



## **ASSESSING AND ADDRESSING LEGAL BARRIERS TO THE CLINICAL INTEGRATION OF COMMUNITY HEALTH CENTERS AND OTHER COMMUNITY PROVIDERS**

Sara Rosenbaum, Marcie H. Zakheim, Jacqueline C. Leifer,  
Michael D. Golde, Jillanne M. Schulte, and Ross Margulies

July 2011

**ABSTRACT:** Collaborations that clinically integrate community health centers with hospitals, providers, and/or public health agencies have yielded substantial benefits for patients, including an expansion of services and increased access to medical information. These types of collaborations are expected to increase as health centers expand with the \$11 billion in funding the Affordable Care Act provides them. However, the laws and policies governing collaborations between health centers and their partners are complex and failure to comply with them may lead to a loss of federal funding as well as the revocation of important legal protections for health centers. This report outlines the laws and policies that govern clinical collaborations and profiles health centers that have worked within the law to develop partnerships that benefit patients while still adhering to the health centers' core mission, which is to assure health care for all patients regardless of insurance coverage.

Support for this research was provided by The Commonwealth Fund. The views presented here are those of the authors and not necessarily those of The Commonwealth Fund or its directors, officers, or staff. To learn about new Commonwealth Fund publications when they become available, visit the Fund's Web site and [register to receive e-mail alerts](#). Commonwealth Fund pub. no. 1525.



## CONTENTS

About the Authors.....	iv
Acknowledgments.....	v
Executive Summary .....	vi
Introduction.....	1
The Unique Legal Framework in Which Health Centers Operate.....	4
The Provisions of Section 330 .....	5
Beyond Section 330: Other Legal Issues in Analyzing Health Center Collaborations.....	13
Health Center Collaborations: Concepts and Examples .....	18
Example 1: Community Health Center, Inc., Middletown, Conn. ....	22
Example 2: RiverStone Health, Billings, Mont. ....	24
Example 3: Coos County Family Health Services, Northern New Hampshire .....	26
Example 4: South Boston Community Health Center, Boston, Mass. ....	28
Example 5. Glide Health Services, San Francisco, Calif.....	29
Example 6: Cherokee Health Systems, Knoxville, Tenn.....	31
Discussion.....	33
Notes .....	36

## ABOUT THE AUTHORS

**Sara Rosenbaum, J.D.**, is the Harold and Jane Hirsh Professor of Health Law and Policy and founding Chair of George Washington University School of Public Health and Health Services, Department of Health Policy. Professor Rosenbaum has devoted her career to issues of health law and policy affecting low-income and medically underserved populations. An author of a leading health law textbook and over 350 articles and studies focusing on numerous aspects of health law with an emphasis on medically underserved populations, Professor Rosenbaum has received numerous awards for her scholarship and service. She serves on numerous boards, including the CDC Director's Advisory Committee, the CDC Advisory Committee on Immunization Practice, and the Medicaid and CHIP Payment and Access Commission, which advises Congress on Medicaid policy. She received her law degree from the Boston University School of Law.

**Marcie H. Zakheim, J.D.**, is a partner at the law firm of Feldesman Tucker Leifer Fidell LLP in Washington D.C. Ms. Zakheim counsels clients on a variety of issues related to federal grants and grant-related requirements for health care services (including Section 330 of the Public Health Service Act); Medicaid services and legal requirements; health care provider networks and affiliations; fraud and abuse law; non-profit corporation law; corporate compliance programs; and managed care contracting. Prior to joining the firm, Ms. Zakheim served as a consultant to the George Washington University School of Public Health and Health Services and she currently serves as a Professorial Lecturer of Health Policy there. Ms. Zakheim received her law degree from the George Washington University Law School.

**Jacqueline Leifer, J.D.**, is a senior partner at the law firm of Feldesman Tucker Leifer Fidell LLP in Washington D.C. Ms. Leifer counsels clients on a variety of corporate and transactional issues, including development of organizational documents; negotiation and enforcement of contracts; corporate restructuring, consolidations and affiliations; corporate compliance programs; and risk management. In addition, Ms. Leifer provides advice on issues related to Medicare and Medicaid reimbursement, federal grants, federal fraud and abuse laws, antitrust and federal tax exemption. Prior to joining the firm, Ms. Leifer served as an attorney advisor in the Office of General Counsel of the United States Department of Health and Human Services, where she served as principal counsel to the Bureau of Community Health Services (now the Bureau of Primary Health Care). Ms. Leifer received her law degree from Cornell Law School.

**Michael D. Golde, J.D., M.P.H.**, currently practices as an “of counsel” attorney with Feldesman Tucker Leifer Fidell LLP in Washington, D.C., and as a solo practitioner in California in the field of health care law. Mr. Golde’s practice specializes in counseling nonprofit and public health care organizations (particularly Federally Qualified Health Centers) in general corporate matters, business transactions and federal regulatory compliance related to health care delivery and collaborative affiliations. Mr. Golde received his law degree from the George Washington University Law School and a master’s degree in public health (health policy) from the George Washington University School of Public Health and Health Services.

**Jillanne M. Schulte, J.D.**, is an associate at Feldesman Tucker Leifer Fidell LLP in Washington, D.C. Ms. Schulte focuses on health care law with a special emphasis on federally-funded programs (such as Section 330 of the Public Health Service Act). Ms. Schulte works with federal grantees and their community partners on a variety of matters, including the structuring of collaborative arrangements and nonprofit and corporate compliance issues. She received her law degree from American University’s Washington College of Law.

**Ross Margulies** is a health policy specialist in the government strategies practice at Foley Hoag LLP. His expertise includes federal health law and policy issues related to Medicaid and Medicare coverage and reimbursement, as well as health care fraud and compliance issues related to pharmaceutical and medical device companies, hospitals, practitioners, and provider organizations. Most recently he has served as a senior research assistant in the department of health policy at George Washington University School of Public Health and Health Services. Mr. Margulies is a J.D. candidate at George Washington University Law School and an M.P.H. candidate at George Washington University School of Public Health and Health Services.

## **ACKNOWLEDGMENTS**

The authors extend their special thanks to the many staff at the community health centers who participated in the case studies presented in this analysis.

---

*Editorial support was provided by Sarah Klein.*

## EXECUTIVE SUMMARY

Clinical integration of health care organizations is often seen as a means of boosting health care quality and efficiency. Interest in it has grown in recent years with a rapid escalation in health care costs and mounting evidence of the role of integration in slowing cost increases. The Patient Protection and Affordable Care Act (Affordable Care Act) encourages clinical and financial integration, doing so through its support of accountable care organizations and other innovations that promote partnership among health care providers.

Clinical integration through affiliation and collaboration has also been a long-established goal of community health centers, which now provide primary care services to approximately 20 million mostly uninsured Americans. Health centers are expected to provide care to millions more as the Accountable Care Act expands health care coverage to low-income Americans, many of whom live in the medically underserved communities where health centers operate.

Partnerships among health centers, hospitals, and clinics have enabled health centers to expand and enhance the services. For this reason, the Health Resources and Services Administration (HRSA), the federal agency that oversees health centers, supports collaboration including the formation of provider networks for shared services and joint contracting arrangements that serve to assure patients obtain the full range of services they need.

Despite the potential benefit of partnerships and encouragement from federal agencies, many health centers and their potential partners see the unique laws that govern health centers as impediments to their integration efforts. The concern is not without foundation. Section 330 of the Public Health Service Act, the statute that authorizes the establishment and operation of health centers, imposes significant requirements on health centers, including the legal obligation to serve all community residents regardless of their income, insurance status, or ability to pay for necessary health care. These requirements extend to a health center's collaborator. And failure to comply with the statute has serious consequences. The health centers not only risk losing Medicare, Medicaid, and Children's Health Insurance Program (CHIP) payments, but also other benefits and protections such as eligibility for a prescription drug discount program, special antifraud "safe harbors," and malpractice liability coverage.

The federal affiliation policy derived from the section 330 statute is designed to assure that in core matters—governance, senior financial and medical management, and overall clinical practice—health centers remain independent actors, free of the types of external pressures that could erode adherence to federal statutory obligations or cede operational and governance control as a result of economic, business, or personnel pressures.

Thus while federal guidelines encourage hospital referral arrangements, affiliations with specialty providers, admitting privileges and established arrangements for hospitalization, discharge planning and patient tracking, after-hours coverage, and participation in integrated delivery systems, they also impose certain affiliation limits, including a bar on arrangements in which a corporation obtains actual or effective control over a health center's board.

Despite these limitations, close examination of the legal framework of the health center program reveals that the law not only permits but encourages collaborations that further the health center mission. And as a review of ongoing affiliations reveals, health centers are widely engaged in collaborative activities. These affiliation and collaboration activities advance the goals of access, comprehensive care, quality improvement, and efficiency. Such health center collaborations are varied, but experts have identified several common types including:

- *Referral arrangements* in which the parties seek services from one another on a preferred basis and furnish services to the patients of each party.
- *Co-location arrangements* in which a provider, maintaining its own practice and control, agrees to treat patients referred to it, but in the referring provider's physical location. For example, a health center might agree to provide medical care to patients of a community mental health center, at the mental health center's site.
- *Nonexclusive contractual arrangements* in which health centers and their partners jointly contract for the purchase or provision of services or capacity, and operate with respect to these services on behalf of each other. As an example, a health center might enter into a relationship with a family planning program receiving federal support under the Public Health Service Act to offer enhanced services for adolescent patients because of the program's expertise in serving this population.
- *Umbrella affiliation agreements* in which a health center and its partner agree to undertake multiple collaborations and engage in joint planning under a broad and binding affiliation agreement. Health centers remain independent partners but

generally agree to act collaboratively in order to achieve specific goals. An umbrella affiliation might include a broad agreement to evaluate and develop shared systems or services, with specific subagreements around the purchase and management of electronic health record (EHR) systems or the joint purchase of specialized laboratory services.

- *Corporate integration strategies* that involve legal arrangements in which the partners develop a formal involvement in (but not control over) each entity's corporate governance, which in turn allows for a greater alignment of corporate activities and strategy while continuing to maintain the corporations as separate entities. This type of affiliation, which may require amendments to corporate bylaws as well as board resolutions, might be used when a health center desires to form a close affiliation with a major supplier of goods and services, such as the local hospital.
- *New health center sites*, a particularly fast-growing area in which a non-health center health care provider essentially converts an existing non-health center primary care clinic(s) into a health center service site that meets all federal health center requirements and is governed and operated by an existing health center with partner input.
- *Creating new non-health center entities* that are separate from the health center but are jointly governed by a health center and its partners.

This report outlines the laws and policies that govern collaborations between health centers and their partners, and profiles health centers that have worked within the legal framework to develop partnerships that benefit patients, while adhering to the health centers' core mission to assure health care for all patients regardless of insurance coverage, income, or ability to pay for services.

Similar collaborations will be increasingly common, as the federal government's \$11 billion investment in community health centers under the Affordable Care Act makes clinical integration between health centers and community partners even more feasible.

As this report illustrates, a well-designed federal strategy will foster such innovation both through policy issuance and expanded technical support, training, and learning opportunities that allow health centers and their partners to grow from one another's experience.



