

AFFILIATIONS

BETWEEN HEALTH CENTERS AND

OTHER COMMUNITY-BASED

PROVIDERS

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Acknowledgments/ Disclaimer

Affiliations Between Health Centers and Other Community-Based Providers highlights the legal and policy-related issues that are uniquely relevant to arrangements to which health centers are a party, as well as other Federal law considerations common to health provider collaborations.

This publication was prepared for the National Association of Community Health Centers, Inc. (“NACHC”) by attorneys with the law firm of Feldesman Tucker Leifer Fidell LLP. It is designed to provide accurate and authoritative information in regard to the subject matter covered. While based on the principles of Federal law, this manual is published with the understanding that it does not constitute, and is not a substitute for, legal, financial or other professional advice. Health centers should consult knowledgeable legal counsel and financial experts to structure and implement an affiliation arrangement that is appropriate given the particular parties’ respective goals, objectives, and expectations.

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Table of Contents

	<u>Page</u>
CHAPTER 1: Introduction	1
A. What is an Affiliation	2
B. Reasons to Form an Affiliation	3
C. Establishing New Health Center Sites and/or Organizations	4
D. Legal Considerations related to Affiliation Arrangements	8
CHAPTER 2: Affiliation Options	10
A. Informal “Handshake” Agreements	11
B. Formal Contracts	12
C. Establishment of a New Entity	22
D. Corporate Participation and/or Integration	28
E. Public Entity Model	32
F. Health Center to Health Center Corporate Affiliations	35
CHAPTER 3: Predictable Steps in Negotiating Affiliations	43
Step 1: Value Assessments	44
Step 2: Affiliation Alternatives and Partners	46
Step 3: The Confidentiality Agreement	47
Step 4: The Non-Binding Memorandum of Agreement (“MOA”)	49
Step 5: The Joint Planning Process	51
Step 6: Mutual Due Diligence	52
Step 7: Regulatory Approvals	53
Step 8: Definitive Agreements	55
CHAPTER 4: Legal Considerations Related to Affiliations	56
A. Section 330 Grant-Related Requirements and Policies Regarding Affiliations	57
B. Other Section 330-Related Requirements and Policies	66
C. Federal Tax Considerations	83
D. Federal Antitrust Law	93
E. Federal Anti-Kickback Law	104
F. Federal Physician Self-Referral (Start I & II) Law	125
G. Federal False Claims Laws	134
H. State Laws and Regulations	139
CHAPTER 5: Conclusion	140

CHAPTER 1:

Introduction

Affiliations Between Health Centers and Other Community-Based Providers presents an overview of the range of opportunities and options available to Federally Qualified Health Centers (FQHCs) seeking to affiliate with other health care providers.¹ The manual:

- Discusses the kinds of affiliations that may be most appropriate and beneficial to a particular health center (Chapter 2);
- Serves as a tool for identifying and addressing issues that may arise in modifying existing and/or developing new affiliation arrangements (Chapter 2);
- Defines and explains the steps to develop and negotiate a successful affiliation, including engaging in an appropriate due diligence process and securing necessary regulatory approvals to finalize the collaboration; (Chapter 3)²

¹ For purposes of this manual, the terms “FQHC” and “health center” will be used interchangeably, and refer to public or nonprofit private entities that receive grants under Section 330 of the Public Health Service Act (“Section 330”) to provide a comprehensive scope of primary and preventive health care services, including enabling and support services, to medically underserved populations or residents of medically underserved areas regardless of ability to pay, as well as to entities that have been determined by the Department of Health and Human Services (DHHS) to meet the requirements to receive funding without actually receiving a grant (an FQHC “look-alike”).

² For purposes of simplicity, this manual assumes that any transaction will involve a health center and one other party. Of course, it is possible for a health

- Discusses various legal and policy requirements for health centers to consider when evaluating whether to affiliate with another organization or multiple organizations (Chapter 1, section D and Chapter 4); and
- Explains how to develop and structure the affiliation arrangements to comply with legal and policy requirements (Chapter 4).

This introductory chapter includes sections on:

- A. **WHAT IS AN AFFILIATION**
- B. **REASONS TO FORM AFFILIATION ARRANGEMENTS**
- C. **ESTABLISHING NEW HEALTH CENTER SITES AND/OR ORGANIZATIONS**
- D. **LEGAL CONSIDERATIONS RELATED TO AFFILIATION ARRANGEMENTS**

center to engage in a transaction involving more than one other party, in which case, the health center would need to negotiate with, and conduct a due diligence review for, each of the other parties to such transaction.

A. WHAT IS AN “AFFILIATION”?

As used in this manual, the term "affiliation" means . . .

an "agreement that establishes a relationship between a [health center] and one or more entities."³

The range of potential affiliation partners is as broad as the range of available affiliation options, including other health centers, local hospitals and health systems, public health departments, family planning agencies, rural health clinics, private practice groups, behavioral health organizations, social service agencies, faith-based organizations, and multi-service agencies. Most health centers have or are contemplating multiple affiliation arrangements with multiple partners.

