an individual's inability to pay for such services and that any fees or payments required by the FQHC for such services will be reduced or waived to enable the FQHC to fulfill the assurance."²⁸

FQHCs must apply their fee schedules and corresponding schedules of discounts to all patients, for all services provided within its scope of project. For example, an FQHC is prohibited from providing LHD patients with free care, unless such individuals qualify for a full discount based on their income level.

Procurement Requirements and Standards

FQHCs that are Section 330 grantees must comply with the federal procurement requirements and standards regarding the purchase of goods and services using federal grant funds.²⁹ The purpose of the federal procurement requirements and standards is to ensure that goods and services are obtained in an effective and efficient manner. In general, the procurement requirements and standards contain provisions requiring FQHCs to: (1) establish and maintain written standards of conduct for all employees, contractors, agents, and directors, including a conflict of interest provision; (2) provide for, and maximize, open and free competition; (3) establish and maintain written procurement procedures; (4) maintain procurement records; and (5) maintain a contract administration system to ensure conformance with the terms and conditions of the contract, including procedures to monitor and oversee a contractor's performance.

The federal procurement requirements and standards, as well as the FQHC's applicable policies and procedures, must be reviewed closely if, as part of a partnership with an LHD, the FQHC purchases goods and/or services.

Governing Board Requirements

A core component of the FQHC model is the community-based governing board. Section 330, its implementing regulations, and guidance require the following:

*Board Composition*³⁰

- The board size should be between 9 – 25 members.
- At a minimum, a majority of the board members must be active consumers of the FQHC's services (i.e., persons who utilize the FQHC as their principal source of primary care and have done so within the last two years) who collectively represent the individuals being served by the FQHC in terms of various demographic factors, such as economic status, race, ethnicity, and gender.
- The remaining non-consumer board members must be representative of the FQHC's community, and should be selected for their expertise in various fields.
- No more than one-half of the non-consumer board members may be individuals who derive more than ten percent of their annual income from the health care industry.
- No member of the board of directors may be an employee of the FQHC or an immediate family member of an employee (i.e., spouse, child, parent, or sibling), by blood, marriage, or adoption.

²⁸ 42 U.S.C. § 254b(k)(3)(G)(iii).

²⁹ 45 C.F.R. Part 74 (or Part 92 if the entity is a public health center). For more information regarding key FQHC contract issues, see NACHC Issue Brief, Risk Management Series #2: *Key Contract Issues Facing Health Centers*, November 2002 available at http://iweb.nachc.com/Purchase/ProductDetail.aspx?Product_code=RM_2_02.

³⁰ 42 C.F.R. § 51c.304.

FQHC Board Responsibilities and Authorities

The FQHC board must exercise the following authorities:³¹

- Directly employ and approve the selection, annual evaluation and dismissal of the Executive Director/Chief Executive Officer.
- Prepare and approve the annual budget and project plan, including the annual Section 330 grant application or FQHC look-alike certification/application.
- Adopt and, as necessary, update financial management practices, personnel policies and procedures, and health care policies and procedures.
- Evaluate the FQHC’s activities.
- Establish and maintain collaborative relationships with other health care providers and social agencies in the relevant service area.
- Maintain a commitment to provide services to the medically underserved populations(s) served by the FQHC.
- Evaluate itself for compliance with Section 330 requirements.
- Assure that the FQHC is operated in compliance with applicable federal, state and local laws, regulations, and policies.

For more information regarding public health center co-applicant board authorities, see page 15.

Role of the FQHC Board in Implementing FQHC-LHD Partnerships

It is critical that an FQHC’s board of directors is involved in key decisions about LHD partnerships. This is particularly relevant if a partnership involves establishing a new site and/or the expansion of services.

In evaluating potential FQHC-LHD partnerships, FQHC board members should ask the following questions:

- Is the partnership with the LHD consistent with the FQHC’s mission?
- Is the partnership with the LHD financially viable or would it jeopardize the financial stability of the FQHC and/or its ability to provide the full continuum of required primary care, preventive, and enabling services?
- Is prior regulatory approval necessary to establish the proposed partnership with the LHD?

In all circumstances, the board of directors must approve changes in an FQHC’s clinical, fiscal, and quality assurance or quality improvement policies and procedures; the scope of services; and the site locations and hours of operation.

Participation in the FQHC’s Board of Directors: Benefits and Limitations

An FQHC and LHD may collectively decide that it would benefit the partnership to allow the LHD to nominate a representative to serve on the FQHC’s board of directors. It is essential that FQHCs and LHDs consider the following HRSA restrictions regarding board member selection and removal in such situations where another organization (i.e., the LHD) is granted representation on the FQHC’s governing board, or some other level of involvement in an FQHC’s governance.³²

In particular, HRSA policies establish that individuals that are representatives of another organization may not comprise a majority of the FQHC board members, a majority of the non-consumer

³¹ 42 C.F.R. § 51c.304.

³² HRSA PIN 97-27: *Affiliation Agreements of Community and Migrant Health Centers*, p. 13 available at <http://bphc.hrsa.gov/policy/pin9727.htm> and HRSA PIN 98-24: *Amendment to PIN 97-27 Regarding Affiliation Agreements of Community and Migrant Health Centers* available at <http://bphc.hrsa.gov/policy/pin9824.htm>.

members, or a majority of members of the Executive Committee, and may not serve as the Board Chairperson. In addition, no other organization may preclude the selection, or require the dismissal, of board members it has not appointed.

With respect to the board's authorities, as described on the previous page, no other organization may:

- have overriding approval authority,
- have veto authority (through "super-majority" requirement or other means), and/or
- have "dual majority" authority.

3. Cost-Based Reimbursement, Federal Tort Claims Act, Section 340B Drug Pricing, and Anti-Kickback Safe Harbor Protection

Participation in the FQHC program provides numerous benefits that may support FQHC-LHD partnerships. The four most notable include access to the following:

1. Cost-related reimbursement for services provided to Medicare, Medicaid, and Children's Health Insurance Program (CHIP) beneficiaries;
2. Coverage for the FQHC and its providers under the Federal Tort Claims Act (FTCA);
3. Discount drug pricing under Section 340B of the Public Health Service Act; and
4. Federal Anti-Kickback statute protection under the safe harbor for FQHC grantees.

Some benefits, such as FTCA coverage and the Anti-Kickback statute FQHC safe harbor protection, are only available to FQHCs that receive Section 330 funding. Other benefits, such as cost-related reimbursement and Section 340B drug pricing, are available to FQHCs that receive Section 330 funding and to FQHC look-alikes.

Take special note that the FQHC benefits are *only available* when services are provided by the FQHC within its scope of project (i.e., the FQHC is the billing provider, services are provided on behalf of the FQHC, services are provided to FQHC patients, etc.). (Scope of project is described more in depth beginning on page 23.)

Both FQHCs and LHDs should consider these benefits when evaluating partnership opportunities, with an eye towards reducing costs and increasing access to services across the entire community health care system.

Cost-Related Reimbursement

In recognition of the support and enabling services provided by FQHCs for which they do not get separately reimbursed and to ensure that they don't have to use Section 330 funds for patients without a payor source (e.g., Medicare and Medicaid), FQHC grantees and look-alikes have access to reimbursement for Medicare, Medicaid, and CHIP services through (1) the prospective payment system or an alternative, state-approved payment methodology, which, for Medicaid and CHIP services, is predicated on a cost-based reimbursement methodology; and (2) cost-based reimbursement for Medicare services.³³ This means that, for the most part, FQHCs will receive a higher rate of reimbursement from Medicaid, Medicare, and CHIP than most other health care entities do for similar services.

³³ According to the health reform law, Medicare reimbursement will transition to a prospective payment system in 2014. Section 10501 of Patient Protection and Affordable Care Act of 2010.

Federal Tort Claims Act Coverage (FTCA)

FTCA provides professional liability and medical malpractice coverage for services provided by an FQHC within its scope of project.³⁴ To be eligible for FTCA coverage, an FQHC must receive funds under Section 330 and be deemed eligible for coverage. Once deemed under FTCA, the FQHC, its officers, directors, employees, and eligible contractors are considered federal employees immune from suit for medical malpractice claims while acting within the scope of their employment and providing services within the HRSA-approved scope of project. If an FQHC patient decides to bring a malpractice lawsuit against the FQHC, its employee, covered contractor, etc., the patient cannot sue the FQHC or the provider directly, but must file the claim against the United States. Such claims are reviewed and/or litigated by the DHHS, Office of the General Counsel and the Department of Justice.

FTCA is specifically *only* available for:

- The deemed FQHC (as well as its directors and officers);
- FQHC employees that provide services on a full-time or part-time basis;
- Individually contracted providers who furnish services in the fields of general internal medicine, family practice, general pediatrics, and obstetrics and gynecology, regardless of the number of hours worked; and
- Individually contracted providers who furnish services in other fields of practice, so long as they provide such services to FQHC patients for an annual average of 32 ½ hours a week (i.e., on a full-time basis).

As such, FTCA coverage is available only to the FQHC and to the employees/contractors listed above; it cannot be extended to an LHD or its em-

FTCA Checklist

FQHCs must respond “yes” to all of the following questions to assure that FTCA coverage is available for services provided by the FQHC providers under the FQHC-LHD partnership. Satisfying these questions does not, however, guarantee FTCA coverage. FQHCs are encouraged to consult with HRSA to confirm FTCA coverage.

- Does the FQHC receive Section 330 funding?
- Is the FQHC deemed eligible for FTCA coverage?
- Are the services provided on behalf of the FQHC and included within the FQHC’s approved scope of project?
- Is the site where services are provided included within the FQHC’s approved scope of project (or does the site meet a defined exception for non-FQHC facilities)?
- Does the individual qualify as an FQHC patient and is he or she appropriately registered?
- Are the providers FQHC employees, OR, if the providers are contractors to the FQHC, is the contractual agreement directly between the FQHC and the individual health professional providing services to the FQHC’s patients, and does the contracted provider meet the hour requirements described above?
- Are the services provided included within the provider’s scope of employment/contract?
- Is the FQHC responsible for billing the payor for the FQHC’s services provided to the patients?

³⁴ Extensive discussion of the legal basis for FQHC FTCA coverage as well as the legal requirements and limitations to such coverage, can be found in HRSA PIN 99-08; HRSA PAL 99-15; HRSA PIN 2001-11; HRSA PIN 2002-23; HRSA PIN 2005-01; and HRSA PIN 2007-16 available at <http://bphc.hrsa.gov/policy/default.htm>. HRSA plans to release an FTCA Policy Manual, which will provide all FTCA related PINS and PALS in one easy reference. See also HRSA PIN 2008-01: *Defining Scope of Project and Policy for Requesting Changes* available at <http://bphc.hrsa.gov/policy/pin0801/>.

employees (unless they are individually contracted to the FQHC and satisfy the above criteria). In addition, with certain limited exceptions, FTCA only covers services provided to the FQHC’s patients served at a site within the FQHC’s scope of project, as described on pages 23–25.

Discount Drug Pricing Under Section 340B of the Public Health Service Act³⁵

FQHC grantees and look-alikes are eligible to participate in the discount drug pricing program under Section 340B of the Public Health Service Act. Section 340B drugs may be distributed either directly by an FQHC pharmacy or through contract with a retail pharmacy.³⁶

Drugs purchased under the Section 340B program may be dispensed only to the FQHC’s patients. As such, the FQHC cannot supply 340B drugs to individuals who are not registered FQHC patients.³⁷ An individual is not a “patient” for Section 340B purposes if he or she only receives services related to the dispensing of a drug or drugs for subsequent self-administration or administration in the home. In other words, a relationship based solely on case management is insufficient to establish the individual as an FQHC patient.

An FQHC’s ability to purchase drugs at discounted prices provides the FQHC with an effective means to lower drug prices for its uninsured patients and to provide better health care for its patients. The savings is particularly important to consider when structuring partnerships with LHDs given the significant health care needs among individuals that seek care at LHDs. (For more information regarding the availability of Section 340B drugs in the context of a referral arrangement between an FQHC and LHD, see page 44.)

340B Drug Pricing Checklist

FQHCs must respond “yes” to all of the following questions to assure that Section 340B drug pricing is available under the FQHC-LHD partnership. As with FTCA, satisfying these questions does not guarantee access to Section 340B drug pricing. To confirm access to Section 340B drug pricing, FQHCs are encouraged to register and consult with the Office of Pharmacy Affairs at HRSA.