# **ASSESSING AND ADDRESSING LEGAL BARRIERS TO THE CLINICAL INTEGRATION OF COMMUNITY HEALTH CENTERS AND OTHER COMMUNITY PROVIDERS**

## **INTRODUCTION**

For over three-quarters of a century, health care experts have urged greater clinical and financial integration in health care as a means of boosting both the quality and efficiency of care.<sup>1</sup> In studies conducted by The Commonwealth Fund and others, clinical integration has been associated with higher value, stronger performance, and greater resource efficiency in the areas of patient care, case management, and use of health information technology.<sup>2</sup> The mounting evidence of the value of clinical integration in health care delivery and a rapid and continuing escalation in health care costs have spurred policymaker interest in clinical integration, as evidenced by the Patient Protection and Affordable Care Act (Affordable Care Act), which contains provisions that favor integration through the creation of accountable care organizations (ACOs) and the authorization of a range of federal demonstration efforts that promote partnership.<sup>3</sup>

In addition to promoting clinical integration, the Affordable Care Act also seeks to strengthen the nation's capacity for primary care by making a substantial investment in the nation's community health centers. These safety-net clinics, of which there are 1,200, provided primary care to approximately 20 million patients in more than 7,500 locations in 2010.<sup>4</sup> Over a five-year period beginning in 2011, the health reform law will provide \$11 billion in new, mandatory federal spending to support the expansion of health centers in urban and rural medically underserved communities and populations.<sup>5</sup> The funding is intended to enable the health centers to serve the estimated 30 million Americans who, as a benefit of the Affordable Care Act, will be newly insured by 2019.<sup>6</sup> Many of them will be low- and moderate-income individuals and families that live in medically underserved communities, which are disproportionately home to the uninsured and health centers.<sup>7</sup>

Beyond an investment in health center growth through grants and insurance expansion, the Affordable Care Act creates numerous opportunities for them to enter into more integrated and innovative community-based partnerships that broaden and secure patient access to the full continuum of health care services. These initiatives range from new funding to develop community-based collaborative care networks (defined as networks of health care providers, including health centers, that have a joint governance structure and provide comprehensive coordinated and integrated health care services to low-income populations) and to establish residency programs at health centers, to

incentives to form patient-centered medical homes (referred to as “health homes” in the Medicaid amendments enacted as part of the Affordable Care Act). Health center engagement in ACOs is also expected.

These initiatives share a common theme: an emphasis on prevention and continuity of care through the creation of service delivery arrangements that promote effective health care while increasing efficiency. Because they not only dovetail with long-established goals of the health center program, but are also priorities of the Health Resources and Services Administration (HRSA), the federal agency that oversees the health centers program, they offer health centers an unprecedented opportunity to expand and strengthen their operations.

Despite such opportunity, health centers will face challenges in achieving clinical and financial integration with new partners. Organized as private nonprofit health care corporations or public entities, they have already faced significant barriers in achieving fuller health care integration for their patients, particularly in the case of specialty care referrals, because of low Medicaid participation and a limited willingness in the case of the uninsured to treat health center patients for little or no compensation.<sup>8,9,10,11</sup> And questions often arise over the extent to which laws governing health centers and health center practice enable or impede integration and whether these challenges differ from those experienced by other nonprofit clinical providers.

Health centers also may be dissuaded from integrating for reasons wholly unrelated to law, including their desire to remain independent, challenges in finding willing partners, and/or the absence of a business case for integration. Business considerations may be an especially significant factor in the case of health centers because of the unique payment methodology for federally qualified health centers (FQHCs) that now governs health center reimbursement under the Medicare, Medicaid, and Children’s Health Insurance Program (CHIP), and ultimately the state health insurance exchange markets.<sup>12</sup>

The FQHC payment requirement is designed to protect health centers by averting the types of deep third-party payer discounts experienced by other primary health care providers; the quid pro quo, of course, is health centers’ legal obligation to serve all community residents regardless of their income, insurance status, or ability to pay for necessary health care. Health centers considering partnerships with other health care organizations must keep this legal obligation fully intact to preserve their grant funding (or FQHC status) for primary care to the uninsured. Nonetheless, and as discussed at

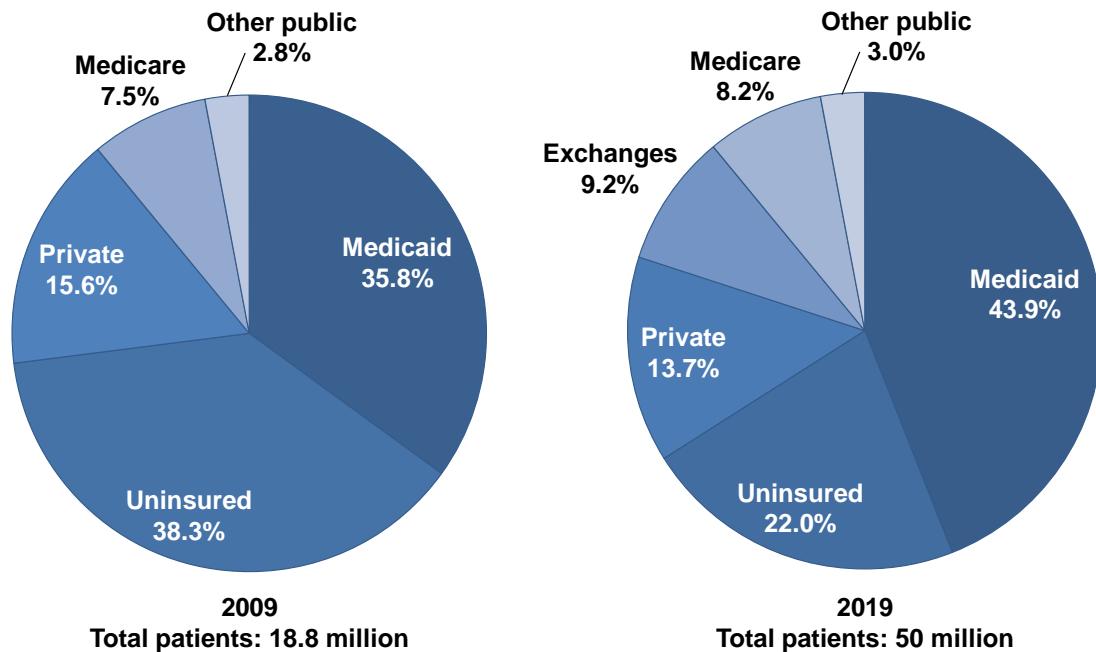
greater length below, the FQHC payment rules may allow health centers to share in savings related to FQHC services that result from fostering quality improvement and greater efficiencies.

Health centers must carefully weigh these legal obligations and consider the broader bodies of law as they apply to any nonprofit health care provider, such as tax law, fraud and abuse law, and antitrust law, all of which may be implicated by joint activities and collaborative arrangements.

But health centers should not be discouraged. Careful examination of the laws governing health centers reveals that health center collaboration is not only permissible but encouraged. And many health centers today are engaged in a dynamic array of clinical integration activities. HRSA has promoted the formation of scores of health center affiliations with community-based organizations, as well as provider networks for shared services and joint contracting, and health centers have long been active participants in Medicaid managed care programs, CHIP insurance products that utilize provider networks, and Medicare Advantage plans that also offer covered Medicare benefits through participating provider networks.

Although no national study has sought to quantify the full scope of health center affiliation activities, the case studies presented in this report underscore a range of health center innovations. With the dramatic expansion of insurance coverage for low- and moderate-income residents of medically underserved communities under the Affordable Care Act (shown in Exhibit 1), the importance of such affiliations can be expected to grow.

**Exhibit 1. Health Center Patients by Insurance Type, 2009 and 2019**



Sources: L. Ku, P. Richard, A. Dor et al., Strengthening Primary Care to Bend the Cost Curve: The Expansion of Community Health Centers Through Health Reform, No. 19 (Washington, D.C.: Geiger Gibson/RCHN Community Health Foundation Research Collaborative, June 2010).

## **THE UNIQUE LEGAL FRAMEWORK IN WHICH HEALTH CENTERS OPERATE**

All health care providers operate within a complex legal framework that is invoked whenever a provider considers engaging in a collaborative enterprise. Tax questions often arise when collaboration between a nonprofit health center and a for-profit provider such as a medical group practice generates revenues that lie outside of the health center’s charitable mission. And if not carefully structured and limited, a collaborative activity may be interpreted as a concerted action in restraint of trade, in violation of federal and state antitrust laws. Shared service and referral arrangements may also raise questions under federal and state fraud and abuse laws.

But beyond the general legal considerations that apply to any health care provider, special legal issues arise for health centers as a result of Section 330 of the Public Health Service Act (PHS Act), the statute that authorizes their establishment and operation. Initiated in 1965 using general legal pilot and demonstration authority, health centers have, since 1975, operated under the authority of section 330.<sup>13,14</sup> The Affordable Care Act further revised section 330 by elevating it to permanent legal authority status akin to

Medicare and Medicaid, thereby making periodic reauthorization no longer necessary as is the case with other PHS Act grant programs such as the Ryan White Care Act.<sup>15</sup>

To secure and maintain grant funding, applicants for grants, as well as program grantees, must agree to comply with all section 330 requirements on an initial and ongoing basis. Qualification as a section 330 grantee determines an entity's status as an FQHC for Medicare, Medicaid, and CHIP payment purposes as well as other protections that extend to FQHCs. Entities that meet section 330 requirements but do not receive a grant are known under the law as "look-alikes" and maintain FQHC status on this basis.<sup>16</sup>

Meeting the section 330 requirements applicable to health centers carries important legal benefits that go beyond eligibility to receive federal operating grants. In addition to FQHC payment protections that will extend to qualified health benefit plans participating in state health insurance exchanges, all FQHCs and FQHC "look-alikes" are eligible to participate in the prescription drug discount program authorized under section 340B of the PHS Act.<sup>17,18</sup> FQHCs also qualify for "safe harbor" protection from prosecution under federal antifraud laws that permit them to waive or reduce patient cost-sharing for Medicare, Medicaid, and CHIP patients.<sup>19</sup> FQHCs that receive section 330 operational funding also qualify for certain other legal benefits, including professional liability coverage under the Federal Tort Claims Act (FTCA) and a special antifraud "safe harbor" that permits health centers to accept no-cost and low-cost goods and services from affiliation partners.<sup>20</sup>

### **The Provisions of Section 330**

Section 330 contains four principal requirements that together define the legal parameters of a health center. Whether federally funded as an FQHC or designated as a FQHC "look-alike," a health center must meet these requirements to maintain its status:

- *Location:* Location in, or service to, communities and populations federally designated as medically underserved by the secretary of U.S. Department of Health and Human Services (DHHS) by virtue of the economic and health status of residents or population members and a shortage of primary care professionals;<sup>21</sup>
- *Comprehensive primary care:* Provision of a comprehensive range of primary health care services, defined in statute and regulation.<sup>22</sup> Most health centers also provide a broad array of supplemental services as permitted under the law.
- *Affordability:* Establishment of a schedule of charges that is designed to cover the health center's reasonable costs of operation consistent with locally prevailing rates

or charges, as well as a corresponding schedule of discounts, adjusted on the basis of patients' ability to pay in the case of individuals with family incomes at or below 200 percent of the federal poverty level. Fully discounted or nominal fees are imposed on individuals with family incomes at or below 100 percent of the federal poverty level.<sup>23</sup>

- *Governance:* Governance by a community-based board of directors, a majority of whose members must be active consumers of the health center's services and who collectively represent the health center's patients in terms of demographic factors such as race, ethnicity, and gender. The board as a whole must autonomously exercise the key authorities inherent in governance, which include the adoption of general operating and health care policies; approval of the health center's budget; evaluation of the health center's activities; and the selection, evaluation, and dismissal of the chief executive officer.<sup>24</sup>

Section 330 requirements reflect two equally important purposes. The first is to establish ground rules for direct federal investment in primary health care clinical services in medically underserved communities. Service to the entire community, including full participation in public insurance programs such as CHIP and Medicaid, is a program hallmark. Although health centers participate to a significant degree in private health insurance, their central mission is service to uninsured and publicly insured patients, who together comprise 75 percent of all health center patients.<sup>25,26</sup>

The second is community governance. The program's unique legal governance requirement is designed to assure that health centers remain formally accountable through an actual governance structure, and not merely advisory status, to their patients and communities. Indeed, the health center governance requirement dates to the program's earliest demonstration period.<sup>27</sup> As with all mission-driven organizations—whether private nonprofit, public, or religious, governance structure effectively becomes a feature of mission.