As Federal grantees, health centers must consider policy requirements of BPHC, and in particular, PIN #97-27, "Affiliation Agreements of Community and Migrant Health Centers," (July 22, 1997), which is attached as **APPENDIX 1**.⁴ From BPHC's perspective, an affiliation arrangement may be contractual in nature, focusing on a particular activity or combination of activities; it may require corporate reorganization of the health center and/or its partners; it may involve the formation of a new entity; or it may involve some combination of these arrangements.⁵

Of particular concern to BPHC are affiliation arrangements that affect the ability of health centers to comply with Federal grant-related requirements and policies pertaining to health center integrity and autonomy. In addition to determining whether a proposed affiliation arrangement impacts Federal grant-related requirements, a health center contemplating an affiliation should assure that the arrangement is consistent with the full range of applicable Federal laws, regulations and policies, as well as those of the relevant State, prior to executing any arrangement.

³ See Bureau of Primary Health Care (BPHC) Policy Information Notice (PIN) #97-27 (July 22, 1997), at p. 5.

⁴ BPHC affiliation policies expressly apply solely to FQHCs that receive funding as “community health centers” under Section 330(e) (including school-based health centers) and/or “migrant health centers” under Section 330(g). However, the principles outlined in those policies serve as good guidance for all health centers entering into affiliations with other parties in that the affiliation requirements are based, in part, on statutory requirements that apply to all Section 330 funded health centers (with certain exceptions regarding governance, which are authorized for health centers supported only to serve migrant and seasonal farm-workers, homeless populations or residents of public housing, and for public entity grantees). Further, those health centers that only serve “special populations” that are considering applying for (or, as a result of a collaboration, may apply for) general Section 330 support for new access points should be prepared to comply fully with all requirements (without exception). Accordingly, we recommend that every health center (regardless of funding authority) consider the requirements on which the affiliation policies are based and, to the extent possible, attempt to comply with the policies as well.

⁵The terms “partner” or “partners” are not intended to connote the legal definitions of such terms, but rather are used generically throughout this manual to refer to parties in any form of collaborative relationship.

B. REASONS TO FORM AFFILIATION ARRANGEMENTS

The reasons for forming affiliations vary based on the particular circumstances, needs and expectations of the individual health center. Some health centers affiliate out of necessity to survive in the health care marketplace. Other health centers affiliate to enhance an already strong position in the marketplace, working with other providers to improve access to, and the availability and efficient coordination of, cost-effective, high quality health care.

The range of specific goals and objectives of affiliations can be as broad as the mission and creativity of the health center and its partner(s) permit and, in turn, the collaborative activities explored by the health center and its affiliation partner may be extremely varied. Typical examples of such goals and objectives include:

- Expanding and enhancing the amount and type of services available (e.g., specialty services), as well as the continuum of care, and reducing service gaps.
- Expanding access locations by co-locating services and staff at existing sites, and/or restructuring existing sites, as well as by establishing new sites.
- Maintaining and improving the ability to deliver the appropriate level of care in an appropriate setting and at an appropriate time.
- Maintaining and enlarging patient bases and target populations.
- Enhancing and improving clinical, administrative and managerial capacities, resources, expertise, procedures and systems, including costly “backroom functions,” by sharing, purchasing, selling or integrating such functions.
- Improving community-based needs assessments, health education and promotion, and outreach services.
- Broadening recognition and acceptance of patients regardless of insurance status and/or ability to pay.
- Minimizing risks and reducing operational costs, thus becoming more cost effective.
- Maximizing and enhancing revenue, including the sale of excess capacity and/or the lease of space/equipment, as well as broadening the pool of payors.
- Obtaining entry into health plans and networks, gaining ownership and control of a managed care organization, and/or developing approaches to managed care participation.
- Increasing sources of and access to capital, financial support, and other resources.

As a health center assesses and develops its corporate expansion and growth plans, it should consider the extent to which its goals might be achieved through affiliation with other providers that are motivated to collaborate. Understanding the other provider’s reasons for considering an affiliation with the health center can be critical to successful negotiations and structuring.

C. ESTABLISHING NEW HEALTH CENTER SITES AND/OR ORGANIZATIONS

Since its inception, the health center program has experienced tremendous, unprecedented growth. Historically, this growth began with the rural and urban health initiatives of the late 1970's, and continued throughout the Medicaid expansions of the 1980's, including the establishment of the Medicaid/Medicare FQHC program, which authorized cost-based reimbursement for FQHCs and FQHC Look-alike entities. The 1990's through the present have demonstrated substantial expansion of health centers in terms of capacity, scope of services and number of patients served. Currently, approximately 900 community-based organizations receive Federal grants to support the operation of more than 3600 health center sites serving nearly 12.5 million persons. The Federal investment in health centers, which totaled \$1.3 billion in fiscal year 2002, has generated over \$3 billion in revenues.

In 2002, the Bush Administration launched a five-year "managed growth" initiative to create new health center access points in 1,200 communities nationwide by the end of fiscal year 2006, and to increase the number of patients served annually by health centers to more than 16 million — up from 10 million in 2001. To support such growth, the Administration pledged a substantial increase in the amount of Federal funds available both to existing health centers wishing to expand their operations (*i.e.*, by developing "satellite sites"), as well as to other entities, including providers that are considering converting ambulatory sites into health centers or establishing new health centers (*i.e.*, by creating "new start organizations").