- Does the individual qualify as an FQHC patient and is he or she appropriately registered?
- Is the FQHC responsible for ordering and purchasing the drugs?
- Can the FQHC, at a minimum, break-even from a reimbursement perspective?
- Can the FQHC establish a tracking system (or an alternative system approved by the Office of Pharmacy Affairs) to ensure that the drugs purchased under the Section 340B program are not resold, transferred, or diverted to non-FQHC patients?

³⁵ Section 340B of the Public Health Service Act (42 U.S.C. 256b), as amended by Section 602 of P.L. 102-585 (11/11/92).

³⁶ Note that federal law precludes a contract pharmacy from dispensing 340B drugs to Medicaid patients unless that pharmacy has made arrangements with the state Medicaid agency that will enable the state to avoid seeking a rebate from a manufacturer for a drug purchased under 340B.

³⁷ According to Section 340B, an individual currently qualifies as a “patient” when the following requirements are satisfied: (See 61 Fed. Reg. 55156 (October 24, 1996): (1) the FQHC has established a relationship with the individual and maintains records of the individual’s health care; (2) the individual receives health care services from a health care professional who is either employed by or provides health care under a contractual or other arrangement (e.g., referral for consultation) with the FQHC, such that the responsibility for care remains with the FQHC; and (3) the individual receives a health care service or a range of services from the FQHC consistent with the service or range of services for which the entity received FQHC status (i.e., the services are within the FQHC’s approved scope of project).

Federal Anti-Kickback Statute Protection Under the Safe Harbor for FQHC Grantees

The purpose of the federal Anti-Kickback statute is to discourage arrangements that could result in higher costs to the federal government or negatively impact the quality of care provided to beneficiaries of federal health care programs, such as the Medicaid and Medicare programs. In particular, the statute prohibits any person or entity from knowingly or willfully soliciting or receiving (or offering and paying) remuneration directly or indirectly, in cash or in kind, to induce patient referrals or the purchase or lease of equipment, goods or services, payable in whole or in part by a federal health care program.³⁸ “Remuneration” is defined broadly to include the transfer of anything of value, including reduced cost (or no cost) rent or equipment, reduced cost (or no cost) purchase of services agreements, rebates, and free goods and/or services. For example, under the Anti-Kickback statute, a private practice physician is prohibited from accepting free space from a hospital in exchange for referring patients that are enrolled in a federal health care program (e.g., Medicare, Medicaid, CHIP).

Congress and the Office of the Inspector General (“OIG”), the federal agency with legal authority to enforce the federal Anti-Kickback statute, have created “safe harbors” to exempt certain business practices from constituting violations of the federal Anti-Kickback statute.

In 2007, the OIG at DHHS established regulatory standards for an “FQHC” safe harbor.³⁹ The safe harbor protects from prosecution certain arrangements between FQHC grantees and providers/suppliers of goods, items, services, donations, and loans that contribute to the FQHC’s ability to maintain or increase the availability or enhance the quality of services provided to its medically underserved patients. For

such protection, the arrangement must be codified in a written agreement and meet several standards that are set forth in regulation.⁴⁰ For example, the FQHC must have a reasonable expectation that the arrangement will contribute meaningfully to services to the underserved, and the FQHC must periodically (at least annually) re-evaluate the arrangement to ensure that it continues to meet the original expectation.

Accordingly, it may be permissible for an FQHC to receive donations (monetary and in-kind) and/or obtain low cost (or no cost) leases and/or purchase agreements from an LHD and/or other community health care providers with which it has a referral relationship, provided that the donations, leases, agreements, etc. are part of an arrangement to maintain/increase services provided to the FQHC’s medically underserved patients, and provided that the parties execute a written agreement that satisfies the safe harbor requirements. If an FQHC seeks to enter into such an arrangement, it should consult knowledgeable local counsel for guidance.

4. Federally Qualified Health Center Scope of Project Considerations

Defining Scope of Project: Sites and Services

Scope of project defines the services, sites, providers, service area, and target population that the total approved Section 330 grant-related project supports (or, in the case of FQHC look-alikes, the services, sites, providers, service area, and target population that the FQHC designation supports).⁴¹

³⁸ 42 U.S.C. § 1320a-7b(b).

³⁹ 72 Fed Reg 56632 (October 4, 2007), as codified at 42 C.F.R. § 1001.952(w).

⁴⁰ 42 C.F.R. § 1001.952(w).

⁴¹ 41 HRSA PIN 2008-01, p. 2 available at <http://bphc.hrsa.gov/policy/pin0801/> and HRSA PIN 2009-06: *Federally Qualified Health Center Look-Alike Guidelines and Application* available at <http://bphc.hrsa.gov/policy/pin0906/>.

- **Services:** As noted on pages 16–17, Section 330 requires FQHCs to provide, either directly or through formal established arrangements, all required primary care services. FQHCs may also provide additional health services that are appropriate to meet the needs of their patients. Once a service is included in scope, it must be reasonably available to all patients and provided, regardless of an individual’s or family’s ability to pay. (Additional information on services is provided below.)
- **Sites:** A site is any place where an FQHC provides services to a defined geographic service area or population on a regularly scheduled basis. (Additional information on sites is provided below.)
- **Providers:** Providers are individual health care professionals who deliver services on behalf of the FQHC on a regularly scheduled basis and who exercise independent judgment as to the services furnished during an encounter.
- **Service Area:** The service area is the geographic area that is served by the FQHC.
- **Target Population:** The target population is the medically underserved community or special population served by the FQHC (which may be a sub-set of the service area or may include the entire service area).

An FQHC’s scope of project is important because it (among other things):

- Determines the maximum potential scope of FTCA coverage (subject to certain exceptions).
- Provides the necessary information which enables FQHCs to purchase discounted drugs through the Section 340B drug pricing program.

- Defines the services and sites eligible for cost-based reimbursement under Medicare, Medicaid, and CHIP.

What is a Health Center “Site” for Purposes of Scope of Project?

HRSA broadly defines a service site as “any location where a grantee... provides primary health care services to a defined service area or target population... as appropriate for providing health care services to the target population.”⁴²

If a location where services are provided satisfies the following four conditions, then the location should qualify as a “site” for purposes of scope of project, subject to approval by HRSA.⁴³

1. Providers generate face-to-face encounters with patients.
2. Providers exercise independent judgment in providing services.
3. Services are provided directly by or on behalf of the FQHC—the FQHC board retains control and authority over the provision of the services at the location.
4. Services are provided on a regularly scheduled basis.

It is important to note that a fully-equipped mobile van that is staffed by FQHC clinicians providing direct primary care services (e.g., primary medical or oral health services) at various locations on behalf of the FQHC is considered a service site.⁴⁴

Evaluating whether a location qualifies as a “site” is of critical importance in the context of FQHC-LHD partnerships where the FQHC seeks to provide services at a new location. If the location does not

⁴² HRSA PIN 2008-01, p. 4.

⁴³ HRSA PIN 2008-01, p. 4.

⁴⁴ HRSA PIN 2008-01, p. 6.

qualify as an FQHC site, then the FQHC may not add the location to its HRSA-approved scope of project, and it is likely that the FQHC will not be eligible to receive cost-based reimbursement, FTCA coverage, Section 340B prescription drugs, and other FQHC-related benefits.

What is an FQHC “Service” for Purposes of Scope of Project?

As described on pages 16–17, Section 330 requires FQHCs to provide, either directly or by contract or referral, certain required primary and preventive health services, as well as enabling services. FQHCs also may provide additional health services that are not required, yet are appropriate to meet the health needs of the population served by the FQHC.⁴⁵ In addition, all of an FQHC’s patients must have reasonable access to the FQHC’s full scope of services, either directly or through formal established arrangements. The FQHC does not have to make its full scope of services available at each of its sites, provided that all patients can reasonably access all services offered by the FQHC, either at the FQHC’s other site(s) or through an established formal arrangement (e.g., contract or referral) with another provider.

There is no formula for determining “reasonable access.” To assess if access is reasonable, an FQHC should evaluate the distance between the two sites and the availability of public transportation.

If an FQHC-LHD partnership includes the FQHC’s addition of a new service and/or site, the FQHC must examine whether all patients will have access to the FQHC’s full scope of services. If an FQHC does not add a new service or site, but rather adds LHD patients as FQHC patients, thereby expanding the FQHC’s patient base, the FQHC must examine whether the new patients will have access to the FQHC’s full scope of services.

Changing a Health Center’s Scope of Project

FQHCs must obtain HRSA’s prior approval before adding or removing a service, or adding, removing, or relocating a site, from its scope of project.

Failure to secure HRSA’s prior approval for the change in scope may have serious consequences, including:

- No FTCA malpractice coverage for the employed or contracted FQHC practitioners, or for the FQHC itself vis-à-vis such services/sites.
- Allegations that the FQHC diverted Section 340B drugs by providing them to individuals who are not “FQHC patients.”

In order to obtain HRSA’s approval, the “change in scope” request must:⁴⁶

- Document that the requested change can be fully accomplished with no additional federal support.⁴⁷
- Not shift resources away from providing services to the current target population.
- Further the FQHC’s mission by increasing or maintaining access and improving or maintaining quality of care for the target population.
- Be fully consistent with Section 330 and the Health Center Program Expectations (HRSA PIN 98-23), including appropriate governing board representation for changes in service sites and populations served.
- Provide for appropriate credentialing/privileging of providers.

⁴⁵ 42 U.S.C. § 254b (2) (b)(1)(A).

⁴⁶ HRSA PIN 2008-01, pp. 20-22.

⁴⁷ HRSA PIN 2008-01, p 20. An FQHC requesting to add a service or site must demonstrate that adequate revenue will be generated to cover all expenses as well as an appropriate share of overhead costs incurred by the FQHC in administering the new service or site.

- Not eliminate or reduce access to a required service.
- Not result in the diminution of the FQHC’s total level or quality of health services currently provided to the target population.
- Demonstrate that the FQHC continues to serve a medically underserved area in whole or in part, or a medically underserved population.
- Demonstrate approval by the FQHC’s board of directors.
- Not significantly affect the current operation of another FQHC located in the same or adjacent service area.

For additional information, FQHCs should review [HRSA PIN 2008-01: *Defining Scope of Project and Policy for Requesting Changes*](#), which provides comprehensive guidance regarding the process for obtaining approval for a change in scope of project.

B. Local Health Department Fundamentals

Function

Local health departments (LHDs) are the governmental public health presence at the local level, responsible for creating and maintaining conditions that keep people healthy. An LHD may be a locally governed health department, a branch of a state health department, a state-created district or region, a department governed by and serving a multi-county area, or any other arrangement that has governmental authority and is responsible for public health functions at the local level. Whether they directly provide a service, broker particular capacities, or otherwise ensure that the necessary work is being done, LHDs have a consistent responsibility to:⁴⁸

- Monitor health status and understand health issues facing the community;

- Protect people from health problems and health hazards;
- Give people information they need to make healthy choices;
- Engage the community to identify and solve health problems;
- Develop public health policies and plans;
- Enforce public health laws and regulations;
- Help people receive health services;
- Maintain a competent public health workforce; and
- Evaluate and improve programs and interventions.

LHDs understand the specific health issues confronting the community, including how physical, behavioral, environmental, social, and economic conditions affect health. They investigate health problems and health threats and prevent and control adverse health effects from communicable diseases, disease outbreaks from unsafe food and water, chronic diseases, environmental hazards, injuries, and risky health behaviors. LHDs also lead planning and response activities for public health emergencies and collaborate with other local responders and with state and federal agencies to intervene in other emergencies with public health significance (e.g., natural disasters).

In an ideal context and environment, LHDs coordinate the broader public health system’s efforts in an intentional, non-competitive, and non-duplicative manner. They implement health promotion programs

⁴⁸ The standards are framed around the Ten Essential Public Health Services, which have been reworded to more accurately reflect the specific LHD roles and responsibilities related to each category. In addition, these standards are consistent with the National Public Health Performance Standards Program (NPHPSP), serving to specify the role of governmental LHDs while the NPHPSP addresses the public health system as a whole.

and engage the community to address public health issues. They develop partnerships with public and private healthcare providers and institutions (such as FQHCs), community-based organizations, and other government agencies (e.g., housing authority, criminal justice, education) engaged in services that affect health to collectively identify, alleviate, and act on the sources of public health problems.