#### *Integration as a Section 330 Operating Requirement*

Integration is a basic element of section 330. The law specifically recognizes that health centers may not be able to furnish all required services directly and thus permits grantees to furnish services “either through the staff and supporting resources of the center or through contracts or cooperative arrangements.”<sup>28</sup> Section 330 thus permits health centers to provide services through contracts and referral arrangements if formally executed to assure the availability of care to patients. In addition, section 330 explicitly encourages health centers to collaborate with other community providers, requiring health centers to “make every reasonable effort to establish and maintain collaborative relationships with

other health care providers in the [service] area of the center...”<sup>29</sup> The law also provides that health centers develop ongoing referral relationships with at least one hospital.<sup>30</sup>

The statute thus not only allows but explicitly promotes collaborative and clinical integrative activities among health centers and between health centers and other providers. Indeed, the Affordable Care Act further amended the section 330 collaboration provisions by explicitly permitting health centers to engage in contractual collaborations with rural primary care providers who agree to accept health center patients without discrimination and prospectively discount their charges consistent with the health center’s discount schedule.<sup>31</sup>

#### *Policy Guidance on Collaboration*

Guidance issued by the Bureau of Primary Health Care (BPHC), the HRSA unit that oversees the health center program, goes into greater depth regarding permissible collaborations, while also identifying activities that, according to BPHC, might adversely affect health centers’ ability to comply with section 330 requirements. This operational guidance principally takes the form of Policy Information Notices (PINs) and Program Assistance Letters (PALs). Taken together, these policies set standards on integration and collaboration.

Of particular importance is the Policy Information Notice *Health Center Program Expectations* (PIN #98-23), which provides clarification and elaboration of the health centers’ legal framework. As PIN #98–23 states:

...collaboration is critical to ensuring the effective use of limited health center resources, providing a comprehensive array of services ... and gaining access to critical assistance and support .... Affiliations are desirable when they lead to integrated systems of care that strengthen the safety net for underserved clients.<sup>32</sup>

PIN #98-23 focuses on assuring that collaborating health centers have arrangements to support patients’ access to an appropriate continuum of care. While acknowledging that health centers should focus on primary and preventive care, BPHC expects them to “assess the full health care needs of their target populations, form a comprehensive system of care incorporating appropriate health and social services, and manage the care of their patients throughout the system.”<sup>33</sup> Key components of this system include: ongoing referral arrangements with one or more hospitals as well as with providers of specialty, diagnostic, and therapeutic services; admitting privileges or

established arrangements for hospitalization, discharge planning, and patient tracking; arrangements for after-hours coverage; and formation of or participation in integrated delivery systems.<sup>34</sup>

PIN #98–23 also places certain limitations on a health center’s ability to collaborate and clinically integrate with other providers. It specifies that when integrating with other providers, health centers:

...must ensure that all the laws, regulations and expectations regarding the health center governing board member selection, composition, functions and responsibilities are protected [and that] the resulting delivery system must contribute to the desired outcomes of availability, accessibility, quality, comprehensiveness, and coordination.<sup>35</sup>

Thus, collaborations cannot compromise health center governance standards, nor can they undermine the principal goal of creating access to health care for health center patients through the use of nondiscriminatory policies and the full use of prospective discounted fees.

Additional parameters and limitations of collaboration are found primarily in three additional policies governing health center operations. These policies relate to health center affiliations as well as the health center’s “scope of project” (the sites, services, providers, service areas, and target populations that comprise the health center project and that can be supported by a health center’s section 330 grant funds, grant-related resources, and certain FQHC-related benefits, as discussed in greater detail below). These policies—which apply to all federally funded health centers and have important application to “look-alike” health centers as well—have been reinforced by more recent policy guidance.

#### *Policy Guidance on Affiliation*

Health centers are expected to establish and maintain reasonable collaborative relationships with other health care providers in the relevant service area.<sup>36</sup> However, in 1997, in response to an increasing number of collaboration and clinical integration arrangements between health centers and other providers that potentially could have compromised legal and policy compliance and thereby jeopardized section 330 eligibility and FQHC status, BPHC issued PIN #97–27: *Affiliation Agreements of Community and Migrant Health Centers*. The key purpose of this PIN is to guide the formation of collaborations that strengthen health centers’ ability to provide comprehensive, cost-effective health care and related services while maintaining legal autonomy and integrity.



The PIN defines an affiliation as an “agreement that establishes a relationship between a [health center] and one or more entities.”<sup>37</sup> From BPHC’s perspective, an affiliation arrangement may be contractual in nature (i.e., focusing on a particular activity or combination of activities). It also may require corporate reorganization of the health center and/or its partners, involve the formation of a new entity, or may require some combination of these arrangements.

Regardless of the structural framework of a particular collaboration or clinical integration arrangement, the BPHC affiliation policy explicitly prohibits arrangements that affect a health center’s ability to comply with federal grant-related requirements as well as policies pertaining to the health center’s fundamental mission, corporate integrity and autonomy, and unique form of community accountability. Thus, while health centers are encouraged to forge collaborative and integrated approaches to clinical care, the arrangements themselves cannot include terms that would:

- impede the health center’s compliance with requirements related to the size, composition, and authority of its board of directors;
- interfere with the autonomy of the health center’s administrative, financial, and/or clinical operations; and/or
- allow another entity, including a collaborating partner, to control the health center’s relationships with other providers unless control will not adversely affect the health center’s ability to collaborate and coordinate with other local providers (that is, does not lock the health center into an exclusive arrangement).

The guidelines pay particular attention to corporate integration strategies between health centers and entities not subject to section 330-related requirements in cases in which the strategy involves an actual change to the corporate structure and identity of one or both parties, through, for example, consolidation or formation of a sole corporate member arrangement or other parent–subsidiary arrangement. Under this type of arrangement, one or more of the specific powers and authorities held by a health center board under law would instead be reserved to the sole corporate member or parent. The federal guidelines bar arrangements in which a sole corporate member (or parent) obtains actual or effective control over a health center board’s statutory powers and responsibilities and prohibit such arrangements unless preintegration approval is obtained and the health center can demonstrate that it remains compliant with all section 330-related requirements.

Thus, for example, BPHC would disapprove an affiliation arrangement in which a health center fully merges with, or becomes a subsidiary of, a hospital, thereby ceding corporate board control to the hospital. On the other hand, this policy does not prohibit a hospital from developing and then spinning off federally qualified health centers as independent corporate entities with their own governing boards, nor does it prohibit, as discussed below, a health center from partnering with a hospital to operate expanded outpatient services.

In 1998, BPHC amended its 1997 policy, issuing a second policy addressing affiliation-related issues. PIN #98–24 clarifies the agency’s position regarding collaboration/integration arrangements that entail modifications to staffing arrangements. BPHC prefers that health centers directly employ certain specified staff, but health center collaborative arrangements often may include the purchase of certain personnel services and/or professional capacity from another organization. PIN #98–24 addresses integration models under which a health center contracts with another entity for certain personnel services to be furnished by the other entity, specifically the positions of chief financial officer (CFO), chief medical officer (CMO), as well as the majority of its primary care clinicians.<sup>38</sup> This second policy limits federal approval to those arrangements that can show “good cause” by demonstrating that the health center derives programmatic benefit from the arrangement and maintains sufficient responsibility and accountability for the operation of the grant-approved project and the expenditure of grant funds in accordance with applicable rules. Thus, for example, a health center affiliation with a hospital or a multipractice specialty group generally might include CFO or CMO personnel only if the health center is able to demonstrate good cause (e.g., documentation that contracting with another entity to provide qualified CMO or CFO services rather than recruitment and direct employment by the health center will result in cost savings and greater expertise, and furthermore, that the contract will include provisions under which the contracted personnel report to and are under the control of the health center’s management and board).

In sum, the thrust of federal affiliation policy is to ensure that in core matters—governance, senior financial and medical management, and overall clinical practice—a health center remains an independent actor, free of the types of external pressures that could erode adherence to federal statutory obligations or cede operational and governance control because of economic, business, or personnel pressures.

### *Policy Guidance on Scope of Project*

In general, a health center's scope of project defines the activities and locations that can be supported by its total approved project budget, including federal grant funds, program income (i.e., revenues earned from Medicare, Medicaid, and private health insurance), and other federal, state, and local funds pledged to the project. Under federal policy, the scope of project comprises five core elements—sites, services, providers, service area(s), and target population(s)—for which the use of section 330 grant funds and related resources has been approved. The scope of project also defines:<sup>39</sup>

- with certain limited exceptions, the maximum scope of coverage under the Federal Tort Claims Act for the providers and activities of federally funded health centers;<sup>40</sup>
- eligibility for the Federal Drug Pricing Program under section 340B of the Public Health Service Act; and
- the service delivery sites and services eligible for enhanced payment under the Medicare, Medicaid, and CHIP programs.<sup>41</sup>

BPHC's scope of project policy does not directly address collaborations. However, the scope of project policy controls how the health center can use its section 330 grant funds and related resources. As a result, it is particularly important for health centers to include in their project scopes (as documented on certain standard forms submitted electronically to BPHC as part of the section 330 grant application) those aspects of their collaborations for which the health center maintains control. It is also important to request, prior to implementation, permission from BPHC to modify their project scopes, as reflected on the forms filed by the health center with BPHC, to reflect new arrangements so that they fall within the allowed scope of project. For example, if a health center and its collaboration partner decide to operate a new site or service that will be integrated into the health center's operation and managed under the FQHC umbrella, the health center would be expected to first secure BPHC permission to add that new site or service to its federally-approved scope if it wants to utilize section 330 funds, receive FQHC coverage and payment, and qualify for related resources/benefits.

Essentially the scope of project requirement assures that health center collaborations are consistent with its core mission and operations. Since service to the entire community is a paramount health center responsibility, this means that before an affiliation can be brought within the scope of project, the health center must assure that as with other required and in-scope supplemental services, the new services are readily available and reasonably accessible to all patients equally regardless of ability to pay and

on a sliding-scale fee/discount schedule.<sup>42</sup> This rule applies regardless of whether the service is furnished directly or through established arrangements with other providers. Thus, for example, if a health center partners with other community health care providers to secure laboratory and diagnostic services, these services—if brought within the scope of project—must be available to all health center patients regardless of their ability to pay and on a sliding-scale fee/discount basis. In a similar vein, health centers that enter into arrangements under which other providers furnish in-scope services to health center patients must obtain assurances from their partners that section 330 access and discount requirements will be met.

### *Guidance on Expansion Efforts*

The BPHC guidance related to certain health center expansion efforts now under way was issued in November 2010 and reaffirms earlier policies on collaboration. In PAL #2011–02 the agency both reiterates the collaboration language in the federal statute while also underscoring its belief that:

[C]ollaboration among safety-net providers is critical to maximizing resources and efficiencies in the health care system in underserved areas. As health centers seek new opportunities to create access to high-quality, coordinated care for patients, this collaboration will become even more important.<sup>43</sup>

Consistent with the Affordable Care Act amendments related to contracting with rural providers, BPHC PAL #2011–02 also recognizes that “collaboration and coordination can be especially critical in rural areas that face unique challenges in providing an integrated system of care ....”<sup>44</sup> Among other things, these challenges include problems in clinician recruitment, the challenge of reducing costs through economies of scale, and overcoming geographic barriers that prevent patients from obtaining care. In the agency’s view, these challenges can be mitigated through clinical coordination and integration among community providers that serve the same medically underserved populations. Accordingly, PAL #2011–02 encourages health centers to:

- evaluate the location of other safety-net providers and the services they furnish when developing expansion plans; and
- reflect in proposed expansion plans how the health center will collaborate with these other providers in furnishing coordinated care to the underserved population in the service area.