Application Requirements – BPHC PIN # 2004-22, which describes requirements for service area competition [project renewal] applications, discusses the importance of health centers collaborating with providers in the same service area. PIN # 2004-22 indicates that all applicants, whether currently funded health centers submitting continuation applications or new organizations proposing to serve the same area/population, should discuss, among other things, the manner by which the organization has or will integrate services with other efforts in the community.⁶ In particular, applicants are encouraged to demonstrate collaboration and coordination of services with other providers through written agreements, memoranda of understanding, etc., as well as to describe the extent to which the project is coordinated with other projects, providers, and programs (including other grantees) that serve the same population.⁷

BPHC guidance detailing the requirements to access annual "New Access Points" section 330 funding also emphasizes that, regardless of whether the applicant proposes to establish a satellite site or is a new start organization, the development of collaborative relationships plays an important role. In PIN #2004-02 (Requirements for Fiscal Year 2004 Funding Opportunity for Health Center New Access Point Grant Applications), BPHC specifically indicates that it will "support those health centers that ... have established collaborative and coordinated delivery systems for the provision of

⁶ See BPHC PIN # 2004-22 (July 9, 2004), at p. 14.

⁷ See BPHC PIN # 2004-22, at p. 25.

health care to the underserved in their communities.”⁸ In particular, BPHC encourages all applicants to address:

- The manner in which the Section 330 funding requested will augment existing funds and resources currently available within the community by developing a system of care to increase access and availability of services and providers;
- The extent to which proposed activities are coordinated and integrated with the activities of other service delivery projects and programs in the same area, including actual and proposed collaborative activities;
- The manner in which the applicant has formed collaborations and partnerships in the service area to assure a seamless continuum of care; and
- The applicant’s role within, and relationship with, the community, including demonstrating community support for the new access point.⁹

Expanding Existing Health Centers

Given the application requirements discussed above, health centers that wish to expand their operations by establishing new satellite sites should develop service delivery models that assure access to a full range of services by developing appropriate and compliant collaborations with other providers in the community, in particular, for the provision of services not provided directly by the health center (*i.e.*, ancillary and specialty services). As discussed above, BPHC encourages applicants for Section 330 funding to integrate services with other projects and programs within the community, thereby avoiding the costly duplication of services. As such, health centers should assess the health care resources currently available within the community in which the proposed satellite will be located and develop collaborations to ensure that patients have access to such resources, while assuring that all collaborations comply with BPHC affiliation policies discussed further in Section D of this chapter and in Section A of Chapter 4. The various types of affiliation arrangements between health centers and other community providers are addressed in Chapter 2 of this manual.

Developing New Health Centers

Increasingly, hospital-sponsored ambulatory care clinics and primary care practices, public health departments, rural health clinics and other community-based providers are experiencing tremendous financial losses associated with providing primary care services to large numbers of uninsured and underinsured individuals and families. The recent growth of the health center program provides a multitude of grant-related opportunities to these other providers, so long as the associated collaborations between the new health center and the existing provider are structured appropriately and consistent with Section 330 grant-related laws, regulations and policies. In their

⁸ See BPHC PIN #2004-02 (September 30, 2003), at p. 2.

⁹ As of the date of publication of this manual, the policy detailing the requirements for FY 2005 New Access Point funding applications has not been issued. However, early drafts indicate that the policy will continue to emphasize the importance of health centers collaborating and coordinating service delivery with other providers and agencies within their communities, in particular, those serving the same populations.

efforts to access Section 330 resources and/or related benefits (e.g., enhanced cost-related Medicaid and Medicare reimbursement, malpractice coverage under the Federal Tort Claims Act (FTCA), discount drug pricing under Section 340B of the Public Health Service Act (Section 340B), non-health center providers desiring to convert their existing ambulatory care clinics and outpatient practices into health centers or to establish new health center sites must consider whether, and to what extent, to seek out existing health centers as collaboration partners.

A non-health center provider interested in developing a new health center site may determine that it is better to collaborate with an existing health center rather than to establish an independent “free-standing” organization. Considerations in making such a determination vary, and may include one or more of the following:

- The non-health center facility is geographically located within or reasonably near to an existing health center’s service area.

Section 330(l)(3)(B) requires that health center applicants demonstrate that “the center has made and will continue to make every reasonable effort to establish and maintain collaborative relationships with other health care providers in the catchment area of the center.” In addition, the implementing regulations for the Section 330 program provide that, when evaluating Section 330 grant applications, DHHS may take into consideration, among other factors: “ ... (b) The relative need of the population to be served for the services to be provided ... (h) Whether the center’s catchment area is exclusive of the area served by another center; (i) The degree to which the applicant intends to integrate services supported by a grant [under this subpart] with health services provided under other Federally assisted health services or reimbursement programs or projects ...” See 42 C.F.R. §§51c.305(b), (h) & (i).

As such, BPHC tends to fund new start organizations in the service area of an existing health center only if:

- the existing health center is supportive of the new health center’s application;
 - there is evidence of close collaboration between the two; and
 - there is significant unmet need in the service area to justify a second grantee in the same service area.
- The non-health center organization would be unable to satisfy independently all Section 330-related statutory and regulatory requirements, as well as BPHC expectations and policies, vis-à-vis the governance and management of health centers, including, but not limited to:
 - requirements regarding the selection, composition and authorities of the health center’s governing Board of Directors;
 - restrictions on the involvement of other parties in the autonomous decision-making process of the health center’s Board of Directors; and
 - direct employment of a separate Executive Director/Chief Executive Officer and, to the extent possible, other key management staff and the majority of primary care clinicians.