LHDs also address health disparities; serve as an essential resource for local governing bodies and policymakers on up-to-date public health laws and policies; and provide science-based, timely, and culturally competent health information and health alerts to the media and to the community. Likewise, LHDs provide expertise to others who treat or address issues of public health significance and ensure compliance with public health laws and ordinances, using enforcement authority when appropriate.

LHDs employ well-trained staff and ensure that they have the necessary resources to implement best practices and evidence-based programs and interventions. LHDs contribute to the evidence base of public health and strategically plan their services and activities, evaluate performance and outcomes, and make adjustments as needed to continually improve their effectiveness, enhance the community's health status, and meet the community's expectations.

All LHDs derive their authority and responsibility from the state and local laws that govern them. LHDs' legal authorities may include interventions such as mandatory isolation and quarantine or the authority to enter and inspect property, records, or equipment and require corrective actions for violations. However, there is wide variability in LHDs' capacity, authority, resources, and composition of the broader local public health system within which

they function. As a result of these differences, how LHDs meet their responsibilities—whether they directly provide a service, broker particular capacities, or otherwise ensure that the necessary work is being done—will vary.

The LHD may have the capacity to perform all of the functions on its own; it may call upon the state to provide assistance for some functions; it may develop arrangements with other organizations in the community or with neighboring LHDs to perform some functions; or it may control the means by which other entities perform some functions. In some jurisdictions, other government agencies may have the authority to perform services that affect public health, and/or resources for public health may be housed in a different agency.

LHDs can help FQHCs address critical elements of ensuring service delivery and expansion in a variety of ways, including the following:

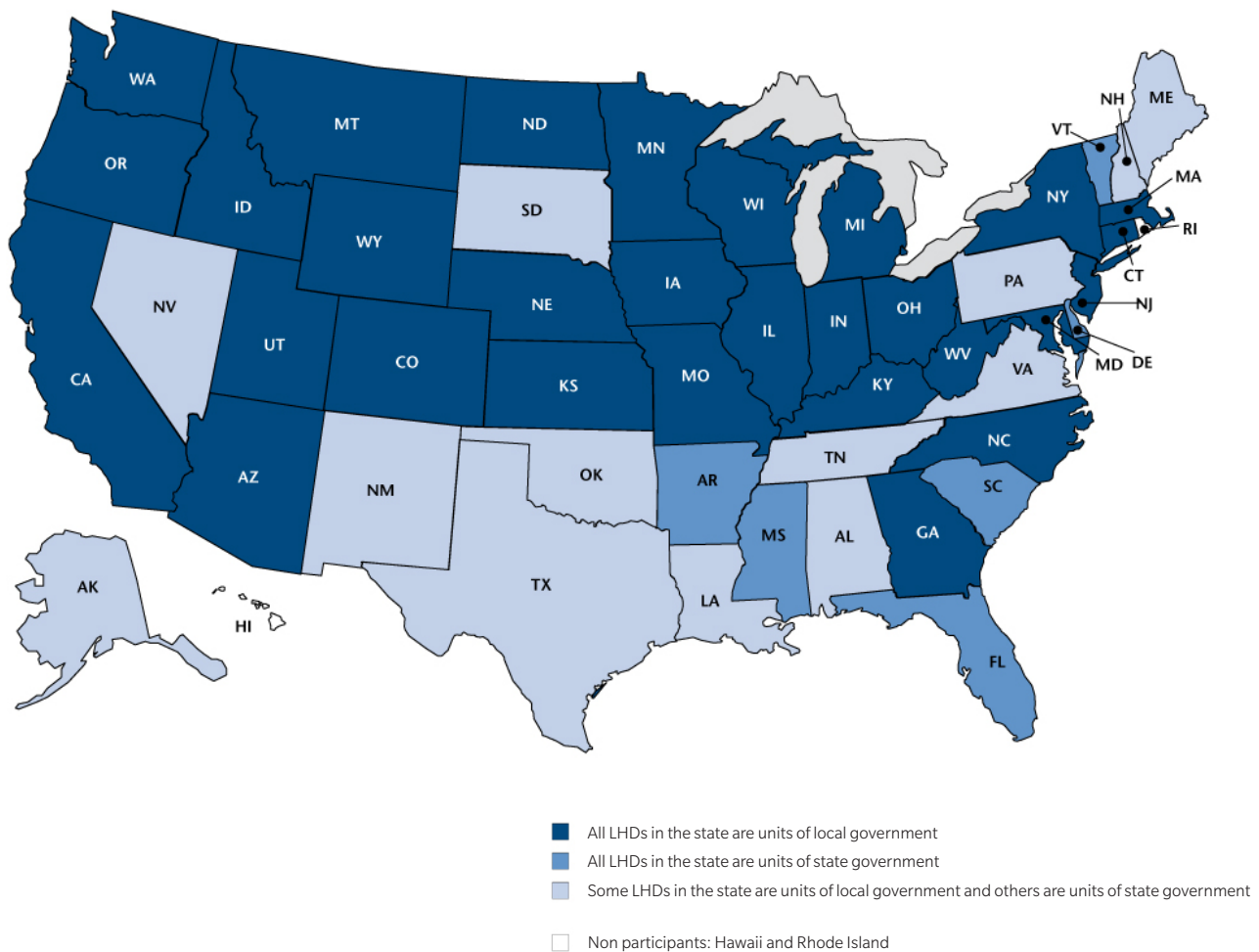
- Contributing infrastructure support;
- Helping FQHCs connect with their community;
- Collecting, providing, and coordinating community data;
- Providing a population-based perspective on local issues to inform FQHC communications;
- Convening community members, with local boards that include FQHC representatives;
- Collaborating on FQHC applications for funding;
- Identifying appropriate populations, geographic areas, and partners for collaboration;
- Using regulatory authority to address identified public health threats; and
- Enforcing public health laws and regulations.

Governance

LHDs can be governed by local authorities (e.g., local board of health, county or city elected officials), by the state health agency, or both. As shown in the map below, as of 2008, LHDs in 29 states had local governance, whereas six states and Washington, DC, had state governance, and 13 had mixed governance. In 2008, about 80 percent of all LHDs reported that they had an associated local board of health. Members of local boards of health may

be elected, appointed, or designated based on an elected or non-elected position. Local boards of health serve many functions within their communities, such as adopting public health regulations, setting and imposing fees, approving the LHD budget, hiring or firing the top agency administrator, and requesting a public health levy. In 2008, adopting public health regulations (73%) and setting and imposing fees (68%) were the two most common functions of local boards of health.

LHD Governance Type, by State

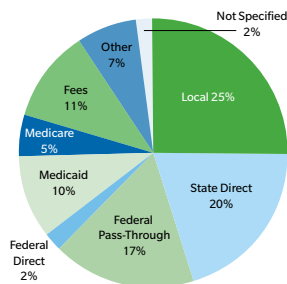


Source: 2008 National Profile of Local Health Departments

Funding

Funding for local public health activities comes from a number of sources, including local, state, and federal government; reimbursement from Medicare, Medicaid, and other insurers; regulatory fees and fees paid for patient services; and miscellaneous sources such as private foundations. In general, it can be said that LHD revenues from local, state, federal pass-through, and Medicare and Medicaid, as a percent of total revenues, vary widely by state. As reflected in the chart below, in 2008, local funds were the highest source of revenue for LHDs, comprising 25 percent of all revenues, followed by state direct (20%), and federal pass-through (17%).

Percentage Distribution of Total Annual LHD Revenues, By Revenue Source



n ranged from 1,458 to 1,629 by revenue source
 Note: Due to rounding, percentages do not add to 100.
 *Among LHDs reporting detailed revenue data.

Source: 2008 National Profile of Local Health Departments

Relationship to the State Health Department

Like LHDs, state health departments also vary widely and have varied structures, functions, governance, and funding. State health departments perform a number of the core public health functions, including the following:

- Disease tracking and investigation;
- Maintenance of birth and death records;
- Delivery of chronic disease prevention and control programs;
- Administration and tracking of immunizations;

- Conducting a wide range of laboratory services;
- Delivery of maternal and child health programs; and
- Managing state bioterrorism preparedness.

State health departments are typically funded by the federal government, state budgets through appropriations made by a state’s legislature, and, less often, by private sources, such as foundations. Federal funding can come in several forms, including: 1) formula grants, such as the Maternal and Child Health Block Grant (Title V) and the Preventive Health and Health Services Block Grant; 2) competitive grants through which departments apply for federal funds for specific initiatives on topics such as nutrition and physical activity; 3) data collection and analysis funds to gather and interpret critical health information about the populations they serve; and 4) health insurance funds to administer such programs as Medicaid and the Children’s Health Insurance Program (CHIP).

The states’ role in governing local public health varies according to the structure and responsibilities of the state health department and includes the following:

- **Centralized:** The state health department operates the LHDs, and the local department functions under the state department’s authority.
- **Decentralized:** Local governments organize and operate LHDs.
- **Shared systems:** LHDs operate under the shared authority of the state health department, the local government, and/or local boards of health.
- **Mixed systems:** LHDs provide local public health services and are organized and operated by units of local government in some jurisdictions and the state health department in other jurisdictions.

State Associations of County and City Health Officials (SACCHOs) are organizations that represent LHDs or officials at the state level. Some SACCHOs are an office in their state’s department of health and many are informal organizations that are administered by volunteers. SACCHOs often host regular meetings of local public health officials and are very involved with local public health issues at the state level. The National Association of County and City Health Officials (NACCHO) collaborates with SACCHOs on many projects, including joint meetings, membership initiatives, education and training, and national advocacy for local public health. SACCHOs also work closely with state departments of health and other state and national public health organizations.

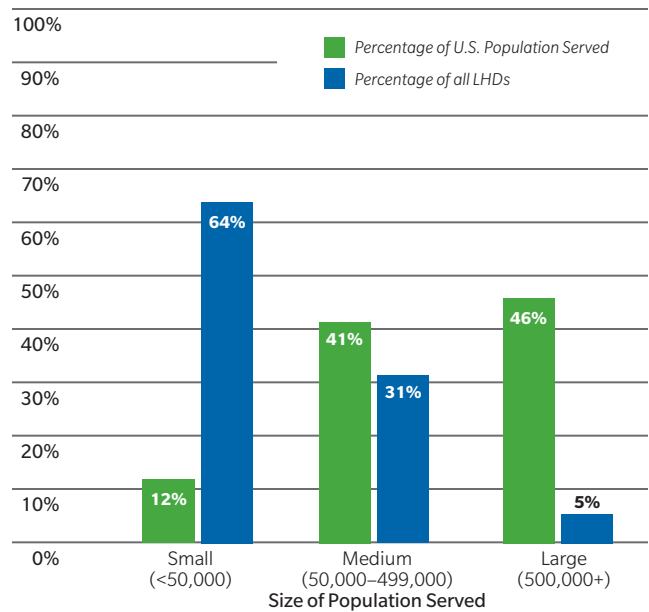
Jurisdictions

LHDs serve a variety of jurisdiction types. As of 2008, most LHDs serve individual counties (60%), while others serve combined city-county jurisdictions (11%), multi-county or other district or regional level jurisdictions (9%), towns or townships (11%), and cities (7%). Local public health capacity varies greatly among states, ranging from states with little local public health infrastructure and few resources to states that serve every county and municipality through local public health. In general, multi-county or regional health departments that have access to more resources provide a more comprehensive set of services than smaller departments. The figure on the right shows the percentage of LHDs serving small, medium and large populations as well as the percentage of U.S. population served within each category.

National Profile Study

The National Association of County and City Health Officials’ (NACCHO) National Profile of Local Health Departments study (Profile study) is the key source of information to characterize LHDs at the national level. The Profile study series collects information on a range of public health infrastructure topics from all LHDs in the United States. The most recent Profile study was conducted in 2008 and surveyed a study population that consisted of 2,794 LHDs. The purpose of the Profile study is to advance and support the development of a database to describe and understand LHDs’ structure, function, and capacities. The 2008 Profile study included an assessment of the overall structure, function, workforce and availability of public health activities and services at the local level; it also included an assessment to understand what governmental and non-governmental entities provided these services at the local level.