As with earlier affiliation policies, however, PAL #2011–02 also stipulates certain considerations that arise when health centers contract with other providers. Thus, while encouraging collaboration, BPHC also establishes factors that may limit health centers in the development of integrated care systems. Specifically, the guidance explicitly directs health centers (both federally funded and “look-alike” centers) as follows:<sup>45</sup>

- Health centers must maintain oversight over all sites and services included in their federally approved scopes of project, including ensuring that all patients have access to the health center’s full range of services.
- Health centers must ensure that all services included in their federally approved scopes of project (whether provided directly or by contract) are available to all health center patients regardless of their ability to pay.
- Grantees must continue to comply with all federal laws applicable to the program.
- To determine whether FQHC payment status under Medicare, Medicaid, and CHIP, as well as eligibility under the FTCA and the section 340B programs, will extend to contractual arrangements depends on whether the arrangements meet the specific requirements of those programs.

Similarly, the 2010 funding announcement for Affordable Care Act “New Access Point” grants emphasizes collaboration while underscoring health centers’ obligations to assure that collaborations benefit all health center patients. Thus, the announcement specifies as a review criterion written evidence of collaboration and coordination with other providers and agencies serving the same population, along with evidence of efforts to coordinate with other social service and community initiatives.<sup>46</sup> Applicants that do not show such collaboration are expected to justify its absence.<sup>47</sup> The presence of collaboration as a weighted factor demonstrates that collaboration has moved beyond an ideal and now functions as a standard element of every health center’s program.

### **Beyond Section 330: Other Legal Issues in Analyzing Health Center Collaborations**

Whether legal questions or considerations arise related to FQHC coverage and payment rules, section 340B drug discount eligibility, and Federal Tort Claims Act coverage in health center collaborations will depend on the type of collaboration and the role of the health center. In addition, in developing collaborations, health centers face legal issues that arise for many other types of health care providers, such as tax, antitrust, and fraud and abuse considerations.

In developing collaborations that accommodate the unique benefits and services that apply to health centers, a health center must continue to meet the requirements on which these benefits and services are conditioned. Essentially this means that a health center must continue to meet the governance autonomy and operational integrity required under section 330 and must limit the extent of the benefits and services for which it qualifies under other laws to its own services, operations, and patients. Put another way, because a health center is providing services under a collaboration arrangement does not absolve it from having to meet the requirements of applicable laws and programs, nor does its participation in the arrangement automatically extend these benefits to other partners.

*Federal Tort Claims Act (FTCA)*

Section 224 of the Public Health Service Act provides professional coverage under the FTCA for section 330 health center grantees, board members, employed health care professionals and certain individually contracted health professionals, if and when the health center successfully applies for and is deemed FTCA-covered by HRSA. Deeming depends on a series of steps including provider credentialing, ongoing risk management and quality assurance and improvement, and an agreement to cooperate with the U.S. Department of Justice. (Similar types of requirements would apply in private malpractice coverage arrangements as well.)

FTCA coverage has very specific parameters; as a result, collaboration with an FQHC does not necessarily result in blanket FTCA coverage for the collaboration. Furthermore, for health centers to maintain their FTCA coverage for collaborative services and activities, these activities must become part of their scope of project.

In general, the FTCA provides medical malpractice coverage for the health center and its qualified health professionals for services provided to health center patients and included in the health center's approved scope of the project. The services must fall within the scope of the professional's employment agreement or individual contract. FTCA coverage would not extend to health professionals employed by other institutions that execute contractual collaborations with health centers such as hospitals; at the same time, employment agreements or contracts that run directly between the health professional and the health center would qualify for FTCA coverage if the contract conforms to federal requirements. The FTCA will not cover medical, dental, or behavioral health students or residents who provide care at the health center under a residency training arrangement unless these clinicians are employed by the health center. Furthermore, health professionals employed by the health center and covered under the

FTCA are not covered if they provide health care services for or on behalf of another entity, even if such care is furnished pursuant to an affiliation agreement.

As a general rule, the FTCA covers only “in-scope” activities performed by the health center and its qualified health professionals to patients of the health center and at health center-operated sites. Federal policy, however, does extend FTCA coverage to certain non-health center patients and/or non-health center care settings (e.g., when conducting on-call and rounding duties at hospitals, carrying out reciprocal after-hours coverage arrangements, furnishing school-based services, or participating in immunization programs and health fairs).

For FTCA coverage to extend to new services or sites operated and controlled by the health center, whether the result of a health center corporate expansion or a collaboration arrangement, will depend, in part, on BPHC approval of a scope-of-project change request. Thus, maintaining FTCA coverage depends on assuring that collaborations fall within the health center’s scope of project, which in turn depends on the assurance that the service will be available to all health center patients regardless of ability to pay. Furthermore, because FTCA coverage is tied to an appropriately deemed health center, the activities of partner entities would not be FTCA-covered.

#### *Section 340B Drug Discounts*

Section 340B of the PHS Act, enacted into law as part of the Veterans Health Care Act of 1992, requires drug manufacturers to enter into agreements with DHHS to provide covered outpatient drugs to covered entities—which include all FQHCs (both federal grantees and look-alike entities)—at discounted prices (PHS prices) pegged to the price paid by state Medicaid agencies.<sup>48</sup> In implementing a section 340B program, a health center may operate an in-house pharmacy, subject to applicable licensing requirements, which can be managed by the health center directly or through a contract with a management services organization or other collaboration partner. Alternatively, the health center may enter into one or more contractual arrangements with licensed retail pharmacies (e.g., free-standing pharmacy, retail pharmacy located in a medical building, or pharmacy located in and operated by a hospital that is available to persons other than hospital patients) to dispense to health center patients the discounted drugs that have been purchased by the health center. Section 340B-purchased drugs may be dispensed only to the health center’s patients; patients of collaborating organizations (e.g., registered patients of a private medical practice that retains its independent corporate status) would not qualify for the discounted drugs. Nor would section 340B benefits extend to patients

of a new entity, even when jointly established and controlled by the health center and another provider(s) or a health center-controlled network or entity.<sup>49</sup>

Health centers remain responsible for assuring compliance with all section 340B requirements, including tracking drug purchases to assure that they benefit only health center patients, compliance with discounting requirements, and governmental and manufacturer audit requirements.<sup>50</sup> An affiliation with an entity that manages a health center's section 340B program or a contract with a retail pharmacy that dispenses section 340B-purchased drugs to health center patients does not absolve the health center of its obligation to assure compliance with federal requirements.

#### *General DHHS Regulatory Requirements*

By virtue of receiving federal grant funds, health centers are subject to various DHHS-wide requirements and regulations, including Office of Management and Budget requirements. Of particular importance are *Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations*,<sup>51</sup> and *Cost Principles for Non-Profit Organizations*.<sup>52</sup> Codified in DHHS regulations, these requirements specify administrative standards in areas that may be pertinent to collaboration, such as property acquisition, maintenance, and disposition; procurement of goods and services; financial management; and reporting systems and record-retention procedures.<sup>53</sup>

The federal procurement and property standards are of particular importance to health center collaborations, since both may affect the way in which certain aspects of clinical integration are developed and implemented. For example, health center affiliations involving the purchase of goods or services paid for in whole or in part with federal funds will be expected to comply with federal procurement standards that are designed to ensure open and fair competition. Thus, unless a particular collaboration partner or vendor can be shown to be uniquely qualified, the health center would be expected to select partners and vendors through competitive bids. However, once an affiliation is established, a health center can guarantee its partner ongoing collaborations in the form of future bidding rights and a right of first refusal if the ensuing bid is competitive and complies with all procurement requirements.

Similarly, health centers are subject to federal rules regarding the use and disposition of real property and equipment (acquisition cost of \$5,000 or more per unit) furnished and supported by federal funds. These rules may affect affiliations and collaborations among health centers, as well as between health center and non-health



center entities that intend to utilize federally supported property. Rules extend to both tangible and intangible property (i.e., intellectual property, in which the federal government retains a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use the work— or data first produced under a grant award—and to authorize others to do so). Accordingly, if a health center (or an entity involved in a collaboration arrangement in which the health center participates) is developing intellectual property (e.g., manuals, training systems) with the intent of treating it as proprietary (perhaps for purposes of resale), the health center should support the costs of development, management, and/or operation of the activity with nonfederal funds.

*Medicare, Medicaid and CHIP FQHC Coverage and Payment Rules and the Vaccines for Children Program*

Medicare and Medicaid provide coverage of federally qualified health center services, defined as a specific set of services that encompasses a range of professional and ancillary services that are furnished to patients of FQHCs.<sup>54</sup> FQHC services are financed in accordance with a prospective payment system (PPS),<sup>55</sup> and PPS payment rates are guaranteed regardless of whether payment comes directly from a state Medicaid agency, the Medicare program, a Medicare Advantage plan, or a Medicaid managed care entity. Comparable payment requirements apply to CHIP. In 2010, Congress extended the PPS payment system to qualified health plans participating in state health insurance exchanges.<sup>56,57</sup>

The PPS coverage and payment rules do not bar collaboration and integration efforts. At the same time, the payment is a guarantee only for the health center and cannot extend to partners. As with other benefits extended to health centers, PPS payments are a special arrangement whose reach is confined to services furnished by FQHCs and cannot transfer or pass through to non-health center entities. Therefore, collaborations must be scrutinized in order to ensure that the PPS payment methodology does not encompass services and activities controlled by a partner, and that any payments made by the health center to its collaborative partners do not reflect the exact amount of PPS payment the health center receives.

The FQHC payment system also raises questions regarding health centers' eligibility to participate in incentive-based payment models that necessitate more aggressive financial integration and require information about performance that may go beyond what is captured on FQHC cost reports, which focus on health center costs but not necessarily on costs to which payment incentives apply.<sup>58</sup> At the same time, the Centers for Medicare and Medicaid Services has stated in guidance that the FQHC

payment structure does not require managed care organizations to recoup incentives such as shared savings, if such incentives will result in payments to FQHCs exceeding the FQHC PPS payment rate (which effectively could discourage health centers from participating in any shared-savings arrangements). Rather, FQHCs are entitled to the full amount of their PPS payments, regardless of whether and the extent to which shared savings are achieved.<sup>59</sup>

In addition to FQHC coverage and payment rules, the Vaccines for Children (VFC) program raises legal issues for health center collaborations. Part of the Medicaid statute, the VFC statute provides for the distribution of vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) to participating health care providers who in turn immunize “vaccine eligible” children.<sup>60</sup> The federal government pays for VFC vaccines when furnished to VFC-eligible children at a 100-percent federal contribution rate rather than a state’s normal federal medical assistance percentage rate (FMAP). The vaccine payment under FMAP drops to the state’s regular rate in the case of vaccines not covered by ACIP recommendations as well as in the case of Medicaid-enrolled children who are not considered VFC-eligible.<sup>61</sup> Children with private health insurance who nonetheless are underinsured for vaccines are VFC-eligible only if they are patients of health centers,<sup>62</sup> meaning that underinsured children who receive vaccines from non-health center providers cannot qualify for VFC vaccines.

The impact of this gap ultimately may be eliminated as a result of Affordable Care Act provisions that extend immunization coverage on a first-dollar basis to members of all private health insurance and employee health benefit plans.<sup>63</sup> At the same time, as with other health center benefits, health centers in collaborative arrangements must assure that children who are not patients of the health center do not receive VFC vaccines. Over the years, questions have arisen as to whether health centers can clinically integrate with local health agencies and deputize agencies to act as FQHC service sites in order to extend VFC immunizations to greater numbers of underinsured children under the health center umbrella. DHHS has not clarified whether FQHCs have the legal authority to proceed with such agreements without creating or increasing the risk of and exposure to legal, operational, and financial liabilities.