- The non-health center organization does not have the internal capabilities or sufficient experience and expertise to provide the comprehensive continuum of primary and preventive health care services (as well as related enabling services) required by health center law and regulations, including, but not limited to:
 - a multi-disciplinary and culturally and linguistically competent staff to provide services; and
 - appropriate health care delivery systems and internal information systems to ensure that services are provided in an effective and efficient manner.
- The non-health center organization is unable to satisfy other core requirements for health centers, including serving a medically underserved area or medically underserved population.

Once the non-health center provider has determined that, based on all or some of the aforementioned considerations, it is better for it to collaborate with an existing health center (as opposed to establishing a free-standing health center), the range of affiliation options is quite broad. For example, the existing health center may apply for Section 330 funds to expand its operations by establishing a satellite site that will be governed and managed by the FQHC. If the non-health center provider wishes to offer clinical capacity, it may propose to assist the health center in staffing the new health center site. In addition, the non-health center provider may lease space/equipment to the FQHC and/or co-locate certain services at the new site.¹⁰

Should a provider choose, however, to establish a new, freestanding health center, Section 330 and regulatory requirements regarding appropriate integration and collaboration with other providers located within its community (including existing health centers) still apply.

¹⁰ Specific options regarding the types of agreements commonly used to implement such arrangements are addressed in Chapter 2 of this manual.

D. LEGAL CONSIDERATIONS RELATED TO AFFILIATION ARRANGEMENTS

Whether an affiliation arrangement with other providers involves an existing health center or a new start applicant, the health center's eligibility for grant funding under Section 330 and designation as an FQHC, as well as eligibility for grant-related benefits, such as enhanced cost-related Medicaid and Medicare reimbursement, FTCA coverage, Section 340B discount drug pricing, is contingent on the center's ongoing compliance with numerous statutory and regulatory requirements (as clarified by BPHC in program policies and expectations), which require, among other things, that:

- Each health center's governing Board of Directors be selected and composed in a prescribed manner, and autonomously exercise authority over certain decisions, such as:
 - adopting policies for financial management practices, personnel policies and procedures, and health care policies including scope, location and availability of services and corporate compliance¹¹;
 - adopting the annual budget and project plan;
 - conducting strategic and operational planning for the organization; and
 - directly hiring, evaluating and, if necessary, dismissing the health center's Executive Director/Chief Executive Officer.
- Each health center must comply with requirements and standards regarding:
 - its scope of project (which, in turn, determines the particular health center's eligibility for certain grant-related benefits);
 - the use and disposition of property/equipment acquired with grant funds;
 - the procurement of goods and services utilizing grant funds, in whole or in part; and
 - its participation in the specific programs under which grant-related benefits may be accessed.

It is of utmost importance that health centers carefully scrutinize each affiliation proposal (whether generated by the health center, by a potential partner, or together) for compliance with all applicable Section 330 statutory and regulatory requirements, policies and expectations, as certain proposals or certain provisions of such proposals may have to be modified in order to maintain required

¹¹ The "public entity" health center model allows for certain exceptions to these requirements. For further discussion regarding the structure and operation of public entity health centers, see Chapter 2, Section E of this manual.

compliance. Further, potential legal exposure under the Federal tax, antitrust, anti-kickback, anti-self referral, and false claims statutes (as well as applicable State laws, including insurance and licensure laws, and employment-related laws) can be minimized through careful structuring of the affiliation agreement and diligent monitoring of performance thereafter.

Section 330 grant-related requirements and other Federal laws and regulations pertinent to affiliation arrangements to which health centers are a party are summarized in Chapter 4 of this manual. However, we strongly caution health centers to seek the assistance of qualified legal counsel and other appropriate professional advisors when developing and/or evaluating particular affiliation options and conducting due diligence reviews to ensure that the affiliation agreement complies with all applicable requirements.

CHAPTER 2:

Affiliation Options

The types of affiliation arrangements in which health centers participate are varied, ranging from very informal agreements to multifaceted, formal arrangements, which, in turn, may involve executing complex contractual arrangements, establishing new entities and/or implementing corporate reorganizations (through corporate participation, integration, or merger agreements). This chapter discusses the various kinds of affiliation arrangements available to health centers, and in particular, provides tips regarding “when,” “why,” and “how” each option can be utilized by health centers and their partners.

- A. INFORMAL “HANDSHAKE” AGREEMENTS**
- B. FORMAL CONTRACTS**
- C. ESTABLISHMENT OF A NEW ENTITY**
- D. CORPORATE PARTICIPATION AND/OR INTEGRATION**
- E. PUBLIC ENTITY MODEL**
- F. HEALTH CENTER TO HEALTH CENTER CORPORATE AFFILIATIONS**

A. INFORMAL (HANDSHAKE) AGREEMENTS

The most informal type of affiliation is an unwritten or “handshake” agreement between two or more parties. These types of agreements, which often develop through the course of dealings between the parties, are relatively easy to negotiate and allow the parties a great deal of flexibility, limited accountability, and ease in modification or termination. However, the “handshake” agreements can be detrimental because the failure to formalize key terms in writing makes the arrangement difficult to enforce and increases the likelihood of misunderstandings and disputes, which can undermine the entire collaboration.

To strengthen an informal agreement, health centers should:

Memorialize agreements in writing – As discussed in Chapter 1, BPHC guidance regarding the submission of applications to secure grant funding for new or expanded services and sites typically emphasizes that, to the extent possible, health centers should memorialize in writing their agreements with other providers furnishing services to health center patients (whether the health center is purchasing services/capacity from the provider or simply referring patients). From a legal perspective, in order to prove compliance with various Federal (and often State) laws, for example the anti-kickback statute, the parties must have a written agreement that meets certain regulatory standards.