Percentage of LHDs and Percentage of U.S. Population Served, by Size of Population Served



n=2,794

Source: 2008 National Profile of Local Health Departments

Workforce

The workforce composition of LHDs varies greatly across jurisdictions. In 2008, most LHDs (89%) had less than 100 full-time equivalents (FTEs), about 20 percent of LHDs had less than five FTEs and only five percent had 200 or more FTEs. The total median number of FTEs ranged from three (for LHDs serving populations less than 10,000) to 585 (for LHDs serving populations of one million or more). The total median number of staff ranged from five (for LHDs serving populations less than 10,000) to 692 (for LHDs serving populations of one million or more).

Although LHD staffing varies across jurisdictions, most LHDs generally maintain a few core job functions. In 2008, more than 90 percent of LHDs employed clerical staff, nurses, and managers. Environmental health workers, emergency preparedness coordinators, health educators, and nutritionists were employed by more than 50 percent of all LHDs.

The 2008 Profile study suggests that occupations represented at LHDs vary by the size of the populations they serve. Among LHDs serving the smallest populations (less than 10,000), 85 percent employed clerical staff and 82 percent employed nurses; among LHDs serving the largest populations (1,000,000 or more), all (100%) employed staff in these categories. Environmental health specialists were employed by 54 percent of LHDs serving the smallest populations and 88 percent of LHDs serving the largest populations. About one fourth of the LHDs serving populations of less than 10,000 employed health educators

and nutritionists, whereas almost all LHDs (97%) serving populations of one million or more reported employment of health educators and 88 percent reported employment of nutritionists.

As of 2008, for all LHDs, the median number of FTEs was 15, which generally included five nurses, four clerical staff, one manager, one environmental health specialist, and one health educator on staff. As size of the population served increased, LHDs tended to have more occupations represented in staffing patterns, with one emergency preparedness coordinator and at least one nutritionist at LHDs serving 50,000 or more, and at least one physician at LHDs serving 100,000 or more. The two tables that follow provide detailed information about the workforce of LHDs by size of population served.

Mean and Median Number of Employees and FTEs at LHDs, by Size of Population Served

Size Population Served	Number of Employees		Number of FTEs	
	Mean	Median	Mean	Median
<10,000	8	5	5	3
10,000–24,999	16	10	13	8
25,000–49,999	26	18	22	15
50,000–99,999	50	35	42	31
100,000–249,999	90	74	80	66
250,000–499,999	185	160	168	147
500,000–999,999	494	331	430	305
1,000,000+	1,080	692	994	585
All LHDs	66	18	58	15

n=2,234 n=2,205

Source: 2008 National Profile of Local Health Departments

Median FTEs and Staffing Patterns for LHDs, by Size of Population Served

Serving 10,000–24,999	Serving 50,000–99,999	Serving 100,000–499,999
8 FTEs, including:	31 FTEs, including:	81 FTEs, including:
1 Manager/Director	1 Manager/Director	5 Managers/Directors
3 Nurses	8 Nurses	17 Nurses
2 Clerical Staff	7 Clerical Staff	18 Clerical Staff
1 EH Specialist	3 EH Specialists	9 EH Specialists
	1 Nutritionist	3 Nutritionists
	1 Health Educator	2 Health Educators
	1 EP Coordinator	1 EP Coordinator
		1 Physician
		1 Epidemiologist
		1 IS Specialist
		1 BH Professional

n ranged from 1,794 to 1,992 based on occupation
 Note: Numbers do not add to totals because listed occupational categories were not exhaustive of all LHD occupations.

Source: 2008 National Profile of Local Health Departments

Services

Services provided by LHDs vary broadly by jurisdiction and population served. These services include but are not limited to immunization services; screening for diseases and conditions; treatment for communicable diseases; maternal and child health services; primary care and other health services; population-based primary prevention services; surveillance and epidemiology; environmental health; regulation, inspection, and licensing; and other activities. The table on the right presents the 10 activities and services provided most frequently in LHD jurisdictions by LHDs.

LHDs engage in a number of activities and provide services that contribute directly and indirectly to the provision of primary care services. While they do not necessarily need to provide primary care services, they do need to assure that the health needs of the community are being met and that vulnerable populations, in particular, have access to high-quality care. The LHD may have the capacity to provide all of these services on its own or may

Percentage of LHD Jurisdictions with 10 Most Frequent Activities and Services Available Through LHDs Directly

Rank	Activity or Service	Percentage of Jurisdictions
1	Adult Immunizations Provision	88%
2	Communicable/Infectious Disease Surveillance	88%
3	Child Immunizations Provision	86%
4	Tuberculosis Screening	81%
5	Food Service Establishment Inspection	77%
6	Environmental Health Surveillance	75%
7	Food Safety Education	74%
8	Tuberculosis Treatment	72%
9	Tobacco Use Prevention	70%
10	Schools/Daycare Center Inspection	68%

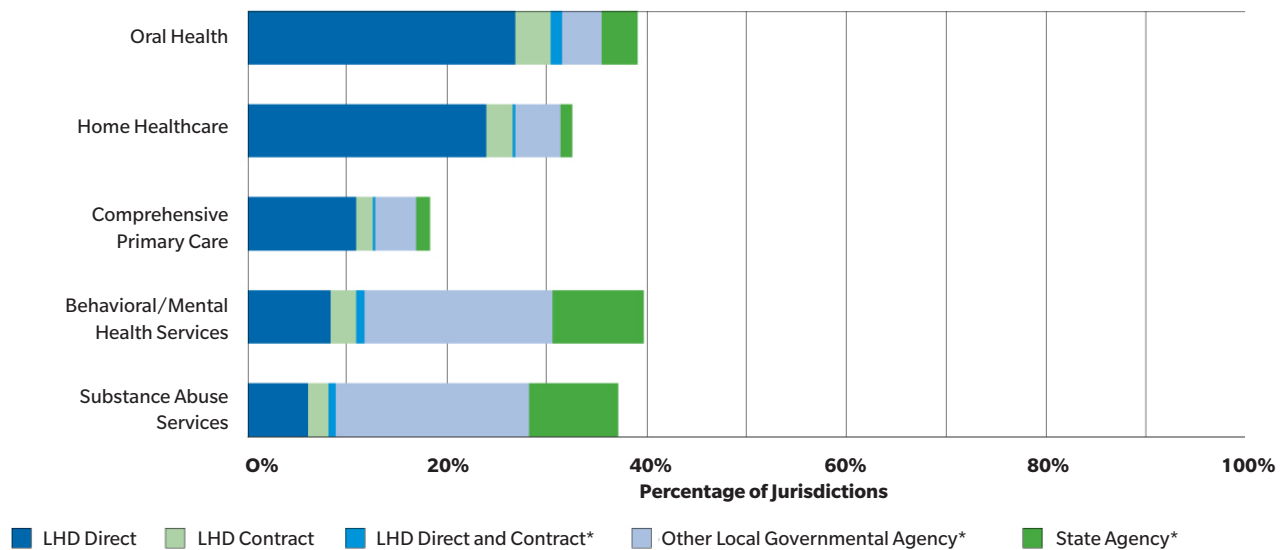
Source: 2008 National Profile of Local Health Departments

develop arrangements with other organizations in the community (such as FQHCs), with neighboring LHDs, or with the state to perform some services.

In 2008, LHDs varied in their capacity to provide personal care and primary preventative services and often provided these services through arrangements with other governmental agencies, including the state. These services include oral health, home healthcare, comprehensive primary care, behavioral/mental health services, and substance abuse services. For oral health, home healthcare,

and comprehensive primary care, the LHD was the governmental agency most likely to provide these services; for behavioral/mental health services and substance abuse services, other local governmental agencies were most likely to provide these services. The first graph that follows shows the percentage of LHD jurisdictions in which primary care and other health services were provided and by which governmental agency. The second graph shows the percentage of LHDs providing each service by the size of the population served.

Percentage of LHD Jurisdictions with Other Health Services Provided by Governmental Agencies



*Provided by other agency only, not LHD. Selected agency combinations only; does not include all possible combinations.

Source: 2008 National Profile of Local Health Departments

Percentage of LHDs Providing Other Health Services, by Size of Population Served

Service	All LHDs	<25,000	25,000–49,999	50,000–99,999	100,000–499,999	500,000+
Oral Health	29%	20%	24%	33%	43%	57%
Home Healthcare	25%	28%	25%	26%	18%	11%
Comprehensive Primary Care	11%	7%	9%	16%	16%	25%
Behavioral/Mental Health Services	9%	5%	9%	12%	13%	27%
Substance Abuse Services	7%	4%	7%	8%	9%	24%

Source: 2008 National Profile of Local Health Departments

Other health care services that most LHDs provided in 2008 were Maternal and Child Health (MCH) home visits (63%), Women, Infants and Children (WIC) services (62%), and family planning services (54%). Early Periodic Screening, Diagnosis, and Treatment (EPSDT) program services were offered by 44 percent of LHDs. In addition, LHDs also provided Well Child Clinics (41%), prenatal care (33%), and obstetrical care (10%).

In 2008, primary prevention services for tobacco, nutrition, chronic disease, unintended pregnancies, and physical activity were found in more than 80 percent of local jurisdictions. However, LHDs reported that primary prevention services were most frequently provided by non-governmental organizations. LHD activity in the area of primary preven-

tion services is described in the first table below. The percentage of LHDs offering population-based primary prevention services ranged from 70 percent (tobacco use primary prevention) to 12 percent (primary prevention of mental illness).

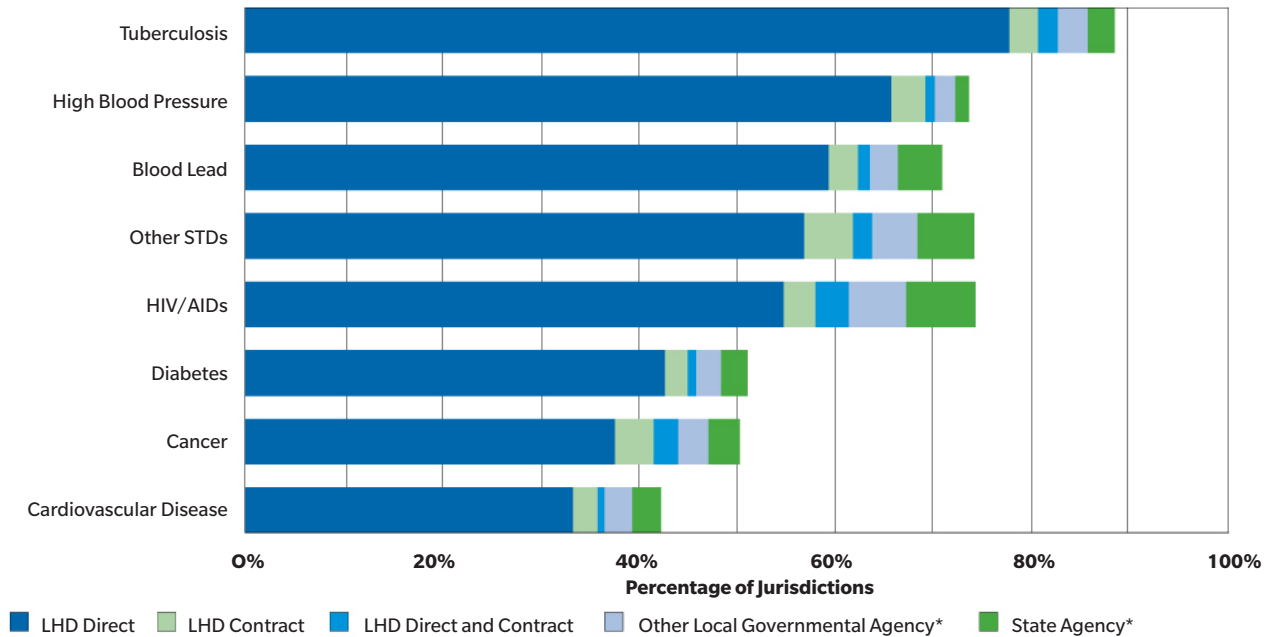
In 2008, governmental agencies provided screening in more than 70 percent of LHD jurisdictions for tuberculosis, high blood pressure, blood lead, HIV/AIDS, and other STDs. For all of these selected diseases and conditions, the LHD was the most often cited governmental agency that providing screening services. The second graph that follows exhibits the percentage of LHD jurisdictions with screening services for select diseases and conditions provided by governmental agencies, including LHDs.