## **HEALTH CENTER COLLABORATIONS: CONCEPTS AND EXAMPLES**

In considering the potential for greater clinical integration by and among health centers, it is important to consider the types of collaboration and affiliation arrangements health centers (as well as other providers) might develop. A comprehensive manual cosponsored by the National Association of Community Health Centers reinforces the basic message

reflected in BPHC policy: collaboration and affiliation are both a survival necessity in the modern health care system and a means of enhancing a strong marketplace position.<sup>64</sup>

The authors of the manual note that affiliation and collaboration may advance important goals and objectives such as expanding and enhancing the types of services available to patients as well as the continuum of care; expanding access locations through the co-location of services, restructuring service sites, and opening new sites; increasing the potential to deliver the appropriate care in the appropriate setting and at the appropriate time; maintaining and enlarging a health center's patient base and target population (for example, by acquiring a clinic previously operated by a hospital and adding the clinic and its patients to the health center's scope of service); improving management through shared functions; improving performance in the area of needs assessment and outreach; broadening visibility; reducing risk; increasing involvement in managed care; gaining access to capital; and providing a health center with the opportunity to be part of a service enterprise that the center could not achieve on its own.

The manual identifies several basic collaboration options:

- *Referral arrangements:* In a referral arrangement, partners formally agree to seek services from one another on a preferred basis and to furnish services to patients of the other provider.
- *Co-location arrangements:* A co-location arrangement consists of a partnership in which the provider, maintaining its own practice and control, agrees to treat patients referred to it, but in the referring provider's physical location (for example, a health center that agrees to provide medical care to patients of a community mental health center, at the mental health center's site).
- *Nonexclusive contractual arrangements:* In this type of arrangement, health centers and their community partners would enter into specific contractual agreements for the purchase or provision of services, or clinical/administrative capacity. Each party to the agreement maintains its own control and governance powers, with agreements focused on a particular service. Unlike a referral or co-location arrangement, the provider furnishing the services does so on behalf of the other provider that "purchased" the services. For example, voluntary family planning services are a primary required service of a health center; a center might enter into a relationship with a Title X clinic to send its adolescent patients to receive services at the Title X clinic because of that clinic's expertise in serving adolescents. The obligation to furnish and bill for the service, as well to ensure that the information about the diagnosis and care provided is recorded in the patient's medical record, remains with

the health center; at the same time, the Title X clinic carries out the actual service obligation on behalf of the health center.

- *Umbrella affiliation agreements:* In an umbrella affiliation agreement, a health center and its partner agree to explore multiple collaborations and proceed through a joint planning process under a broad and binding affiliation agreement, with separate implementation agreements as needed. Health centers remain independent partners in umbrella agreements but generally agree to act collaboratively in order to achieve specific goals while effectuating the activities and services developed under the umbrella agreement through specific subagreements. For example, an umbrella affiliation might include a broad agreement to evaluate and develop shared systems or services, with specific subagreements around the purchase and management of electronic health record (EHR) systems or the joint purchase of specialized laboratory services.
- *Corporate integration strategies:* The relationship of partners can be further extended through a legal arrangement in which the partners develop some involvement in (but not control over) each entity's corporate governance (such as cross-membership of corporate boards or participation on key board committees). This strategy allows an even greater alignment of corporate activities and strategy while continuing to maintain the corporations that are parties to the agreement as separate entities. This type of affiliation, which may require amendments to corporate bylaws as well as board resolutions, might be used when a health center desires to form a close affiliation with a major supplier of goods and services, such as the local hospital. In corporate integration that ultimately enhances the purchase of goods and services, federal procurement rules applicable to federally assisted projects, as well as general legal standards related to conflicts of interest and other matters, would apply.<sup>65</sup>
- *New health center sites:* One of the fastest-growing areas of collaboration involves the creation of new health center sites; that is, situations in which a non-health center health care provider essentially converts its existing non-health center primary care clinic(s) into a health center service site (or establishes a new facility as a health center service site) that meets all federal health center requirements, including autonomous governance by an independent community-based board, for purposes of payment and qualification for benefits such as the section 340B drug discount program, as well as eligibility for section 330 funding. This, in turn, would qualify the new health center site, as well as the services furnished and providers practicing at the site, for protection under certain fraud and abuse safe harbors and coverage under the Federal Tort Claims Act. Important considerations apply to this type of conversion when undertaken alone by the entity, but a partnership with an existing health center

would allow the entity to transfer one or more of its sites to the health center, at which point the sites would become part of the health center's organization for legal purposes of operation and governance. The health center would maintain ultimate control over the transferred sites, but the partners could work collaboratively in certain aspects of service provision or other non-service-related activities. In situations in which the non-health center partner is a hospital or health system, a partnership to convert the hospital or health system clinics into health center sites might be accompanied by a community benefit grant from the hospital/health system (although, in the case of a private nonprofit, tax-exempt hospital, whether such a grant would satisfy its section 501(c)(3) obligation to provide community benefit would remain a separate matter).

- *Creating new non-health center entities.* Health centers may also consider collaborations in which the parties form a completely new and separate entity that is jointly owned and controlled by the partners, through a governance structure that represents the parties to the agreement. Multiple types of new, special-purpose entities may be formed by health centers acting in collaboration with other providers. These include practice management organizations, management services organizations, multipurpose networks such as accountable care organizations or integrated delivery systems, managed care negotiating networks, provider-sponsored networks, and managed care organizations. Such entities may be structured as either for-profit or not-for-profit organizations.

Specific types of community partnership opportunities appear to be spurring modern health center affiliations and collaborations. Examples of these new, distinctive agreements include health center arrangements with critical access hospitals (including co-location of services or purchase of service agreements); local health departments (including co-location of services related to the Women's, Infants, and Children program or the purchase of service and referral arrangements); primary care residency programs that involve the rotation of residents through the health center's sites under which the residency program and the health center split responsibility for various components such as classroom teaching, direct patient care, quality assurance, resident recruitment, selection, and evaluation); emergency room care coordination alternatives (including referral and co-location arrangements, and transition/development of alternative delivery sites); agreements with oral, behavioral health, or specialty providers; and subrecipient agreements among two or more health centers to open a new access site.

All of these collaborative arrangements require adherence to section 330 laws and principles and section 330-related policies, as well as consideration of the types of legal

issues that arise for any health care provider, such as participating in appropriate joint planning processes; developing definitive legal documents; conducting sufficient mutual due diligence; obtaining regulatory approvals; and ensuring compliance with federal and state tax, antitrust, fraud and abuse, physician self-referral, False Claims Act matters, and other federal and state laws. But affiliations and collaborations involving health centers are common, as the Government Accountability Office found in a recent study of integrated delivery systems, and they are flourishing as the case studies included in this report illustrate.<sup>66</sup>

In selecting affiliations to highlight for this analysis, researchers surveyed a broad array of candidates identified through ongoing legal support activities furnished to health centers and their partners. These examples are not random; they are part of a wider group of activities in which health centers have sought qualified legal counsel, both locally and from national experts, to advise and guide their affiliation developments. They also illustrate the range of affiliation developments now under way involving health centers and their affiliation partners nationwide, and have been selected because they help provide understanding of the array of issues that arise in structuring and maintaining a broad array of affiliation agreements.

**Example 1: Community Health Center, Inc. (CHC), Middletown, Conn.**

CHC's model illustrates how health information technology is being used to facilitate clinical integration and improve clinical outcomes on a statewide (rather than local) basis.

*Type of integration.* CHC and its hospital and specialist partners created a statewide electronic health exchange, which allows them to share patient medical records and facilitate a seamless continuum of care.

*Background.* CHC is a statewide FQHC focused on providing services to low-income populations with unmet health care needs. CHC provides medical, dental, and behavioral health services to 100,000 patients in 12 cities at more than 170 service sites across the state of Connecticut. In addition to meeting the challenge of internally integrating such a broad range of operations, CHC expends great effort to closely coordinate care with local hospitals, specialty care providers, and home care providers, as well as other providers with which it shares patients.

*Integration details.* One of CHC's primary clinical integration initiatives has been the creation of electronic health exchanges with hospitals and specialists across the state to facilitate timely access to a complete patient record. As part of this effort, CHC

requires that patients affirmatively “opt in” to allow the sharing of their information through the health information exchange, rather than requiring patients to affirmatively “opt out.” However, in “opting in,” CHC informs patients that it will not withhold any element of the patient’s health record, including sensitive information (i.e., the patient cannot “opt in” for only portions of his or her record, while “opting out” for other portions), thus assuring providers at other sites of care (e.g., a hospital emergency department) that they have been provided the full clinical record. In CHC’s experience, this assurance diminishes an inherent skepticism among providers that they are not getting a full patient record, which frequently results in the duplication of tests. Patients retain the right to decline to have their record in its entirety in the exchange. To promote patient access to information, the health information exchange also includes a patient portal to give patients access to elements of their own record.

*Plans for additional integration.* CHC is in the process of establishing an electronic consultation and referrals exchange with local and statewide providers, including mechanisms for emergency room staff to directly schedule follow-up urgent care visits at CHC. In addition, CHC is collaborating with an academic medical center to improve timely, efficient access to specialists through an “eConsult” process. As part of this endeavor, primary care providers will be able to pose consult questions, along with relevant diagnostic and clinical information, to specialists within an established exchange. The specialist then responds to treatment questions within a designated time period with guidance and direction. This system, implemented effectively in other parts of the country, is expected to reduce the number of in-person patient visits needed as part of a consultation.

*Perceived legal barriers to integration.* CHC regularly involves internal and external legal counsel in establishing integrative collaborations with third parties. CHC reported that Health Insurance Portability and Accountability Act (HIPAA) and patient privacy issues have been the primary concern in establishing collaboratives involving the exchange and sharing of patient information. In developing the eConsult program, CHC has had to evaluate state licensure laws, as well as FQHC-specific legal concerns, including whether FTCA coverage could cover either the primary care providers or the consulting specialists (or both), and the appropriate billing for these services. However, the health center did not consider any of these legal concerns to be major barriers to effectuating integration activities. Instead, CHC reports that the main obstacles are cultural—namely, overcoming external inertia and the inherent opposition to establishing new, innovative models of care.

CHC also noted that the current FQHC prospective payment system, while not serving as a disincentive to integration per se, nevertheless does not effectively reimburse FQHCs for innovations such as the eConsult program or other innovative alternatives to traditional face-to-face encounters.

*Results of integration.* CHC reports that the results of its efforts to clinically integrate with local providers have been substantially positive. The electronic health exchange has materially increased provider access to key patient information at all points of care, promoting the coordination and continuity of care to patients and improved patient outcomes. Access to this broader range of information has served to stimulate new ideas for assessing and measuring patient outcomes and other criteria for determining quality of care. Similarly, the establishment of patient portals has materially improved patient access to information at points of care. In addition, CHC's telemedicine and e-consult initiatives are expected to result in substantial efficiencies in the use of staff and resources, while increasing access to specialists for both providers and patients.

**Example 2: RiverStone Health, Billings, Mont.**

RiverStone Health's model demonstrates a collaboration to develop infrastructure that facilitates integration, including the establishment of new, jointly operated/controlled entities to meet certain unique health care needs of the community.

*Type of integration.* RiverStone Health and its partners, a hospital and behavioral health care provider, established and operate a Web-based service record, as well as a community crisis center and a clinic for acute behavioral health needs that serves as a bridge between the health center and the behavioral health provider.

*Background.* Since 1984, the health department for Yellowstone city and county, now known publicly as "RiverStone Health," has operated a FQHC providing primary care services to the medically underserved residents in the area. In 1996, RiverStone Health became a sponsor of the Montana Family Medicine Residency Program, a program that was fully integrated within RiverStone Health in 2005. RiverStone Health now operates the residency, the only one of its kind in Montana.

*Integration details.* RiverStone Health participates in a number of integrative collaborations through a formal affiliation with two local hospitals in Billings, which is known as the Alliance. The Alliance (originally established through HRSA's Healthy Community Access Program) was created to cooperatively develop infrastructure and other mechanisms to facilitate clinical integration, thus minimizing emergency room and



hospital utilization. One such endeavor was the creation of a Web-based service record that allows each entity, as well as local social service agencies, to access (and add) clinical information at multiple points of care/service, thereby minimizing duplication of services and enhancing care management.