B. FORMAL CONTRACTS

In section B:

1. *Separate Contractual Arrangements*
2. *Development Of An Umbrella Agreement*

1. Separate Contractual Arrangements

In this section:

- *Agreements to purchase/lease clinical staff*
- *Agreements to purchase/lease key management staff or support services*
- *Agreements to jointly develop and/or operate sites*
- *Joint residency training agreements*
- *Other common arrangements*

Formal contracts are written agreements, executed by two or more parties, and are effective for a specified period of time (often with provisions for earlier termination). In a contractual affiliation, each party agrees to provide certain identified services (*i.e.*, specific health care services or administrative support services), space, equipment and/or other goods to the other party in return for payment or for the other party's reciprocal provision of similarly valued services.

An affiliation accomplished through contractual means presents a relatively flexible approach, depending on the terms of the contract. For example, a contractual affiliation may be structured to last for a short period of time (*i.e.*, one year) to provide each party an opportunity to evaluate the strengths and weaknesses of the particular arrangement prior to choosing whether to continue to affiliate via contractual agreement, to end the affiliation, or to affiliate through another manner. Alternatively, a contract may have a term of longer duration to account for substantial up-front expenditure and permit implementation of a broad scope of activities.

Health centers should consider the following elements when developing a contractual affiliation:

Governance – Because formal contracts generally tend not to affect the health center's corporate structure, contracts should not jeopardize compliance with Section 330 requirements regarding governance and other issues. Note, however, that a contract could require a health center to change the composition of its Board or to delegate key responsibilities. Accordingly, contractual affiliation agreements must be reviewed very carefully to ensure compliance with Section 330, the implementing regulations and BPHC affiliation policies that limit another party's involvement in the governance and operation of the health center.

Procurement of goods or services – If the health center is purchasing goods or services from the other party and intends to use Federal funds to cover any portion of the costs associated with the contract it must comply with all regulations governing the procurement of goods or services with Federal funds, as set forth in 45 C.F.R. Part 74.

Collaborations with other providers – Affiliations accomplished through the execution of contracts should not preclude the health center from collaborating or affiliating with other health care providers in order to achieve other purposes. Further, the health center should not be precluded from entering into other arrangements as necessary to (i) implement the Board's policies and procedures, (ii) assure appropriate collaboration with other local providers (as required by Section 330(l)(3)(B)), and/or (iii) enhance patient freedom of choice, accessibility, availability, quality and comprehensiveness of care. See BPHC PIN #97-27, at p. 16. BPHC has voiced particular concern regarding “exclusivity” clauses that:

- Do not permit health centers to contract with other parties under any circumstances (whether for the same or for different services).
- Grant contractual partners absolute rights to provide other services to the health center without requiring that the health center first comply with Federal procurement standards. These standards require Federal grantees (including health centers) that intend to use Federal funds to support payments under the contract to make reasonable efforts to maximize competition, e.g., through procedures offering multiple parties notice and the opportunity to bid, and requiring a fair and objective analysis of all bids received (see 45 CFR Part 74).¹²

Common contractual arrangements – Each contractual arrangement between health centers and its partners involves its own set of terms, statutory conditions, and qualifications to achieve the desired outcomes and to ensure compliance with regulatory and policy requirements. At its heart, however, each arrangement is defined through one or more contracts, which, if implemented separately or in combination, will advance the parties' mutual goals and objectives. The following options represent a few of the more common contractual arrangements implemented between health centers and their community-based partners.

¹² These standards do not flatly prohibit sole source procurements. However, a health center using Federal funds to support significant purchases of goods and/or services without seeking competitive bids must be prepared to justify such decision based on factors such as cost, qualifications, and experience of the partner, and to maintain documentation of the justification. The Federal procurement standards are discussed further in Chapter 4, Section B of this manual.

Agreements to Purchase/Lease Clinical Staff

Agreements under which health centers purchase or lease the services of clinical staff from other providers are common among health centers that do not have sufficient capacity to provide all required and appropriate supplemental services directly through their existing staff. Section 330 specifically provides that health centers may provide services directly or by contract. However, when entering into contracts for the provision of services, health centers should consider the following:

- BPHC prefers that health centers directly employ the majority of their primary care clinicians (from an organizational, rather than site-by-site perspective). Whenever a health center considers purchasing some level of clinical service capacity, it should first consider whether it is more beneficial for it to contract for services rather than to perform such services directly (e.g., if the work cannot be performed directly on a more efficient basis).
- If a health center can demonstrate that a purchase/lease arrangement for the majority of primary care clinicians will result in programmatic benefit and that the health center will maintain accountability for the services provided through the contracted provider(s), BPHC may approve an exception to its direct staffing preference.¹³

To establish an agreement to purchase or lease clinical staff, health centers should consider:

Oversight, accountability and responsibility – All agreements under which health centers purchase/lease the services provided by non-health center clinical personnel should contain certain provisions ensuring that the health center maintains appropriate oversight, accountability and responsibility for the services provided to its patients through capacity purchased from its collaboration partner. In particular, the health center should retain the right to:

- Monitor and evaluate whether contracted personnel are complying with applicable policies, procedures and operational and professional standards (as discussed more fully below); and
- Terminate the contract (if the contract is with an individual provider) or request removal and replacement of personnel (if the contract is with another entity), in the event that any individual is:
 - A. Not in compliance with policies, procedures or standards, or

¹³ The policy and process by which a health center can request and obtain an exception to direct employment preferences is addressed in BPHC PIN #98-24, “Amendment to PIN #97-27 Regarding Affiliation Agreements of Community and Migrant Health Centers,” (August 17, 1998), attached hereto in **APPENDIX 2**, and is described in more detail in Chapter 4, Section A of this manual. The health center is not required to obtain a formal exception to the direct staffing model if it purchases or leases less than a majority of its primary care clinicians; nevertheless, the health center should maintain accountability for the services provided by purchased/leased clinicians.