Percentage of LHD Jurisdictions with Selected Population-Based Primary Prevention Services Provided by LHDs, by Size of Population Served

Primary Prevention Service	All LHDs	<25,000	25,000–49,999	50,000–99,999	100,000–499,999	500,000+
Tobacco	70%	63%	73%	75%	75%	84%
Nutrition	68%	58%	68%	73%	81%	85%
Chronic Disease Programs	53%	44%	57%	58%	62%	79%
Physical Activity	53%	45%	55%	57%	63%	73%
Unintended Pregnancy	51%	44%	53%	53%	60%	71%
Injury	39%	33%	38%	43%	49%	62%
Substance Abuse	24%	21%	25%	28%	24%	33%
Violence	22%	18%	22%	24%	28%	44%
Mental Illness	12%	10%	11%	15%	13%	20%

Source: 2008 National Profile of Local Health Departments

Percentage of LHD Jurisdictions with Screening for Selected Diseases and Conditions Provided by Governmental Agencies



*Provided by other agency only, not LHD. Selected agency combinations only; does not include all possible combinations.

Source: 2008 National Profile of Local Health Departments

The Role of LHDs in Community Health Assessments

FQHCs seeking to conduct a community health assessment should look to their LHD as a key partner with unique skills, capacities, and perspectives in population health.

As part of their charge to monitor health status to identify and address community health problems, LHDs often conduct or partner with other organizations to conduct community health assessments (CHAs). Nearly two thirds of LHDs have either conducted a CHA in the past year or plan to do so in the next three years.

In 2011, the Voluntary National Accreditation of Local Health Departments Program will provide an additional incentive for conducting CHAs. A condition for LHD accreditation will be participation in or conduct of a CHA that will inform additional requirements for the development of a community health improvement plan (CHIP) and a department strategic plan.

There are many frameworks, models, and tools for CHAs that can be used independently or in conjunction with one another, including the following:

- Mobilizing for Action Through Planning and Partnerships (MAPP);
- Planned Approach to Community Health (PATCH);
- Assessment Protocol for Excellence in Public Health (APEX PH);
- Protocol for Assessing Community Excellence in Environmental Health (PACE-EH); and
- National Public Health Performance Standards Program (NPHPSP).

Types of Data LHDs Collect and/or Compile

FQHCs should consider LHDs a resource for community health data.

In 2008, 88 percent of LHDs in the U.S. reported conducting communicable/infectious disease surveillance while 75 percent reported conducting environmental health surveillance (NACCHO, 2009). LHDs may be responsible for collecting this data for the community either on their own or with partners in the community. For example, in many states, those communicable diseases that are reportable by law are reported to LHDs who then compile, analyze, and report this data to state health departments or federal public health agencies as required. Other environmental health data, such as elevated blood lead levels in children or cases of food borne illness, are collected and analyzed regularly by LHDs.

The types of data each LHD collects, analyzes, and reports may differ significantly based on the public health laws of the state in which the LHD resides, the LHD's capacity, and by what other community health partners, including the state health department, are doing. Types of data include the following:

- Demographic characteristics (e.g., population size, population distribution by age, income, gender, race/ethnicity);
- Socioeconomic characteristics (e.g., median income of the population);
- Health resource availability (e.g., ratio of types of health care providers per capita, number of hospitals);
- Morbidity data (e.g., infectious/communicable disease data or injury data);
- Mortality data (e.g., death rate, primary causes of death);
- Maternal and child health (e.g., birth rate, infant mortality rate, percent of preterm births);
- Behavioral risk data (e.g., adult smoking rate, health care coverage, physical activity rates, adherence to preventive screening guidelines); and
- Social data (e.g., crime rates, education data [high school dropout rate]).

In other cases, LHDs may compile this data from other sources and use it in their own strategic planning or to develop a community health improvement plan (CHIP) for their community. In either case, most LHDs have access to a variety of public health data not necessarily available elsewhere.

3 | The Planning Process: Laying the Foundation for a Successful Partnership

“If we are together, nothing is impossible.” —Winston Churchill

Developing FQHC-LHD partnerships requires extensive coordination, shared knowledge, open and clear lines of communication, the commitment of both parties, and the establishment of a shared vision.

A. Essentials of a Successful Partnership

As stated previously, FQHC and LHD partnerships are essential to improve quality, conserve resources, and establish a health care medical home. In addition, establishing a partnership helps position both FQHCs and LHDs to apply for funding opportunities that may arise under the health reform law.

The building blocks to develop a productive and ongoing partnership include the following key elements:

- A knowledgeable and committed stakeholder group;
- Establishment of trust;
- Understanding of each organization’s strengths and limitations;
- Establishment of a clear objective;
- Understanding of the health care needs and trends within the community; and
- Commitment to serve the community’s vulnerable populations.

Collaboration: a mutually beneficial and well-defined relationship entered into by two or more organizations to achieve common goals.

—Amherst H. Wilder Foundation

Establishing a Partnership

To establish an orderly planning process to identify, evaluate, and implement a partnership model, as well as to avoid having negotiations break down because of “deal-breakers” that could have been resolved if identified and discussed early in the partnership process, the FQHC and LHD are advised to develop and execute a non-binding agreement, which is often referred to as a “Memorandum of Agreement.” Although the document is not legally binding, it is often more effective than simply implementing a handshake agreement to collaborate.

Key topics that may be addressed in the Memorandum of Agreement include, but are not limited to, the following:

- Proposed scope of joint activities;
- Timeline for evaluating and implementing the partnership;
- Management and staff members that will be involved in the planning process (i.e., the planning “team”);
- Consultants (if any) to be hired, by which party and at whose expense;
- Requirements that the parties will agree on any publicity and/or third party disclosure regarding the collaboration;
- Requirements for disclosure to one another of other pertinent negotiations; and
- The parties’ expectations—financial and otherwise.

To the extent feasible, all commitments should be mutual, and must be compliant with applicable laws and regulations, including, but not limited to, Section 330, its implementing regulations, and related policies.

Note: Even if FQHCs and LHDs are not currently interested in establishing a partnership, they may nevertheless wish to establish a process to ensure that there is ongoing and open communication between the organizations. For example, both the FQHC and LHD may designate an individual to meet collectively on a monthly basis to discuss changes in operations, recent health trends in the community, funding opportunities, and any other applicable topic.

Questions to Guide the Planning Process

FQHCs and LHDs may wish to review the following questions from Himmelman (1996) to aid with the planning process:⁴⁹

- Who should be involved in the partnership?
- What is the shared vision that motivates the collaboration?
- What expectations does each of the organizations have for one another?
- What is the mission statement for the partnership? What are the short and long term goals and objectives?
- What skills and resources can each partner contribute?
- How will work get done to meet goals and objectives?
- Who will administer and manage the partnership? Who will make key decisions?
- What sources of funding are required? What additional sources of funding may be available?

⁴⁹ Himmelman, A.T. 1996. "On the Theory and Practice of Transformational Collaboration: From Social Service to Social Justice." In *Creating Collaborative Advantage*, C. Huxham, ed., pp. 16–43. London, England: Sage Publications, Ltd.

Confidentiality Agreement

If the FQHC and LHD are sharing information during the process of identifying and evaluating partnership opportunities, they should implement a Confidentiality Agreement to protect the unauthorized disclosure and use of confidential and/or proprietary information that may be exchanged during the planning and negotiation process. The agreement should identify and broadly define the confidential information to be protected by the agreement, as well as what kind of information is not considered "confidential," and should address the return of such information (and all copies) when the planning process ends.

Building Trust: Identify the purpose for gathering, assign and clarify expectations, establish a reasonable timeframe, let every voice be heard, embrace diversity and creative ideas, and craft working agreements.

Getting to Know Your Neighbor

Members from both the FQHC and LHD can organize a retreat or social activity shortly after solidifying the partnership. Engaging in such activity allows each entity to get to know one another, enables open and stronger lines of communication, and allows for an understanding of the organizational makeup of each entity. It may also benefit the partnership to plan such activities even after the partnership has existed for a period of time, in order to reaffirm the relationship, introduce new faces, and strengthen bonds.

B. Health Information Exchange and Patient Privacy Considerations

Within an FQHC and LHD partnership, there will be opportunity and necessity for health information exchange to help formulate the objectives and

activities of the collaboration; to inform community needs assessments, services, and programming; to demonstrate value to funders and evaluators; to advocate for new or improved policies and regulations; and to ultimately ensure the health and safety of the community. In a new collaborative system, FQHCs and LHDs may want to consider sharing population-based information on the following:

- Immunizations;
- Screenings;
- Disease management;
- Surveillance;
- Patient self-management;
- Measurement of clinical performance;
- Measurement of service performance;
- Measurement of patient access and communication;
- Population/community health assessments; and
- Contextual information such as indicators of the determinants of health.

This information should be shared using established standards, where possible.

FQHCs and LHDs are rich with patient medical data, but are bound to protect the privacy of patients under both state and federal law. Thus, although this data may be useful to share between the two organizations, it is critical to take appropriate steps to ensure that any exchange of protected information is in compliance with applicable privacy laws.

What information is protected under the federal privacy rules?

The Privacy Rule under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) establishes a foundation of federal protections for the privacy of individually-identifiable health information (a.k.a. “protected health information” (PHI)) that is

This guide provides a brief overview of federal law and regulation regarding privacy and confidentiality requirements. Privacy and confidentiality requirements also may be found in state law and regulation, including laws and regulations pertaining to public health (e.g., HIV status, mental health, and substance abuse). As such, it is advisable to consult local knowledgeable counsel to ensure compliance. Where state law provisions regarding the privacy of protected health information offer more protection than that which is required under HIPAA, the state law is controlling.

maintained or transmitted in an electronic format. PHI includes individually-identifiable information relating to individual medical diagnoses, tests, and treatments. This information includes, but is not limited to, the patient’s name, address, social security number, and health status.⁵⁰

The Privacy Rule sets a federal “floor” regarding patient privacy. It does not preempt state laws with stricter standards, unless a specific exception applies.⁵¹ Accordingly, in order to ensure compliance, FQHCs and LHDs must review applicable state laws in addition to HIPAA.

The HIPAA Security Rule requires that covered entities, as defined below, implement administrative, physical, technical, and organizational safeguards to protect the integrity, confidentiality, and availability of electronic PHI. This includes establishing appropriate policies and procedures to govern the creation, storage, transmission, modification, and destruction of electronic PHI.⁵²

⁵⁰ DHHS Office of Civil Rights Privacy Brief: Summary of the HIPAA Privacy Rule (May 2003), p. 4.

⁵¹ 42 U.S.C. § 1320d-7 (Section 1178 of HIPAA).

⁵² For more information on the HIPAA Security Rule, see 45 C.F.R. § 164 Subparts A and C.

The Privacy Rule governs the acts of “covered entities.” Covered entities include health plans, health care clearinghouses, and health care providers who furnish, bill, or receive payment for health care in the normal course of business, and transmit any covered transactions electronically.⁵³ FQHCs and LHDs are subject to the Privacy Rule as covered entities if they transmit any protected health information regarding a transaction covered by HIPAA (e.g., claims for payment, coordination of benefits) electronically.⁵⁴

What are the permitted uses and disclosures of data that do not contain PHI?

FQHCs and LHDs may share data that does not contain PHI or where the PHI has been de-identified in compliance with the HIPAA Privacy Rule, provided that the exchange of the information is permitted under state law.⁵⁵

What are the permitted uses and disclosures of PHI?

The Privacy Rule permits a covered entity to use and disclose an individual’s protected health information for treatment, payment, and health care operations activities, within certain, specified limitations, without obtaining the individual’s consent. “Treatment” is particularly relevant for purposes of this guide.⁵⁶ Treatment is defined as “the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.”⁵⁷ Apart from treatment, payment, health care operations, or disclosures required by law, covered entities generally must obtain a patient’s written consent to use or disclose PHI.

The Privacy Rule permits, but does not require, a covered entity to disclose PHI for certain public health purposes without an individual’s authorization.⁵⁸ Generally, the rule permits covered entities to disclose PHI to public health authorities that are legally authorized to receive such information for the purposes of preventing or controlling disease, injury, or disability.⁵⁹

When must a covered entity obtain a patient’s written authorization to use and disclose PHI?