In addition, the Alliance (in conjunction with a local mental health center) has worked to fill a significant gap in the local health system by establishing a community crisis center—an intervention program designed to avoid emergency room treatment for individuals undergoing a psychological crisis, but who are otherwise medically stable. The crisis center is a nonprofit, limited liability company with the two hospitals and the regional mental health center as members. RiverStone Health assumes a governance role. In addition to providing short-term counseling, the center assesses patient health needs and establishes a referral plan to facilitate ongoing care. This collaboration included the creation of assessment tools to assist emergency medical service providers in determining the appropriate point of care for individuals, as well as extensive crisis intervention training for local law enforcement officers.

RiverStone Health and a local hospital psychiatric center have established a bridge clinic that provides behavioral health services to patients whose behavioral needs are too acute for RiverStone Health's scope of practice, but do not warrant inpatient psychiatric treatment. The bridge clinic is a program of the psychiatric center that serves to stabilize these patients, who are then referred back to RiverStone Health for primary care needs. RiverStone Health assists in defining the level of care and stabilization status at which care management and oversight can be transitioned to the primary care provider. In implementing this collaboration, both RiverStone Health and the hospital have worked to reassess and redefine their respective scopes of practice in order to determine the appropriate point of care for individual patients.

*Plans for additional integration.* RiverStone Health reports it is continuing to work closely with the Alliance, as well as other local providers, to create new strategies to fill unmet community needs. Those strategies, however, have not yet been determined.

*Perceived legal barriers to integration.* Despite the complexity of its clinical collaborations and its regular use of legal counsel in establishing arrangements, RiverStone Health has perceived few legal barriers. Instead, assuring compliance with HIPAA and patient privacy laws, as well as state licensure standards, has occupied most of RiverStone Health's attention. The health center considers limited resources and other

financial barriers as well as the inertia and skepticism to change to be primary obstacles to implementing clinical integration.

*Results of integration.* RiverStone Health reports that working collectively through the Alliance has facilitated its ability to confront problems, identify community solutions, and overcome an inherent resistance to change. In addition to significantly reducing unnecessary emergency room utilization, the crisis center also serves as the assessment facility for individuals who, in the past, might have been sent to the county jail, thus substantially reducing the number of inmates in the jail, as well as the time spent by law enforcement officers in emergency rooms or at the jail processing and booking arrests.

### **Example 3: Coos County Family Health Services (CCFHS), Northern New Hampshire**

CCFHS' model illustrates how geographically isolated providers can achieve clinical integration through technology that facilitates the coordination of clinical information exchange.

*Type of integration.* CCFHS and a nearby critical access hospital created and maintain an electronic medical records system. CCFHS also shares data nationally through its participation in multiple disease registries.

*Background.* CCFHS is an FQHC serving a sparsely populated area in northern New Hampshire. CCFHS is the only source of primary care within 30 miles. A local critical access hospital is the only other major provider serving this area and between the two organizations, they employ nearly all of the primary care and specialty providers in a broad frontier service area. Accordingly, CCFHS and the hospital have established a close working affiliation and cooperate extensively to coordinate care for a largely shared patient population.

*Integration details.* CCFHS links hospital departments and specialists to its EHR, giving them read-only access to patient records to facilitate the treatment and coordination of care for shared patients. Conversely, laboratory/diagnostic results and discharge notes from the critical care hospital are automatically sent to CCFHS for inclusion in its EHR.

In addition, CCFHS participates in multiple disease registry initiatives, including a nationwide pharmacy registry project. In conjunction with local pharmacies, nursing homes and home health agencies, CCFHS engages in activities designed to coordinate the

timely exchange of information necessary to promote medication management for patients using the blood thinner Coumadin, with the larger goal of decreasing adverse outcomes. Data results are electronically shared nationwide and participating organizations exchange information about care strategies to facilitate the creation of a best practices model.

CCFHS also participates in a nationwide diabetes registry project designed along similar lines to promote case management of diabetic patients. The local hospital assists in this initiative through the involvement of its certified diabetic educator, who serves as an invaluable resource in developing and managing treatment strategies for this difficult patient population.

*Plans for additional integration.* CCFHS is moving toward implementing a new telepsychiatry initiative with the local Veterans Administration to provide psychiatric counseling to military families and to support case management and treatment provided by CCFHS' behavioral health counselor. CCFHS recognizes the potential of telemedicine technology to help overcome the geographic barriers its rural area presents.

*Perceived legal barriers to integration.* CCFHS has perceived very few legal barriers to clinically collaborating with third-party providers, other than ensuring compliance with HIPAA and other patient privacy laws. CCFHS reports that neither federal antitrust and fraud and abuse laws, nor any FQHC-related laws and policies, have been encountered by either CCFHS or by the other participating providers as obstacles to collaboration. As a small organization with limited staff and other resources, financial concerns have represented the primary barrier to expanding clinical integration efforts with other local providers to date.

*Results of integration.* CCFHS reports many benefits resulting from its efforts to engage in integrative collaborations with local providers. The facilitated exchange of timely patient health information with the local hospital and CCFHS' participation in the pharmacy registry initiative have significantly improved continuity of patient care and patient outcomes as demonstrated by CCFHS' improvement in meeting required quality and clinical performance measures. Moreover, participation in a nationwide disease collaborative allows CCFHS to overcome the prevalent sense of geographic isolation by working closely with organizations across the country on ways to improve the efficiency and quality of care it provides to its patients.

**Example 4: South Boston Community Health Center (SBCHC), Boston, Mass.**

SBCHC's model provides an example of how participation in a citywide network comprising a large number of providers can provide access to technology, other resources, and clinical capacity that might not otherwise be available.

*Type of integration.* SBCHC and its hospital and community health center partners developed a large citywide provider network that participates in various electronic exchanges to share clinical information and coordinate care. Through its network connections, SBCHC also has access to additional providers, including specialists and residents in training programs.

*Background.* SBCHC is an FQHC that serves the medically underserved residents of South Boston. While SBCHC is governed and managed as a freestanding FQHC, it operates under the license of Boston Medical Center (BMC), as do other provider-based clinics. Thus, in some respects, SBCHC is able to access benefits from both worlds—as a provider-based clinic, SBCHC is able to access certain funds available through the state to support the costs of charity care provided by the hospital, and as a freestanding FQHC, it is able to gain access to FQHC benefits.

*Integration details.* SBCHC participates in significant clinical integration collaboratives through its membership in Boston HealthNet (HealthNet), a provider network that includes BMC and 15 local community health centers. Through HealthNet, SBCHC and eight local FQHCs have implemented an EHR that is linked with BMC's EHR system and which allows for the timely and efficient exchange of clinical information among participating providers, including access to inpatient notes and specialty notes. To ensure access to specialty services, SBCHC co-locates BMC cardiac and pulmonary specialists as well as BMC and Tufts University obstetricians at its facility. Additionally, BMC rotates 12 internal medicine residents through SBCHC. Boston University dental students provide pediatric dental care at SBCHC.

Through HealthNet, SBCHC also participates in an electronic referral system that substantially expedites and simplifies the process of scheduling referrals and tracking patients as part of case management activities. In addition, through its membership in the Massachusetts League of Community Health Centers, SBCHC participates in various disease collaboratives, as well as a patient-centered medical home collaborative that ultimately is aimed at enabling Massachusetts health centers to qualify for financial incentives through federal "meaningful use" requirements.

*Plans for additional integration.* Through the infrastructure established with HealthNet, SBCHC intends to participate in a new e-prescribing initiative that will allow SBCHC to access and track patient prescriptions across Massachusetts. SBCHC also plans to engage in a mutual effort with the HealthNet FQHCs to review respective disease registries, with the goal of creating one model registry.

*Perceived legal barriers to integration.* SBCHC relied extensively on HealthNet in addressing legal and other barriers in shaping these collaborations. In this respect, HealthNet executives indicated that there were substantial legal, financial, and cultural barriers (primarily establishing a sufficient level of trust between the health centers) that had to be overcome, with BMC's internal legal counsel having a predominant role in the resolution of those challenges. Compliance with HIPAA and other patient privacy laws has been perceived as the most significant legal obstacle. Further, given the number of collaboration partners and the potential impact the collaborations could have on the marketplace, antitrust also was identified as a notable legal concern.

*Results of integration.* SBCHC attributes a number of positive improvements in its provision of patient care to its participation in the clinical integration collaboratives. Through HealthNet, SBCHC has been able to establish an EHR system that it otherwise would not have been able to afford. The increased access and exchange of patient information among providers, as well as the expedited turnaround of, and ability to track, patient referrals has resulted in a noticeable improvement in patient outcomes, as demonstrated by SBCHC's improvement in meeting required quality and clinical performance measures. Additionally, the EHR system allows for the extraction and manipulation of data that SBCHC has used to enhance its ability to identify gaps in care and to support ongoing quality improvement activities.

**Example 5. Glide Health Services (GHS), San Francisco, Calif.**

GHS' model provides an example of how an FQHC focused on serving a special population—homeless individuals and families—collaborates with other local providers to integrate technology as well as non-service-related programs that work effectively to meet the unique challenges in serving this population.

*Type of integration.* GHS collaborates with other community clinics, local hospitals, and the local schools of nursing and pharmacy to provide all participating providers with electronic access to key information regarding shared patients. The collaborations enable the health center to provide FQHC patients with access to enhanced behavioral health and specialty care.

*Background.* GHS is a nurse-managed FQHC serving the homeless population in San Francisco and is a member of the San Francisco Community Clinic Consortium. GHS has a long history of partnership and shared mission with two local hospitals and the University of California, San Francisco (UCSF) Schools of Nursing and Pharmacy, all of which have established extensive clinical collaborations with GHS. These collaborations focus primarily on creating ways to enhance case management for the homeless, thus improving the efficiency and quality of treatment and minimizing acute care/emergency room episodes.

*Integration details.* With area hospitals, GHS has created linkages among electronic medical records systems to facilitate the electronic tracking and distribution of key patient information (including laboratory and diagnostic results, prescriptions, and discharge information) for shared patients. This has led to significant improvements in case management efforts, particularly with diabetic patients. In addition, GHS and one of its hospital partners have created a respite housing program to transition patients from the inpatient setting to an outpatient setting, thereby avoiding recurrent patient visits to the emergency room. This program utilizes patient navigators to facilitate case management between the hospital discharge department and GHS.

Other important clinical integration initiatives have focused on behavioral health case management and the enhancement of specialty care access for its high-need population. In particular, GHS has partnered with the local hospitals to bring a psychiatrist, two nurse practitioners, and two social workers on staff to help meet patient needs. To promote case management efforts, the collaboration includes a high level of ongoing interaction and conferencing with the hospital's case management department.

*Plans for additional integration.* The success in managing behavioral health care treatment has been significant, resulting in efforts to expand the model by establishing a wellness center focused on patients with chronic illness.

To facilitate access to specialty services, GHS is in the process of creating telemedicine consultation arrangements, including one with the UCSF School of Pharmacy.

*Perceived legal barriers to integration.* GHS indicated that at the outset of these collaborative activities there were few perceived legal barriers to clinical integration. Instead, cultural differences (including concerns regarding the ability of its collaborative partners to understand and address both language barriers and the unique cultural issues

faced by GHS' homeless patients, and the impact of these barriers and issues on the provision of health care services) were the primary barriers to collaboration. Further, as a nurse-managed center, GHS often encounters initial resistance from other providers unfamiliar with that organizational model and its clinical model of care, which centers on primary care provided by nurses rather than primary care physicians.