- B. Is the subject of an action, claim, proceeding or investigation that has resulted in or could result in the revocation, termination, suspension, limitation or restriction of his or her license, certification or other authorization to provide services,

or IMMEDIATELY if the health center determines, in good faith, that the health, safety and welfare of patients may be jeopardized by the continuation of services.

Responsibilities of the other provider – As part of oversight and monitoring, the contract should contain assurances that the other provider and its personnel will:

- Furnish services consistent with health center policies, procedures and standards related to clinical services, including, but not limited to, clinical guidelines, productivity standards, quality assurance standards, and preparation of medical records.
- Act in accordance with other applicable health center policies and procedures, such as standards of conduct and patient's rights and responsibilities.
- Satisfy certain health center professional standards, including, but not limited to, credentialing and privileging policies, and other qualifications.
- Develop, maintain and furnish to the health center certain programmatic and financial records and reports pertaining to the services provided, and provide appropriate access to such reports.

Contract provisions – Additionally, contracts executed by grantee health centers should include certain provisions consistent with 45 CFR Part 74 (or 45 CFR Part 92 if the health center grantee is a public entity).¹⁴ In particular, these provisions:

- Address termination in the event of contractor breach;
- Provide the health center, DHHS and the U.S. Comptroller General with access to the contractor's financial records pertaining to the services provided; and
- Require contractor compliance with certain Federal laws and regulations. The specific requirements are discussed in further detail in Chapter 4, Section B of this manual.

¹⁴ Throughout this manual, we refer to the uniform administrative requirements pertaining to grants and cooperative agreements with non-profit entities as contained in 45 C.F.R. Part 74. Please note that DHHS has announced that, at some point in the next several months, it will move those administrative requirements from title 45 of the Code of Federal Regulations to title 2, subchapter B of the Code of Federal Regulations. There is no indication, however, that DHHS plans to make any substantive revisions to those requirements when it effectuates that move.

Agreements to Purchase/Lease Key Management Staff and/or Administrative Support Services

Similar to agreements to purchase/lease clinical staff, health centers may execute agreements with other providers or vendors to purchase/lease the services of certain key management staff. However, in doing so, health centers should consider the following:

- In all instances, the health center must directly employ its Chief Executive Officer (CEO).
- BPHC prefers that health centers directly employ key management staff, such as the Chief Financial Officer (CFO) and Chief Medical Officer (CMO). However, if a particular health center can demonstrate that (i) it is more economical and/or efficient to purchase or lease these services, and (ii) the health center will maintain ultimate responsibility for the services provided, BPHC may grant an exception to its preference regarding direct employment of key management (other than the CEO).¹⁵

Should a health center decide to go down this path, the agreement should contain provisions similar to the ones discussed in the previous example, ensuring that the health center maintains appropriate oversight, accountability and responsibility for the services provided under contract.

To establish an agreement to purchase or lease key management staff and/or support services, health centers should also consider:

Compliance with procurement standards – Whether the health center purchases services from an entity with which it does business (e.g., the local hospital) or from an entity that is owned/controlled, in whole or in part, by the health center (e.g. a health center network), the health center should assure and document that:

- The procurement of services was conducted consistent with Federal procurement standards; and
- The agreement contains adequate conflict of interest provisions.

For example, if a health center purchases financial management support services from the local hospital or from the CFO of the network in which the health center participates, it should first engage in a competitive bid process to ensure that the proposal from the hospital or network is the one that is the most beneficial to the center (considering price qualifications and other criteria). Further, the purchase agreement between the parties should specifically prohibit the contracted personnel from participating in the selection, award or administration of any contract between the health center and the hospital or network (or, at a minimum, any such contract in which Federal funds are used to support payment).

Term of the contract – The health center should not execute a long-term arrangement, unless it :

¹⁵ See PIN #98-24, described in Chapter 4, Section A of this manual.

- Retains the ability to review and re-evaluate the effectiveness and efficiency of performance (preferably each year) and to terminate if not satisfied; and
- Assures and documents that (i) the procurement of services was conducted consistent with Federal procurement standards; and (ii) the agreement contains adequate conflict of interest provisions.

Agreements to Jointly Develop and/or Operate Sites

An agreement under which a health center and its partner agree to develop/operate sites often involves multiple contracts. When these contracts are combined, they establish the operational framework for the site. A common example of such an arrangement involves the health center's assumption of financial and legal responsibility for operating one or more primary care clinics that were previously operated by a hospital and that had been sustaining substantial annual losses. Under this scenario, the hospital typically will retain its investment in the facility/equipment and will continue to provide certain specialty or ancillary services to the patients served by the clinic. To implement the arrangement, the health center may lease space, equipment and certain clinical and/or support personnel from the hospital. In addition, the hospital may co-locate specialists and other non-competing services in the facility.