The HIPAA Privacy Rule requires a covered entity to obtain a written authorization from an individual who is the subject of the protected health information, or the individual’s personal representative, before releasing any PHI for any purpose that is not explicitly exempt from the Privacy Rule. Valid authorizations must be in writing, describe the information to be disclosed, and, among other things, include certain required statements set forth in the Privacy Rule. See Appendix A for a sample authorization form that can be adapted for use in the covered entity’s practice. An individual’s treatment may not be conditioned on the signing of an authorization except where the treatment is research-related and the authorization is for disclosure for the research-related purpose.⁶⁰

⁵³ 45 C.F.R. § 160.103.

⁵⁴ 42 C.F.R. § 160.103 (defining “covered transaction”).

⁵⁵ 45 C.F.R. §§ 160.103 and 164.514.

⁵⁶ 45 C.F.R. § 164.506(c).

⁵⁷ 45 C.F.R. § 164.501.

⁵⁸ 45 C.F.R. § 164.512.

⁵⁹ Covered entities may also enter into data use agreements in order to share limited data sets. For more information on this option for data sharing, see 45 C.F.R. § 164.514(e).

⁶⁰ 45 C.F.R. § 164.508(b)(4).

4 | Federally Qualified Health Center-Local Health Department Partnership Models

“Today, the two cultures “medicine” and “public health” seem to live in different, often unfriendly worlds. This was not always the case. Experiences with universities, health departments, and governments during four decades have convinced me that continued separation of the two enterprises greatly diminishes their combined scientific, organizational and institutional potentials.”

—Kerr L. White, *Healing the Schism: Epidemiology, Medicine, and the Public’s Health, 1991*

Key Partnership Models

This guide focuses exclusively on the following three partnership models:

- A. One organization refers its patients to the other organization for services (i.e., a Referral Arrangement)
- B. One organization co-locates to the other organization’s facility (i.e., a Co-Location Arrangement)
- C. FQHC purchases services and/or capacity from the LHD (i.e., a Purchase of Services Arrangement)

Selecting a partnership model is a strategic decision. Every partnership will vary depending on the specific goals of the FQHC and LHD, a community’s health care needs, and the organizational structure of both the FQHC and LHD.

It is important to note that there are numerous potential partnership models in which the organizations may engage that are not discussed in this guide (including models involving greater levels of integration).

Several pertinent Section 330 grant-related requirements are summarized in Chapter 2 of this guide, and should be reviewed prior to implement-

ing any partnership. It is important to note, however, that this guide does not provide a comprehensive review of applicable federal laws, and does not address state law considerations. Accordingly, FQHCs and LHDs are strongly advised to seek the assistance of qualified local legal counsel and other appropriate professional advisors when evaluating and implementing partnerships.

Must the partnership be documented in the form of a written agreement?

A written agreement is critical to demonstrate compliance with various federal (and often state) laws and regulations, and helps to articulate roles and responsibilities for both the FQHC and LHD. Furthermore, the Health Resources and Services Administration (HRSA), the federal agency that oversees the FQHC program, generally requires evidence of FQHC affiliation relationships as part of all grant applications (i.e., New Access Point, Expanded Medical Capacity, Service Expansion), for designation as an FQHC, and for purposes of including the services provided under the agreement within the FQHC’s approved scope of project.

A. Referral Arrangement

A referral arrangement is a partnership under which a provider agrees to furnish services to those patients who are referred to it by another provider. The provider referring the patient typically agrees to utilize the other provider as its preferred, albeit not exclusive, provider of choice for particular services. For purposes of this guide, the organization referring the patient is referred to as the “Referring Organization,” and the organization providing the referral services is referred to as the “Referral Provider.”

Under a referral arrangement, both the FQHC and the LHD retain their own separate and distinct patient care delivery systems and locations, and each is only accountable and legally and financially responsible for the services it directly furnishes to patients.

A referral arrangement may serve as a useful precursor to a more collaborative relationship, providing both the FQHC and LHD with an opportunity to become familiar with the other organization before implementing a more integrated partnership. The main tool by which the parties would implement this arrangement is a “Referral Agreement,” executed by both the FQHC and LHD.

Key Referral Arrangement Considerations

Scope of Project

Under a referral arrangement, both the FQHC and the LHD typically continue to perform the same scope of services.

All services provided within an FQHC’s scope of project via referral to another provider must be provided through a **formal referral arrangement**. Under a formal referral arrangement, the FQHC maintains responsibility for the patient’s overall treatment plan and provides and/or pays/bills for appropriate follow-up care based on the outcome of the referral. It is also important to note that such ser-

vices must be equally available to all of the FQHC’s patients, regardless of their ability to pay and in accordance with a schedule of discounts, as described on pages 17–18. As described below, these referral arrangements should be formally documented in a written agreement that, at a minimum, describes the manner by which the referral will be made and managed and the process for referring back to the FQHC for appropriate follow-up care. Under formal referral arrangements, if the actual service is provided and paid/billed for by another entity, then the service is not included in the FQHC’s scope of project. However, establishment of the referral arrangement and any follow-up care provided by the FQHC subsequent to the referral is considered to be part of the FQHC’s scope of project. Formal referral arrangements are included in an FQHC’s Form 5-Part A, Column III.⁶¹ Adding a service included on Form 5-Part A, albeit by formal referral arrangement, requires prior approval from HRSA.⁶²

Under an **informal referral arrangement**, which cannot be used to provide required or other in-scope services, the FQHC refers a patient to another provider who is responsible for the overall treatment plan and billing for the services provided and no grant funds are used to pay for the care provided. These informal arrangements are not required by HRSA to be documented in a written agreement and do not require the other provider to refer patients back to the FQHC for appropriate follow-up care. For services provided by informal referral arrangements, the referral arrangement and the service and any follow-up care provided by the other entity, are considered outside of the

⁶¹ HRSA PIN 2008-01: *Defining Scope of Project and Policy for Requesting Changes*, p. 11 available at <http://bphc.hrsa.gov/policy/pin0801/>.

⁶² HRSA PIN 2008-01, p. 16.

FQHC's scope of project and are not captured on Form 5-Part A.⁶³ Accordingly, it is not required that an FQHC obtain HRSA's prior approval to add an informal referral arrangement.

Referral Methodology

The LHD and FQHC should develop a protocol describing the manner in which the referrals between the LHD and FQHC would be made and processed. For example, referrals could be made in writing, over the telephone, or through electronic means.

If the LHD is the Referral Provider and provides a required FQHC service or another service which the FQHC includes in its approved scope of project, then the FQHC and LHD must have a mechanism in place to ensure that patients have actual access to, and follow through on, the referrals, such as patient tracking and case management services. For example, if the FQHC is the Referring Organization and the LHD is the Referral Provider, the FQHC could assist the patient in making his/her appointment with the LHD and could function as the coordinator to ensure that the patient presents at the LHD (and, as appropriate, presents back at the FQHC). By assisting the patient in making the appointment, certain barriers to access can be eliminated or minimized. In addition, in order to support patient tracking, the FQHC and LHD should determine how to identify shared patients in their patient records.

Although the above referral methodology considerations are only required for services that are within the FQHC's scope of project, they are nevertheless recommended practices for *all* referral relationships.

Fees and Discounts

If the FQHC is the Referral Provider, it must charge the patients referred by the LHD in accordance with

the FQHC'S fee schedule and schedule of discounts, as described on pages 17–18. In addition, the FQHC is statutorily obligated to serve all patients referred by the LHD, regardless of ability to pay, subject to reasonable capacity limitations.

If the LHD is the Referral Provider and provides a required FQHC service (e.g., dental) or another service which the FQHC includes in its approved scope of project, then the LHD must make such services available to all FQHC patients, regardless of ability to pay, and must establish a schedule of discounts for patients under 200% of the Federal Poverty Level.⁶⁴ Under certain scenarios, the FQHC may agree to provide financial support to the LHD for the reasonable costs it incurs in providing the referral services to the referred FQHC patients that are uninsured or underinsured.

Financial Systems

The FQHC and LHD each maintain separate financial systems. The billing and coding functions of the organizations remain non-integrated, and each organization bills payors and patients, as appropriate, for the services it provides.

Provider Capacity

Under the referral arrangement, the FQHC and the LHD maintain their own employees and contractors. Further, the credentialing requirements, by-laws and clinical policies of the organization providing services govern.

In general, prior to referring a patient to or entering into a referral arrangement, the FQHC and LHD should perform due diligence to ensure that the Referral Provider has capacity to see additional

⁶³ HRSA PIN 2008-01, p.11.

⁶⁴ HRSA PIN 2008-01, p.11.

patients. The FQHC and LHD should also consider training both organizations' health care professionals regarding the referral process, the process for sharing medical records, and any special linguistic and cultural needs of the patients.

Medical Records

Under the referral arrangement, the LHD and the FQHC each maintain their own complete medical records and only share referral records and notes for purposes of treatment. As such, the Referral Agreement should include provisions clarifying what types of information may be shared and how this "sharing" process will occur (as well as any limitations on the sharing of information).

Federal Tort Claims Act

FTCA coverage is available to the FQHC if it is the Referral Provider and if the arrangement otherwise satisfies the FTCA requirements (see pages 20–22). FTCA coverage is not available for the LHD or its contracted or employed health care professionals, regardless of whether the LHD is the Referring Organization or the Referral Provider.

Section 340B Prescription Drugs

As stated on page 22, drugs purchased under the Section 340B prescription drug program may be dispensed only to the FQHC's patients. If prescriptions are written by a LHD health care professional and the patient presents back at the FQHC to have them filled, the FQHC may be able to fill the prescription using Section 340B prescription drugs if the patient qualifies as a patient of the FQHC under the Section 340B definition of "patient," and the FQHC maintains an active, primary role for monitoring and managing the patient's particular course of treatment. The fact that the referral to the LHD originated at the FQHC does not trigger the ability to

use Section 340B prescription drugs for that patient. Under no circumstances may the FQHC rewrite the LHD health care professional's prescription.

Exclusive Referral Relationships

HRSA has voiced concern regarding exclusive arrangements that do not provide FQHCs with leeway to develop any and all referral and/or collaborative relationships necessary to provide the full continuum of care and to meet all statutory and regulatory requirements and policy expectations regarding coordination and collaboration with other providers. HRSA prefers that FQHCs maintain the freedom to enter into other arrangements as necessary (1) to implement the policies and procedures established by the FQHC's board of directors, and (2) to assure appropriate collaboration with other local health care providers⁶⁵ to enhance patient freedom of choice, accessibility, availability, quality and comprehensiveness of care.⁶⁶ As such, the Referral Agreement should not foreclose either party from entering into arrangements with other providers, whether for the same or for similar services, if such party deems it necessary.

Key Terms of a Referral Agreement:

Note that although written agreements are only required in the context of formal referral arrangements, as described on page 42, we suggest that FQHCs and LHDs also execute such agreements to implement informal referral arrangements. All Referral Agreements should include, at a minimum, the following terms:

⁶⁵ 42 U.S.C. § 254b(k)(3)(B).

⁶⁶ HRSA's position regarding the limitations on an FQHC's ability to form relationships with other providers is addressed in HRSA PIN 97-27: *Affiliation Agreements of Community and Migrant Health Centers* available at <http://bphc.hrsa.gov/policy/pin9727.htm>.

- The Referring Organization will not be liable for any damages arising from any acts or omissions in connection with the services provided under the referral arrangement by the Referral Provider.
- The Referring Organization does not guarantee that it will make referrals to the Referral Provider, whether by committing to a specific number or a minimum level of referrals.
- Nothing in the arrangement will, or is intended to, impair the exercise of professional judgment by any and all health care professionals employed by or contracted to either party when making referrals.
- Nothing in the arrangement will, or is intended to, impair the exercise of freedom of choice of provider by any and all patients served by each party.
- Both the FQHC and LHD maintain the right to enter into arrangements with other providers, whether for the same or for similar services.
- The FQHC and LHD agree to comply with any federal or state law governing the privacy and confidentiality of the individually identifiable health information of patients originating with either party.
- The Referral Provider will furnish all services consistent with the prevailing standard of care and will be solely liable for all services provided by it and its health care professionals.

If the Referral Agreement is for a formal referral arrangement whereby the FQHC is the Referring Organization and the LHD is the Referral Provider, the Referral Agreement must also:

- Describe the manner by which the referral will be made and managed and the process

for referring back to the FQHC for appropriate follow-up care.