Over time, legal counsel for GHS and its partners have taken an expanded role in ensuring legal compliance when establishing collaborative activities, although GHS reported no particular federal or state laws (including HIPAA or other patient privacy laws) as a material obstacle. Instead, financial barriers have been, and remain, paramount. GHS continues to rely upon the hospitals to provide substantial financial support for the integrative initiatives, but the current economic climate in California has negatively impacted and slowed the development of such initiatives. Moreover, the ability to receive local funding for behavioral health services is an ongoing challenge.

*Results of integration.* Overall, GHS has recognized numerous benefits from its efforts to enhance clinical integration with its key provider partners, including marked improvements in minimizing hospital acute care utilization for its homeless population. It has greatly enhanced the coordination and management of care among the providers, as well as the ability of each provider to access critical, timely patient information at various points of care. GHS also reports that the integration has led to an increased understanding of how the linguistic barriers and cultural concerns faced by GHS' homeless patients affect the provision of health care services to such population, promoting a more unified advocacy for the health needs of the homeless population. The integration efforts have spurred the development of other innovative ways to promote quality improvement.

**Example 6: Cherokee Health Systems (Cherokee), Knoxville, Tenn.**

Cherokee's model provides an example of an FQHC that was initially created to integrate primary and behavioral health services, but has since expanded to include external collaborations for services not provided directly.

*Type of integration.* Cherokee integrates a full spectrum of primary care and behavioral health services in a single, seamless system, and externally collaborates with other local providers to offer specialty services that complement Cherokee's services. These external collaborations provide electronic access to health information for shared patients.

*Background.* Cherokee is a large FQHC with 20 sites in 14 counties. Originally established as a mental health center in the 1960s, Cherokee expanded its scope of practice to primary care in 1984 and was an early pioneer in creating a holistic, integrated model of care for the dual provision of primary care and behavioral health care services. This approach closely resembles a patient-centered medical home model wherein primary care and behavioral health clinicians function in teams to seamlessly manage patient care. Primary care patients are automatically screened for behavioral health issues and vice versa, and treatment for both is often provided to patients in the same visit.

*Integration details.* To implement its internal integration efforts, Cherokee has developed numerous evidence-based intervention and treatment protocols over the years. Primary care and behavioral health clinicians undergo extensive and ongoing training to appropriately manage patient care in accordance with this integrated model. To support and further its commitment and belief in an integrated care model, and to utilize its extensive experience in establishing such a model, Cherokee has created an integrative care training academy that educates providers from across the country on establishing this model of care.

Cherokee's integrative approach has been expanded to external collaborations with local specialists interested in adopting Cherokee's integrated approach to care delivery, including a local sleep center. The sleep center works with Cherokee's behavioral health providers to develop evidence-based intervention protocols for Cherokee's patients with sleep disorders. Similar collaborations have been established with other community providers, resulting in intervention protocols used to assess patient care needs quickly and effectively in Cherokee's clinics. In addition, Cherokee has developed technological capabilities with a local hospital to allow electronic access to patient information for shared patients.

*Plans for additional integration.* Cherokee continues to identify ways in which it can externally collaborate with local providers to offer patients a full continuum of services, including specialty care.

*Perceived legal barriers to integration.* Given that Cherokee's initial integration efforts were largely confined to a single entity, the health center perceives few legal barriers to integration. Instead, the primary initial barrier was bridging the cultural divide between mental health and primary care providers. However, Cherokee indicated that legal barriers do exist, most notably those related to payment as an FQHC and



reimbursement for behavioral health services, more generally. Further, barriers involving state-based licensure and corporate practice of medicine laws also have arisen.

Cherokee has noted that the FQHC PPS system may limit more global integration of behavioral health care because the PPS payment methodology covers only a portion of the range of services that patients receive. As a result, in the case of its privately insured patients, Cherokee has sought to test other payment models that allow it to receive a more fully global payment covering all phases of health care, with incentive structures that are tied to patient outcomes.

With respect to its external collaborations, Cherokee has employed legal counsel liberally to ensure legal compliance, and notes federal antitrust law and federal and state fraud and abuse laws as particular areas of concern. However, ensuring such legal compliance has not been viewed as a major barrier to the development of integrative arrangements with local providers.

*Results of integration.* Cherokee reports that its emphasis on integrating primary care and behavioral health and its collaborations to enhance the coordination of care among local providers has had a substantial, positive impact in improving patient care and outcomes. In addition, the close interaction between providers has had a major impact in enhancing provider cultural competency with Cherokee's multiethnic patient population, as well as informal peer review among providers that has increased the qualitative level of provider services and the general standard of documenting patient information and treatment.

## **DISCUSSION**

While federal law and policy underscore the importance of collaboration among health care providers, health centers will inevitably face barriers to collaboration as their collaborators must be willing to honor the core mission of health centers. That mission requires them to provide access to comprehensive primary and preventive health care services to all medically underserved patients in a community in accordance with principles of affordability and to do so in a manner that fully adheres to the governance requirements of the program.

Nevertheless, health centers—with their longstanding history of quality, efficiency, and community accountability—find themselves increasingly drawn to collaboration opportunities with numerous partners. An assessment of collaborative activities reveals a rich array of affiliation activities, from teaching and training to shared

services and integrated health care activities. This range of activities can be expected to grow as health centers expand.

The examples presented in this analysis illustrate collaborative activities ranging from simple partnership agreements to extensively structured legal agreements in which centers are forming new enterprises and acting in collaboration with a range of community providers that share their core mission. The analysis also shows that health center collaborations must and can be carried out in compliance with governing section 330 principles as well as the laws that create services, benefits, and protections for health centers and their patients. These laws and principles can be adapted to the imperatives of a changing health care system.

The basic check on health centers' ability to collaborate and affiliate is agreement among the partners or members of a new enterprise to comply with the fundamental obligation of a health center to serve all members of a community. This fundamental obligation has two dimensions to it: first, the obligation of a health center to assure that the services that fall within the "scope of its project" remain fully available and accessible to all members of the community regardless of ability to pay, even when those services are provided by partners at sites other than the health center; and second, the health center program's governance obligation, which dates to the earliest days of health center pilots and which assures a voice in health care by patients themselves. All mission-driven providers face the legal challenge of how to respond to changing health system dynamics without sacrificing their core mission. In the case of health centers, this core mission relates to the consumer- and patient-driven nature of the health center program, rather than the broader community benefit standard that governs private, nonprofit health care corporations or the special mission that guides religious institutions.

Furthermore, health centers, like other community providers, face other challenges to collaboration that fall well outside the legal arena. A health center, like a physician practice or a community hospital, may value its independence and control. Like a physician practice or hospital, health centers need to understand the business and clinical case for affiliation. From a legal perspective, however, BPHC/HRSA policies encourage rather than inhibit collaboration, as evidenced by both written policies and the broad array of health center collaboration activities now under way.

A well-designed federal strategy that promotes collaboration innovations not only through policy issuance but also with expanded technical support and training and collaborative learning opportunities that allow health centers to learn and grow from one

another would foster greater diffusion of innovations—as well as greater clarity of and evolution in the legal issues that surround collaboration. Were the federal government to establish a health center collaboration innovation program as part of its efforts to advance clinical integration throughout the health care system, it could create a home for collaboration while at the same time allowing health centers to derive the benefits of collective efforts and to share technical assistance and support.

## NOTES

<sup>1</sup> See, e.g., W. H. Smith, “Report on the Committee on the Cost of Medical Care,” *Canadian Medical Association Journal*, Feb. 1933 28(2):198–99.

<sup>2</sup> See, e.g., A. Shih, K. Davis, S. C. Schoenbaum, A. Gauthier, R. Nuzum, and D. McCarthy, [\*Organizing the U.S. Health Care Delivery System for High Performance\*](#) (New York: The Commonwealth Fund, Aug. 2008); Medicare Payment Advisory Commission, *Report to Congress* (Washington, D.C.: MedPAC, June 2009); H. H. Pham, P. B. Ginsburg, T. K. Lake et al., *Episode-Based Payments: Charting a Course for Health Care Payment Reform* (Washington, D.C.: Center for Studying Health System Change, Jan. 2010); and E. S. Fisher, M. B. McClellan, J. Bertko et al., “Fostering Accountable Health Care: Moving Forward in Medicare,” *Health Affairs* Web Exclusive, Jan. 27, 2009 28(2): w219-w231.

<sup>3</sup> See, e.g., Patient Protection and Affordable Care Act (PPACA) §2705, which authorizes a Medicaid Global Payment System that emphasizes safety net hospital systems and networks; PPACA §2706, which authorizes Pediatric Accountable Care Organization demonstration projects; PPACA §3021, which establishes Health Innovation Zones and the Center for Medicare and Medicaid Innovation to test care coordination and fully integrated care for dual eligibles, as well as other reforms; PPACA §3023, which authorizes a national pilot program on payment bundling around hospitalization-related episodes of care; PPACA §3024, which authorizes Independence at Home Demonstration Programs; PPACA §3025, which establishes a hospital readmission reduction program aimed at incentivizing better coordination of care around hospital discharges; and PPACA §3026, which authorizes a community-based care transitions program for high-risk Medicare beneficiaries spanning both inpatient and outpatient care.

<sup>4</sup> National Association of Community Health Centers, “America’s Health Centers,” Fact Sheet (Aug. 2010), <http://www.nachc.org/client/America's%20Health%20Centers%20updated%2009%2010.pdf>.

<sup>5</sup> The continuing resolution for FY 11 (HR 1473) reduces discretionary health center outlays by \$600 million, thereby reducing total available expansion funding by the amount needed to maintain current operations.

<sup>6</sup> S. Rosenbaum, P. Shin, E. Jones et al., *Community Health Centers: Opportunities and Challenges of Health Reform* (Menlo Park, Calif.: Kaiser Family Foundation, Aug. 2010), <http://www.kff.org/uninsured/upload/8098.pdf>.

<sup>7</sup> S. Rosenbaum, E. Jones, P. Shin et al., *National Health Reform: How Will Medically Underserved Communities Fare?* Policy Research Brief #10 (Washington, D.C.: Geiger Gibson/RCHN Community Health Foundation Research Collaborative, July 2009), [http://www.gwumc.edu/sphhs/departments/healthpolicy/dhp\\_publications/pub\\_uploads/dhpPublication\\_5046C2DE-5056-9D20-3D2A570F2CF3F8B0.pdf](http://www.gwumc.edu/sphhs/departments/healthpolicy/dhp_publications/pub_uploads/dhpPublication_5046C2DE-5056-9D20-3D2A570F2CF3F8B0.pdf).

<sup>8</sup> A health center may be a private 501(c)(3) corporation. A health center also may be formed by a public agency or corporation (e.g., a local health department or a public hospital system), which then operates the entity under the direction of a “co-applicant board” meeting the patient-majority requirements.

<sup>9</sup> See e.g. A. Dor, Y. Pylypchuk, P. Shin et al., *Uninsured and Medicaid Patients’ Access to Preventive Care: Comparison of Health Centers and Other Primary Care Providers* (Washington, D.C.: Geiger Gibson/RHCN Community Health Foundation Research Collaborative, Aug. 2008); M. H. Chin, S. Cook, M. L. Drum et al., “Improving Diabetes Care in Midwest Community Health Centers with the Health Disparities Collaborative,” *Diabetes Care*, Jan. 2004 27(1):2–8; B. E. Landon, L. S. Hicks, A. J. O’Malley et al., “Improving the Management of Chronic Disease at Community Health Centers,” *New England Journal of Medicine*, March 1, 2007 356(9):921–34; J. Hadley, P. Cunningham, and J. L. Hargraves, “Would Safety-Net Expansions Offset Reduced Access Resulting from Lost Insurance Coverage? Race/Ethnicity Differences,” *Health Affairs*, Nov./Dec. 2006 25(6):1679–87; L. S. Hicks, A. J. O’Malley, T. A. Lieu et al., “The Quality of Chronic Disease Care in U.S. Community Health Centers,” *Health Affairs*, Nov./Dec. 2006 25(6):1713–23; K. D. Frick and J. Regan, “Whether and Where Community Health Centers Users Obtain Screening Services,” *Journal of Healthcare for the Poor and Underserved*, Nov. 2001 12(4):429–45; and R. M. Politzer, A. H. Schempf, B. Starfield et al., “The Future Role of Health Centers in Improving National Health,” *Journal of Public Health Policy*, 2003 24(3/4):296–306. See also “Studies of Health Center Quality of Care,” a compilation of quality studies in the literature published by the National Association of Community Health Centers, <http://www.nachc.org/client/documents/HC%20Quality%20Studies%2008.09.pdf>.