To establish an agreement to jointly develop and/or operate sites, a health center may want to include:

Community benefit grant – Initially, many health centers entering this type of arrangement stand to incur significant costs associated with the provision of otherwise uncompensated primary and preventive health care and related, supplemental services. To help defray a portion of these costs, the hospital may award to the health center a “community benefit grant,” which typically is memorialized in a written agreement. The agreement should include narrowly tailored terms to ensure that the benefit provided to the health center does not exceed that which is necessary to accomplish the stated purpose, and that neither the patients’ freedom of choice nor the individual provider’s professional judgment is limited or restricted. Further, the parties should carefully construct the agreement to minimize the potential for abuse of Federal health care program dollars, in accordance with the proscriptions of Federal anti-kickback law.¹⁶

¹⁶ In advisory opinion #01-9 (July 19, 2001), the OIG approved an arrangement similar to the one described. The specific details of the advisory opinion (as well as the advisory opinion process) are discussed further in Chapter 4, Section E of this manual; however, health centers should note that, while providing insight into the OIG’s enforcement intentions regarding certain transactions, advisory opinions are limited to the requesting parties only and cannot be cited as precedent for similar transactions. Of greater importance to health centers, Congress recently passed a statutory safe harbor to protect arrangements between health center grantees and other providers/suppliers of goods, services, loans, donations, etc. This safe harbor is also discussed further in Chapter 4, Section E of this manual.

Joint Residency Training Agreements

Another common arrangement between health centers and hospitals involves residency-training agreements under which the parties establish or arrange to maintain a training program at the health center site. It is extremely important to differentiate in the agreement between direct patient care services and teaching activities.

To establish an agreement for joint residency training, health centers should consider:

Authority for patient care services -- In general, the health center should maintain responsibility and ultimate authority for patient care services (at least the primary care component), including oversight and monitoring of the range and type of services provided, direction of the clinical performance of contracted hospital faculty and/or the residents, and the billing and collection of clinical service revenues. The health center would purchase the time preceptors spend on providing or supervising clinical care (which is billed by the health center).

Responsibility for teaching activities – In contrast, the hospital generally will retain responsibility and ultimate authority for teaching activities, including curriculum development, resident placement, scheduling and evaluation, and recruitment of faculty and residents (although the parties typically agree to a certain level of health center involvement in these activities). If the hospital incurs substantially all costs of these activities, the agreement should specify that it would bill and collect direct and indirect Graduate Medical Education (“GME”) payments from Medicare. In this respect, the hospital retains overall responsibility for covering teaching costs, including the salaries and benefits of residents. In addition, if the health center’s clinicians provide certain teaching-related activities, the hospital should reimburse the health center for the fair market value of such services (as well as for support staff time, equipment and space utilized in connection with teaching activities).¹⁷

¹⁷ Legally, if the health center incurs all or substantially all of the costs of operating a teaching program, it may bill direct GME expense. Health centers, however, are not authorized to seek indirect cost reimbursement for teaching medical residents.

Other Common Arrangements

In addition to the aforementioned arrangements, other contractual options include:

- Contracts for the provision of specific health care services.
- Leases for space, equipment, non-clinical personnel.
- Contracts to co-locate services (e.g., provision of primary care or triage services on hospital site; provision of specialty/ancillary services on the health center site).
- Contracts to purchase/lease management, administrative, and/or financial services, other than key staff (e.g., contracts with vendors to provide some or all of the health center's operational infrastructure, such as Management Information Systems ("MIS") and billing and claims management).
- Joint purchasing arrangements.

2. Development of An Umbrella Agreement With Specific Follow-On Implementing Agreements

Under another form of contractual relationship, the parties may wish to undertake multiple collaborative activities under a broad, binding affiliation agreement, with specific implementing agreements as needed. Unlike arrangements that involve the execution of separate or multiple (but distinct) contracts, this arrangement typically consists of a single "umbrella agreement" that governs the basic operational and financial relationship between the parties, with specific implementing agreements (similar to those discussed above) that address the terms and conditions of particular activities, as determined by the parties.¹⁸

To establish an "umbrella agreement" affiliation, health centers should consider:

Joint planning process – While umbrella agreements can vary in detail, organizations should consider a joint planning process and planning body to determine the scope of collaborative activities, which activities will remain within the approved Section 330 scope of project (and controlled by the health center) versus "outside the scope," and the manner by which monitoring and oversight will be performed as such activities are implemented.

¹⁸ An umbrella affiliation agreement setting forth the parties' commitments to conduct planning efforts in furtherance of specific activities should not bind the parties to collaborate in any particular manner (or at all, if agreement cannot be reached during the planning phase). However, other aspects of the umbrella agreement, e.g., confidentiality, financing of planning activities, may be binding. In this respect, an umbrella agreement should be distinguished from a joint planning agreement, which is typically a non-binding Memorandum of Agreement that establishes an orderly process for negotiations and agreement "in principle" regarding the terms of the planning process (which, in turn, may culminate in one or more separate binding agreements, or a binding umbrella agreement with follow-on agreements to implement specific activities). Non-binding joint planning agreements are discussed further in Chapter 3, Step 4 of this manual.

Priorities and time frames – The parties should think about and, to the best of their abilities, determine priorities and associated time frames, for both short-term and long-term activities.