- The LHD agrees to accept all FQHC patients referred to it by the Referring Organization, regardless of ability to pay, subject to reasonable capacity limitations.
- The LHD agrees to offer the referral services on a sliding fee scale.
- The LHD agrees that the health care professionals providing the referral services are properly credentialed and licensed to perform the activities and procedures expected of them by the FQHC.

The Referral Agreement must also describe the manner by which the referral will be made and managed (e.g., development of a referral protocol and procedures for tracking patients and ensuring appropriate follow-up care) and the process for referring the patient back to the FQHC for follow-up care. It is recommended that the Referral Agreement also describe the division of services between the Referring Organization and the Referral Provider (e.g., identify which organization will make appointments).

B. Co-Location Arrangements

Similar to the standard referral arrangement, a co-location arrangement is a partnership under which a provider agrees to treat patients who are referred to it by another provider, maintains its own practice and control over the provision of the referral services, and is legally and financially responsible for the referral services. However, unlike the referral arrangement, the health care professional furnishing the referral services is physically located at the other organization's site, either on a full or part-time basis.

As described in the “Distinguishing Providers” section below, it is advisable to distinguish between the FQHC and LHD health care professionals. It is important to note that, depending on how the relationship is structured, it may be necessary that the FQHC and LHD have separate entrances in order to obtain a separate Medicare site certification.⁶⁷ FQHCs and LHDs are also advised to review state law for any requirements regarding providers sharing clinical space.

Patient access may be significantly increased under this arrangement because co-location reduces transportation barriers and may allow patients to obtain services from both the FQHC and LHD in one visit.

The main tool by which the parties would implement this arrangement is a “Co-Location Agreement,” executed by both the FQHC and LHD.

Although this section specifically addresses co-location within one facility, it is important to note that the key considerations and terms outlined below (other than “Distinguishing Providers” and “Lease of Space and Equipment”) are applicable to arrangements whereby one organization establishes a new site next to or otherwise nearby the other organization. Although these close proximity arrangements do not provide for the level of coordinated services available under the traditional co-location arrangement, they nevertheless reduce transportation barriers and increase access.

Key Co-Location Arrangement Considerations

Scope of Project Considerations

Sites

If the LHD establishes a site within the FQHC, the FQHC is not required to change its approved scope

of project because it is not adding or removing a site. Patients are simply referred to the LHD as they would be under the standard referral relationship.

If the FQHC establishes a site within the LHD, the FQHC must obtain prior approval from HRSA to add the site to its scope of project. Prior to seeking HRSA approval to add a new site to an FQHC’s scope of project, an FQHC must consider whether the location qualifies as an FQHC “site” (see page 24). It is important to note that the location will only qualify as a site if the FQHC provides services at the co-located location on a regularly scheduled basis. For information regarding scope of project change requirements, see pages 25–26.

Services

As stated on page 42, if the co-location includes a formal referral arrangement that will be included in the FQHC’s Form 5-Part A, and therefore in the FQHC’s scope of project, then the FQHC must receive HRSA’s prior approval.⁶⁸

Distinguishing Providers

To avoid unintended legal liabilities, the co-located provider should be clearly identified as a provider furnishing services separate from the other organization. In addition, it should be clear that the co-located health care professional(s) is not employed by, or contracted to, the other organization. For example, if the LHD co-locates at an FQHC site, and a patient believes one of the LHD health care professionals violated a duty and provided sub-standard care that harmed the patient, the patient would likely sue both the LHD and the FQHC. Unless it was clear to the patient at the time services

⁶⁷ 42 C.F.R. § 491.8.

⁶⁸ HRSA PIN 2008-01, p.11.

were rendered that the health care professional(s) was employed by or contracted to the LHD, that the LHD is a legal entity separate from the FQHC, and that the services in question were provided in the LHD health care professional's capacity as a separate provider, should a jury find for the patient, the FQHC might be held legally liable as well (of course, this would depend on the facts of the situation and how the patient's legal claim was drafted, but caution is always advisable).

Accordingly, there should be separate entrances for the co-located FQHC and LHD, if possible, and very clear signage in multiple places, including the waiting room, the billing area, and the room where the co-located provider's services will be provided, as well as brochures and pamphlets placed throughout the area. Further, the FQHC and LHD may agree on the placement of external signage identifying the co-located provider.⁶⁹ In addition to signage and materials, both organization's health care professionals, as they explain the referral process to the patient, may also consider explaining that the FQHC and LHD are separate, but housed in the same place for patients' convenience.

Lease of Space and/or Equipment

The FQHC and LHD should execute a lease covering the actual space, equipment, utilities, supplies, and support personnel that will be utilized by the co-located provider, as well as other associated costs incurred by the co-located provider in furnishing services at the other organization's facility. For example, the co-located provider may need use of an exam or conference room, access to a computer, phone, fax machine, and copier. The lease provisions may be included within the Co-Location Agreement or as a separate agreement.

The space, equipment, utilities, supplies, and support personnel should be leased by the co-located provider based on a fair market, arm's length negotiated rate, unless the FQHC is the "purchaser" and the parties structure the arrangement to comport with the FQHC safe harbor under the Anti-Kickback statute (see page 23).

Referral Methodology

As with the standard referral relationship, if the LHD is the Referral Provider and provides a required FQHC service (e.g., dental or another services which the FQHC includes in its approved scope of project), then the FQHC and LHD must develop a protocol describing the manner in which the referrals between the two providers would be made and processed and a mechanism in place to ensure that patients have actual access to, and follow through on, the referrals, such as patient tracking and case management services. Note that the FQHC and LHD *must* develop a referral protocol if, under the referral arrangement, the LHD provides the FQHC patients with services within the FQHC's scope of project.

The appointments could occur on the spot, so that the patient would be able to present directly to the co-located provider at the time that a need for services is identified (assuming the co-located provider's schedule permitted). Alternatively, a case manager or coordinator could make the referral appointment with the co-located provider, based upon both the patient's and the co-located provider's schedule. In addition, in order to support patient tracking, the FQHC and LHD should determine how to identify shared patients in their patient records.

⁶⁹ It is important to note that depending on the FQHC patient population, linguistic and cultural competency, as well as literacy, may be an issue and, as such, all signage and materials should be available in the prevalent languages spoken by, and at the appropriate grade-level of, the patient populations.

Provider Capacity

Provider capacity considerations under the co-location arrangement mirror those addressed under the referral arrangement, as described on page 43. However, there are additional considerations because the health care professional(s) will be co-located in the other facility. Specifically, the Co-Location Agreement should contain certain assurances from the co-located provider regarding the professional qualifications, licensure, certification, insurance, eligibility to participate in federal programs, etc. with regard to the other organization and its health care professionals who will be providing the services. In addition, the organization that houses the co-located provider may want to retain the right to request the removal of any co-located health care professional who fails to meet necessary qualifications or who could jeopardize the health, safety and welfare of patients if he or she continues to provide services at the co-located site.

Federal Tort Claims Act

As stated on page 21, FTCA coverage is available for deemed FQHCs, its employees, and certain contracted providers for services provided within the FQHC's scope of project. Accordingly, if the FQHC co-locates to an LHD facility, adds the site to its scope of project, and provides services within its scope of project, FTCA coverage is generally available for the FQHC, its employees, and certain contracted providers.

Under the co-location arrangement, FTCA coverage is not available for the LHD, its employees and its contracted health care professionals. The LHD would need to obtain and carry its own professional liability insurance.

Referral Provider Fees and Discounts, Financial Systems, Medical Records, Section 340B Prescription Drugs and Exclusive Referral Relationships

As stated above, the co-location arrangement is a form of referral relationship. The FQHC and the LHD retain their own separate and distinct patient care delivery systems despite the shared space. Accordingly, for more information regarding fees and discounts, the FQHC's and LHD's financial systems, Section 340B prescription drugs and exclusive referral relationships, readers should refer to the applicable headings under the Key Referral Arrangement Considerations on pages 43–44.

Key Terms of a Co-Location Agreement

Because a co-location arrangement is a form of referral relationship, the Co-Location Agreement should include the key terms listed for Referral Agreements (see pages 44-45). If applicable, the FQHC and LHD may wish to include terms regarding the lease of certain space, equipment, supplies, utilities, and support and clerical staff to assist the co-located provider, which should be leased by the co-located provider based on a fair market, arm's length negotiated rate, unless, as stated above, the FQHC is the "purchaser" and the FQHC and LHD wish to structure the arrangement in accordance with the FQHC safe harbor to the Anti-Kickback statute (see page 23).

C. Purchase of Services Arrangements

Under the purchase of services arrangement, one organization purchases services from the other organization, which provides such services as a vendor and on behalf of the other "purchasing" organization. Although this guide exclusively addresses the purchase of health care professional services, it is important to note that FQHCs and LHDs may enter into arrangements for the purchase of administrative services.

The purchasing organization is the provider of record for the contracted services rendered to its patients, maintains control over the provision of such services, and remains legally and finally responsible for the services provided by the contracted provider. The services provided by the vendor organization may be provided at either the purchasing organization's facility or at the vendor organization's facility. It is important to note, however, that the FQHC and LHD still remain separate entities under this arrangement.

This guide only addresses the arrangement whereby an FQHC purchases services from an LHD. Although the alternative model (i.e., LHD purchases services from an FQHC) is feasible, it is difficult to summarize the key considerations because LHDs are entities with governmental authority, and are therefore subject to local and state procurement requirements that vary extensively across the country. In addition, purchasing services from an FQHC does not maximize resources. Specifically, if an FQHC provider is contracted from another organization, the FQHC benefits (namely FTCA, Section 340B prescription drugs, and cost-based reimbursement under Medicare, Medicaid and CHIP) are not available for that provision of services.

The main tool by which the parties would implement this arrangement is a "Purchase of Services Agreement," executed by both the FQHC and LHD (or the individual LHD provider).

Note: Municipal statutes may limit an LHD's authority to contract with private or public organizations to provide services. Accordingly, it is critical that the parties review local and state laws when determining whether it is permissible to contract with the LHD or directly with the LHD provider(s).

Key Features of the Purchase of Services

Arrangement

Scope of Project Considerations

If the service(s) provided to the FQHC's patients by the contracted LHD health care professional(s) are not currently within the FQHC's scope of project, then the FQHC must request and obtain prior approval from HRSA to add the service(s) to its scope of project. In addition, if it is anticipated that the contracted services will be furnished to FQHC patients at a site that is not currently within the FQHC's scope of project, then the FQHC must confirm that the location qualifies as a "site" (e.g., services are provided on a regularly scheduled basis, see pages 24–25 for more information), and must accordingly request and obtain prior approval from HRSA to add the site to its scope of project. The process for applying for a change in scope of project is described on pages 25–26.

Compensation for Services

The FQHC compensates the LHD for the provision of services based on a fair market, arm's length negotiated rate, which should be incorporated, along with the specific payment methodology, into the written contract. Note that a fair market value rate may not be necessary if the FQHC is the "purchaser" and the parties structure the arrangement to comport with the FQHC safe harbor under the Anti-Kickback statute (see page 23).

Reimbursement from Payors and Patients

The patients served under this arrangement would be considered FQHC patients for all services provided and, as such, the FQHC (and not the LHD health care professional) would bill appropriate third party payors and, as applicable, collect fees from patients.

Health Care Professionals

Because the LHD health care professional is furnishing services to FQHC patients on behalf of the FQHC, the LHD health care professional should receive relevant training regarding the applicable laws, regulations, and FQHC clinical policies, procedures, standards, and protocols that govern the provision of services to FQHC patients. Further, the LHD health care professional should receive training in other areas relevant to the provision of services, including, but not limited to, the FQHC's employment-related policies, cultural and linguistic competency, and the FQHC's corporate compliance program and HIPAA-related policies.

Assurances and Oversight

As described in the key terms section below, the Purchase of Services Agreement should include provisions to ensure that the LHD health care professional provides services to the FQHC patients in the same manner as if the FQHC was providing such services directly. Further, the Purchase of Services Agreement should include provisions under which the FQHC maintains certain rights in order to fulfill its oversight responsibilities, including approval of all LHD health care professionals assigned to the FQHC; evaluation of performance; compliance with policies, procedures, standards, and protocols; and, as necessary, termination or suspension of individual health care professionals.