<sup>10</sup> Primary Care Development Corporation, *Safety Net Providers Qualify as Medical Homes* (New York: PCDC, Nov. 2009), [http://www.pcdcnyc.org/index.cfm?fuseaction=cms.viewPage&organization\\_id=128&page\\_id=7950&section\\_id=1896&command=DISPLAY\\_DETAILS&news\\_id=125](http://www.pcdcnyc.org/index.cfm?fuseaction=cms.viewPage&organization_id=128&page_id=7950&section_id=1896&command=DISPLAY_DETAILS&news_id=125).

<sup>11</sup> M. K. Gusmano, G. Fairbrother, and H. Park, “Exploring the Limits of the Safety Net: Community Health Centers and Care for the Uninsured,” *Health Affairs*, Nov./Dec. 2002 21(6):188–94.

<sup>12</sup> All federally funded health centers, as well as clinics funded through other sources that receive federally qualified health center certification (“look-alike” FQHCs), are eligible for special coverage and payment recognition under Medicare and Medicaid, as well as certain payment protections under the separately administered Children’s Health Insurance Program. FQHC payment rules will also apply to qualified health plans operating in state health insurance exchanges.

<sup>13</sup> K. Davis and C. Schoen, *Health and the War on Poverty: A Ten-Year Appraisal* (Washington, D.C.: Brookings Institution Press, 1977).

<sup>14</sup> Section 330 of the Public Health Service Act, codified at 42 U.S.C. §254b.

<sup>15</sup> PPACA §10503.

<sup>16</sup> As of 2010, approximately 100 FQHCs operated as “look-alike” health centers; while they do not receive federal operating funds, they are certified as community health centers for FQHC payment and other purposes.

<sup>17</sup> CHIP programs operated as part of Medicaid expansions must comply with Medicaid’s FQHC coverage and payment rules under 42 U.S.C. §1397gg(e)(1). FQHC services are not a category of service coverage under separately administered CHIP programs, but FQHC payment rules apply to the CHIP covered benefits furnished by FQHCs.

<sup>18</sup> PPACA §1302(g).

<sup>19</sup> 42 U.S.C §1320a-7b(b)(3).

<sup>20</sup> 28 U.S.C. §§1346(b), 2401(b), and 2679-81; 42 U.S.C. §1320a-7b(3), implementing regulations at 42 C.F.R. §1001.952(w).

<sup>21</sup> See 42 U.S.C. §254b(a)(1).

<sup>22</sup> The statute identifies the following “required” services: diagnostic, treatment, consultative, referral and other services rendered by physicians and allied health professionals; pharmaceutical services as appropriate for the health center; diagnostic laboratory and radiologic services; preventive health services; medical social services; nutritional assessments and referrals; preventive health education; prenatal and postpartum care; well-child care, including vision and hearing examinations; immunizations; voluntary family planning services; emergency medical services, including provision for access to health care for medical emergencies during and after regularly scheduled hours; health education, outreach, and transportation; and preventive dental services. See 42 U.S.C. §254b(b)(1). Health centers also may furnish certain supplemental services defined as inpatient and outpatient hospital services, home health services, extended care facility services, rehabilitative services, mental health services, dental services, vision services, ambulatory surgical services, and other services as needed by their specific communities.

<sup>23</sup> See 42 U.S.C. §254b(k)(3)(G); see also 42 C.F.R. §51c.303(f).

<sup>24</sup> See 42 U.S.C. §254b(k)(3)(H); see also 42 C.F.R. §51c.304. Health center regulations also provide additional requirements for the nonconsumer members of the governing board, including selection based on expertise in various fields and limitation on the number of individuals earning more than 10 percent of their annual income from the health care industry.

<sup>25</sup> Participation in private health insurance comes at a considerable cost: health centers lost an estimated \$8.98 billion in revenues from 1997 to 2007 in serving privately insured patients. Private health insurance covers an estimated 57 percent of health centers’ operational costs compared with more than 80 percent in the case of Medicaid. S. Rosenbaum, P. Shin, and B. Finnegan, *Community Health Centers in an Era of Health System Reform and Economic Downturn: Prospects and Challenges* (Menlo Park, Calif.: Kaiser Commission on Medicaid and the Uninsured, 2009), <http://www.kff.org/uninsured/upload/7876.pdf>.

<sup>26</sup> Rosenbaum, *Community Health Centers: Opportunities and Challenges*, 2010.

<sup>27</sup> The impact of this governance requirement on health center performance is discussed in Davis and Schoen, *Health and the War on Poverty*, 1977.

<sup>28</sup> See 42 U.S.C. §254b(a)(1).

<sup>29</sup> See 42 U.S.C. §254b(k)(3)(B).

<sup>30</sup> See 42 U.S.C. §254b(k)(3)(L).

<sup>31</sup> PPACA §5601(b), amending §330(r)(2)(4). Rural providers include but are not limited to rural health clinics, low-volume hospitals, critical access hospitals, sole community hospitals, and Medicare-dependent share hospitals.

<sup>32</sup> See PIN #98–23 at p. 9.

<sup>33</sup> *Ibid.* at pp. 15–16.

<sup>34</sup> *Ibid.* at p. 16.

<sup>35</sup> *Ibid.* at pp. 9–10.

<sup>36</sup> This requirement has been interpreted to discourage health centers from entering into exclusive arrangements with other entities, under which the health center would be prohibited from contracting with other parties and/or would be required to grant affiliation partners absolute rights to provide other services to the health center without requiring that the health center first comply with federal procurement standards.

<sup>37</sup> See PIN #97–27 at p. 5.

<sup>38</sup> The policy bars contracting for a health center’s CEO and requires that the CEO be directly employed by the health center.

<sup>39</sup> See PIN #2008–01 at pp. 2–3.

<sup>40</sup> BPHC scope of project standards are critical in determining the extent to which health center staff and the health center itself can claim coverage under the Federal Tort Claims Act. For example, BPHC may include in-scope those services and activities provided by part-time, non-primary care contractors, organizational (rather than individual) primary care contractors, and volunteers. These individuals would not be covered under the FTCA under current FTCA rules, although the health center would still be covered. In addition, BPHC may allow a health center to include in its approved scope of project certain services provided to non-health center patients (for example, coverage of another community physician’s patients by a health center physician) or services provided at non-health center sites (for example, rounds made by a health center physician at an area nursing home to patients, some of whom are not patients of the health center). Despite the fact that these activities are within the health center’s approved scope of project, the U.S. Department of Health and Human Services Office of General Counsel and the Department of Justice take the position that they do not qualify for FTCA coverage unless the arrangements satisfy certain very specific conditions.

<sup>41</sup> It is not yet clear how BPHC scope of project policies will operate in relation to FQHC payments by qualified health plans operating in state health insurance exchanges, since such plans are not “government programs.”

<sup>42</sup> See PIN #2008–01 at pp. 10–11.

<sup>43</sup> See PAL #2011–02 at p. 2.

<sup>44</sup> *Ibid.*

<sup>45</sup> *Ibid.* at p. 3.

<sup>46</sup> See HRSA-11-017 at p. 47.

<sup>47</sup> *Ibid.* at pp. 47–48.

<sup>48</sup> See 42 U.S.C. 256b, as amended by §602 of P.L. 102-585 (Nov. 11, 1992).

<sup>49</sup> Diversion of the covered drugs to individuals who are not health center patients constitutes a violation of Section 340B and may subject the health center to disqualification from the 340B program, audit by the federal government and pharmaceutical manufacturers, and an obligation to pay the 340B discount differential back to pharmaceutical manufacturers with interest.

<sup>50</sup> A health center participating in Section 340B provides information to the Office of Pharmacy Affairs regarding its Medicaid billing arrangements, including its Medicaid billing number. This information is used to avoid duplicative discounts/rebates being paid by manufacturers for the same drug (i.e., a discount to the health center upon purchase of the drugs and a rebate to the state Medicaid agency for claims submitted for Medicaid beneficiaries served by the health center).

<sup>51</sup> OMB Circular A-110 (Nov. 19, 1993, as amended Sept. 30, 1999; relocated to 2 C.F.R. Part 215).

<sup>52</sup> OMB Circular A-122 (May 10, 2004, relocated to 2 C.F.R. Part 230).

<sup>53</sup> 45 C.F.R. Part 74.

<sup>54</sup> 42 U.S.C. §§1395(l) & 1396a(bb).

<sup>55</sup> Ibid.

<sup>56</sup> 42 U.S.C. 1397gg(e)(1).

<sup>57</sup> PPACA § 1302(g).

<sup>58</sup> As Medicaid has moved to a PPS rate, some states no longer require the filing of FQHC Medicaid cost reports. It remains to be seen whether the same will hold true for Medicare cost reports upon implementation of the Medicare PPS rate.

<sup>59</sup> In a letter to state Medicaid directors, the Centers for Medicare and Medicaid Services stated that managed care organizations (MCOs) may offer FQHCs incentives to promote savings, and that “these incentive amounts (whether positive or negative) are separate from the MCO’s payment for services provided under the subcontract, do not include any additional federal funding, and should not be included in the state’s calculation of supplemental payments due the FQHC/RHC.” Centers for Medicare and Medicaid Services, State Medicaid Director Letter: Policy Regarding FQHCs/RHCs (Sept. 27, 2000), <http://www.cms.gov/SMDL/SMD/itemdetail.asp?filterType=none&filterByDID=0&sortByDID=1&sortOrder=ascending&itemID=CMS063855&intNumPerPage=10>. Following the passage of the Benefits Improvement and Protection Act of 2000, CMS reaffirmed this policy against including incentives in determining FQHC payment rates. See CMS, “Benefits Improvement and Protection Act (BIPA) of 2000, Section 702, Prospective Payment System for Federally Qualified Health Centers and Rural Health Clinics: Q’s and A’s,” question #38.

<sup>60</sup> See 42 U.S.C. § 1396s. Vaccine-eligible children consist of children under 18 who are Medicaid-eligible, uninsured, Native American children as defined under the law, and certain children with private health insurance who are uninsured for immunizations. 42 U.S.C. §1396s(b).

<sup>61</sup> The VFC program ends at age 18; as a result, vaccines would be paid at the normal FMAP rate for those ages 18–21.

<sup>62</sup> 42 U.S.C. §1396s(b).

<sup>63</sup> PPACA §1001.

<sup>64</sup> J. C. Leifer and M. H. Zakheim, *Collaborative Arrangements 2011—A Guide for Health Centers and Their Partners* (Washington, D.C.: National Association of Community Health Centers, 2010) [pre-publication draft].

<sup>65</sup> 45 C.F.R. Part 74.

<sup>66</sup> U.S. Government Accountability Office, *Health Care Delivery: Features of Integrated Systems Support Patient Care Strategies and Access to Care, but Systems Face Challenges* (Washington, D.C.: GAO 11-49, Nov. 2010). GAO noted the following challenges: nonpayment by private insurers for case management; finding specialty services for medically underserved populations; sharing clinical and management systems; and practice culture. The GAO study specifically identified CHC collaborations as part of the integrated delivery system activities of Denver Health, Parkland Health & Hospital System, the Henry Ford Health System, and the Marshfield Clinic.