Procurement Standards

Prior to entering into an arrangement involving a grant-supported purchase of goods and/or services from an LHD, an FQHC should ensure that the purchase complies with a procurement process designed to assure that the FQHC obtains the best quality goods and services at the lowest possible cost. The

procurement process must satisfy the requirements set forth in the federal procurement standards, 45 C.F.R. Part 74, as described briefly on page 18.

Medicare/Medicaid Issues

Whether a visit to see the contracted LHD health care professional and a primary care visit that occurred on the same day can be billed as separate visits will depend largely on whether the state has promulgated applicable limitations. It is advisable that FQHCs and LHDs request an opinion from their Medicaid Department to determine whether state law precludes reimbursement for two or more services that are performed by different providers, even though the second provider is performing services on behalf of the first.

In addition, state law may preclude or limit the ability of the FQHC to bill Medicaid for services furnished by the LHD health care professional to FQHC patients, even when such services would be provided on behalf of (and under the control of) the FQHC. Alternatively, state law may allow the FQHC to bill such services, but not as "FQHC services" eligible for cost-based reimbursement. As such, it is advisable to review state law and, if such review indicates that there will be (or might be) an issue under state law pertaining to the structure of this arrangement, to request an opinion letter from the appropriate state agency approving the arrangement prior to implementation.

Medical Records

Insofar as the LHD health care professional is furnishing services to FQHC patients, on behalf of the FQHC, pursuant to a Purchase of Services Agreement, the FQHC would maintain responsibility and ownership for all patient records developed in connection with such services. Of course, the FQHC would still be

bound to the same requirements and restrictions for a health care provider under HIPAA and FQHC regulations, as well as corresponding state regulations.

FTCA Considerations

As noted on page 21, for clinical capacity purchase arrangements to be eligible for FTCA coverage, the agreement must, at a minimum, be directly between the FQHC and the individual health professional providing services to the FQHC's patients. An agreement between the FQHC and an LHD will not extend FTCA coverage to the individual health professional who is an LHD employee. Accordingly, under such arrangements the LHD should obtain and carry professional liability insurance for both itself and its contracted provider.

Section 340B Prescription Drugs

As stated on page 22, drugs purchased under the Section 340B program may be dispensed only to individuals that qualify as patients of the FQHC, in accordance with the Section 340B definition of "patients." Under the purchase of services arrangement, patients seen by LHD providers are seen under the auspices of the FQHC. Technically, there is not a "referral back" to the FQHC for primary and preventive care because all services are technically provided by the FQHC. Unlike referral relationships or co-location arrangements, the FQHC maintains control for the patient's care at all times and, as such, Section 340B drugs may be utilized.

Exclusive Purchase Relationships

As stated on page 44, HRSA has voiced concern regarding exclusive arrangements. As such, the Purchase of Services Agreement should not foreclose either party from entering into arrangements with other providers, whether for the same or for similar services.

Key Terms of a Purchase of Services Agreement

If the FQHC purchases capacity from the LHD, the following terms should be included in the Purchase of Services Agreement. While these terms provide a general overview of key provisions, the specifics of each agreement will vary based on the particular affiliation arrangement.

- All patients receiving services from contracted providers will be registered as patients of the FQHC; the FQHC will be solely responsible for the billing of services rendered to such patients, as well as third party payors (including Medicaid and Medicare), and the collection and retention of any and all payments due.
- The FQHC will:
 - Maintain responsibility and authority for approving, monitoring, evaluating, and, as necessary, suspending or removing contracted health care professionals from providing services to FQHC patients.
 - Pay a fair fee based on arm's length negotiation for services rendered by contracted LHD staff, unless the parties structure the arrangement to comport with the FQHC safe harbor under the Anti-Kickback statute (see page 23).
- The LHD will be responsible, as the employer of the contracted health care professionals, for securing and maintaining Worker's Compensation and comprehensive general and professional liability insurance for the contracted providers, unless such health care professionals are directly contracted to the FQHC and are eligible for FTCA coverage.

- The LHD health care professional(s) will:
 - Provide clinical services to patients on behalf of the FQHC.
 - Provide services consistent with the FQHC's Section 330 grant (or FQHC project requirements) and applicable health care and personnel policies, procedures, standards and protocols, and under the direction of the FQHC's management team.
 - Satisfy the FQHC's licensure, credentialing and other professional qualifications requirements.
 - Be and remain eligible to participate in federal health care programs, including the Medicaid and Medicare programs.
 - Not be debarred/suspended from participating in federal contracts.
 - Develop, maintain and furnish programmatic reports and records, as required by the FQHC.
 - Prepare medical records consistent with the FQHC's standards (which records will be the property of FQHC); and
 - Comply with any federal or state law governing the privacy and confidentiality of the individually identifiable health information of the FQHC's patients.
- Nothing in the arrangement will, or is intended to, impair the exercise of professional judgment by any and all health care professionals employed by or contracted to either party when making referrals.
- Nothing in the arrangement will, or is intended to, impair the exercise of freedom of choice of provider by any and all patients served by each party.
- Each party maintains the right to enter into arrangements with other providers, whether for the same or for similar services, if such party deems it necessary.
- If the FQHC is a Section 330 grantee, any agreement to purchase clinical capacity will need to include certain provisions consistent with 45 C.F.R. Part 74. In short, these provisions address remedies in the event of contractor breach, record keeping obligations, and compliance with various federal laws and regulations.

5 | Additional Legal Considerations

There are additional legal issues that should be addressed in structuring FQHC-LHD partnerships. The types of legal issues depend on the nature and complexity of the partnership. In particular, FQHCs and LHDs may need to review the following to ensure compliance with applicable laws, regulations, and policies:

- Federal tax considerations (Internal Revenue Code);
- Federal fraud and abuse law (e.g., anti-kickback, false claims);
- Federal physician self-referral law (Stark);
- Federal Antitrust law;
- Health Insurance Portability and Accountability Act; and
- DHHS Uniform Administrative Requirements (45 C.F.R. Part 74).

FQHCs and LHDs should also be aware of state and local law requirements that may affect a particular partnership. These laws may include, but are not limited to:

- State counterparts to federal laws, including fraud, abuse, and physician self-referral;

- Clinic licensure and certificate of need laws;
- Professional licensure, certification and/or other authorization to render services;
- Zoning laws;
- Corporation/LLC statutes;
- Privacy of patient health information;
- Insurance; and
- Scope of practice (including supervision requirements for particular providers).

We strongly caution both FQHCs and LHDs to seek the assistance of qualified legal counsel and other appropriate professional advisors when:

- Developing and/or evaluating particular partnership options; and
- Conducting due diligence reviews and drafting or reviewing definitive agreements.

6 | Conclusion and Next Steps

While forming an FQHC-LHD partnership can involve complex legal issues and limitations, experience has demonstrated that the benefits to creating a community system of care may be well worth the effort.

As an initial step, the FQHC and LHD should:

1. Secure community support and leadership to implement the partnership.
2. Establish measures to evaluate the partnership and its impact on the community.
3. Evaluate community needs.
4. Clearly define their goals and objectives for entering into a partnership, with careful consideration of the Patient Protection and Affordable Care Act, regulations for Meaningful Use of Health Information Technology, and the standards of the patient-centered medical home.

5. Carefully consider and determine the appropriate partnership to achieve the FQHC's and LHD's identified goals and objectives.
6. Ensure that the partnership is financially feasible and beneficial.

To ensure that all issues and considerations are well thought-out and measured, the FQHC and LHD should engage in a deliberative, step-by-step process to plan, negotiate, and establish the chosen partnership approach. Finally, the FQHC and LHD must consider all legal and policy requirements and ramifications related to establishing the partnership, to ensure not only smooth implementation, but also a successful future.

Concluding Tips

- Celebrate achievements.
- Foster an environment that welcomes new ideas.
- Focus on the shared mission to improve public health and primary care.

Appendix A | Useful Resources

Organizations

Feldesman Tucker Lefier Fidell LLP (FTLF) is a law firm located in Washington, DC, that has an extensive, national health law practice representing community-based health care providers. Clients include, but are not limited to, federally qualified health centers (FQHCs), hospitals, health systems, and state primary care associations that have as their mission the improvement of access to high-quality, cost-effective health care services to medically underserved and vulnerable populations. FTLF is also counsel to the National Association of Community Health Centers. www.ftlf.com

National Association of Community Health Centers (NACHC) is the trade association for health centers nationwide and is dedicated exclusively to expanding health care access for America's medically underserved through the Community Health Center model. www.nachc.com

National Association of County and City Health Officials (NACCHO) is the national organization representing local health departments. NACCHO's vision is: health, equity, and well-being for all people in their communities through public health policies and services. NACCHO's mission is to be a leader, partner, catalyst, and voice for local health departments in order to ensure the conditions that promote health and equity, combat disease, and improve the quality and length of all lives. www.naccho.org

Medical Home Resources

- National Academy of State Health Policy
www.NASHP.org
- Primary Care Development Corporation
Medical Home How-To Manual
www.pcdcnny.org/index.cfm?organization_id=128§ion_id=2047&page_id=8829
- National Committee on Quality Assurance
www.ncqa.org/tabid/631/Default.aspx
- Patient-Centered Primary Care Collaborative
www.pcpcc.net/content/patient-centered-medical-home
- Center for Medical Home Improvement
www.medicalhomeimprovement.org/index.html
- Commonwealth Fund
www.commonwealthfund.org/Topics/Patient-Centered-Care.aspx
- Improving Chronic Illness Care
www.improvingchroniccare.org

Meaningful Use Resources

- The Office of the National Coordinator for Health Information Technology (ONC)
<http://healthit.hhs.gov/portal/server.pt>

NACCHO Resources

- Developing Quality Applications for Community Health Center Funding
<http://www.naccho.org/topics/HPDP/primary-care/upload/CHCIssueBrief1-19-2006.pdf>

National Strategies

- National HIV/AIDS Strategy
<http://www.whitehouse.gov/administration/eop/onap/nhas>
- National Health Care Quality Strategy and Plan
<http://www.hhs.gov/news/reports/quality/nationalhealthcarequalitystrategy.pdf>
- National Prevention and Health Promotion Strategy
<http://www.healthcare.gov/center/councils/nphpphc/strategy/>

Routine HIV Screening Resources

- Integrating HIV Screening into Routine Primary Care: A Model, Tools and Templates
<http://www.nachc.com/hivmodel.cfm>
- Northwest AIDS Education and Training Center HIV Web Study Interactive Tutorials
<http://depts.washington.edu/hiv aids/index.html>
- Health Research and Educational Trust HIV Testing and Screening Cost and Reimbursement
<http://www.hret.org/disparities/projects/hiv-testing-and-screening-cost-and-reimbursement.shtml>

Sample Forms

- Sample Patient Authorization Form

SAMPLE AUTHORIZATION FORM

Note: This document is intended to serve as guidance and is not a template. It does not reflect the requirements of your state's patient information privacy laws. You are advised to consult with knowledgeable legal counsel prior to using a Patient Authorization Form.

Patient Authorization for Use and Disclosure of Protected Health Information

By signing, I authorize [insert organization name] to use and/or disclose certain protected health information (PHI) about me to _____.

This authorization permits [insert organization name] to use and/or disclose the following individually identifiable health information about me: [specifically describe the information to be used or disclosed, such as date(s) of services, type of services, level of detail to be released, origin of information, etc.]

The information will be used or disclosed for the following purpose(s):

The purpose(s) is/are provided so that I may make an informed decision whether to allow release of the information.

This authorization to use and/or disclose certain protected health information (PHI) about me will expire on [enter date or defined event].

[Insert organization name] will ___ will not ___ receive payment or other remuneration from a third party in exchange for using or disclosing the PHI.

I do not have to sign this authorization in order to receive treatment from [insert organization name]. In fact, I have the right to refuse to sign this authorization. When my information is used or disclosed pursuant to this authorization, it may be subject to redisclosure by the recipient and may no longer be protected by the federal Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. I have the right to revoke this authorization in writing except to the extent that the practice has acted in reliance upon this authorization. My written revocation must be submitted to the privacy officer at:

[Insert name and address of entity]

Signature of Patient or Legal Guardian

Relationship to Patient

Print Patient's Name:

Date

Print Name of Patient or Legal Guardian, if applicable

Patient/guardian must be provided with a signed copy of this authorization form.



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