Governance/management of activities within the Section 330 scope of project – The parties should consider the governance/management of collaborative activities within the Section 330 scope of project and FQHC designation (i.e., whether, and to what extent, the non-health center party will participate in decision-making, consistent with Section 330 requirements that the health center maintain ultimate authority and responsibility for the FQHC services provided to health center patients).

Governance/management of activities outside the Section 330 scope of project – The parties also should address the nature of joint control and management of activities "outside" the Section 330 scope of project and FQHC designation (i.e., whether the parties will agree that one party will assume some level of control over the collaboration's decision-making versus an agreement to jointly decide matters related to collaborative activities covered by the affiliation agreement).

Possible preferred relationship -- The agreement should clarify whether the parties will have a preferred relationship and, if so, the extent of such relationship, provided that the health center retains the right to form collaborative relationships with other providers, as required by Section 330 and its implementing regulations. Options include:

- Maintaining a non-exclusive relationship.
- Defining certain collaborative activities that, during the affiliation's planning and negotiation phases, will not be discussed with other parties.
- Employing best efforts to include the other party in all relevant discussions with other third parties.
- Offering the other party a right of first refusal with respect to future collaboration opportunities, provided that, if the collaboration includes the purchase of services, space, equipment, etc., bids are received from the affiliation partner and evaluated consistent with the health center's procurement procedures (see Chapter 4, Section B of this manual for additional guidance regarding Federal procurement standards).

Financial expectations and commitments – The umbrella agreement should clarify each party's financial expectations and commitments for the costs of participation in the planning process.

Right to modify terms – The parties should retain the right to modify the terms of the affiliation (and/or certain activities) over time as circumstances change (e.g., the health center's ability to assume risk increases; the parties express a desire to change the affiliation's level of integration or the type of preferred relationship).

Dispute resolution – The agreement should include a dispute resolution provision that promotes informal resolution, so as to support an enduring affiliation between the parties.

Termination circumstances – The parties should agree on the circumstances under which the broad affiliation (or a particular implementing agreement) may be terminated "for cause."

Termination rights – The parties also should retain the right to terminate the planning process and any resulting affiliation agreement if the other party affiliates, or is negotiating with, a competitor of, or an entity whose mission is incompatible with, the terminating party (or if the affiliation partner has, or develops, an incompatible mission).

C. ESTABLISHMENT OF A NEW ENTITY

In section C:

1. *For-Profit Entities*
2. *Non-Profit Entities*
3. *Limited Liability Companies (LLCs)*
4. *Scope of the New Entity's Activities and Other Collaborations*

Another approach for health centers considering collaborative opportunities with another organization may be the creation of a completely new and separate entity that is jointly owned and/or controlled by the health center and the other party, or parties, to the affiliation. The governing body of the new entity typically is comprised of representatives of the organizations that created the new entity (the founding organizations or the “founders”), and may include “at large” members. Each of the founding organizations will maintain its independent corporate identity and governance structure, and, usually, the governance structures of the founders are not impacted (although this approach may be combined with cross Board representation – see Section D of this Chapter -- Cross-board representation). Examples of new entities include:

- Practice management organizations.
- Management services organizations.
- Multi-purpose networks, e.g., integrated service delivery initiatives, community access programs.
- Provider-sponsored organizations.
- Managed care negotiating networks.
- Pre-paid health plans.
- Health maintenance organizations.
- Home health service agencies.

The new entity may be structured as a for-profit or nonprofit organization, and organized as a corporation or limited liability company, or as a general or limited partnership. The option chosen should reflect the goals and purposes of the new entity and the owners'/founders' expectations regarding capitalization, ownership, liability and risk, return on investment, taxation and governance.

1. For-Profit Entities

For-profit organizations have many advantages, with the most important being the potential for corporate owners to directly realize a profit. For-profit organizations can be formed for any lawful purpose, and can often raise capital more easily than a nonprofit corporation through private investors, with stock offered in return for capital or as collateral for loans. In addition, ownership may be freely transferred through stock sales, and a for-profit corporation faces few restrictions on the use of funds.

If the collaborators choose to form a for-profit entity, the following considerations apply:

Capitalization – If the founders choose to form a for-profit organization, financing is typically accomplished through the parties' contributions of cash and/or "in-kind" services in exchange for a percentage of ownership. Accordingly, if a health center has little or no financial capital to contribute, it may "purchase" its share of ownership in a for-profit organization by contributing valuable in-kind services or expertise instead (subject to State law).¹⁹ In general, each founding organization provides an equivalent financial/in-kind contribution in return for equal return on investment and voting power. However, other factors that may influence capital structure include the comparative budget of each party; the types of owners and whether they share the same goals; and each party's expectations regarding control and financial return. Specific capitalization options for for-profit corporations include:

- Each party contributes an equal amount of capital and receives equivalent equity.
- Each party contributes differing amounts of capital and equity is divided proportionately.
- Each party provides a "base" contribution in an equal amount and receives equivalent equity associated with that base amount (i.e., Class A stock). An option exists under which additional investment may be made, resulting in greater equity (i.e., Class B stock or preferred debt).

Ownership and distributions – Shared control and sharing of risk extend only to the new entity's activities, thereby shielding the founding organizations from certain liabilities. Each party's share in any profits (and/or downside financial risk) associated with the new entity typically is equivalent to its percentage ownership in the entity.²⁰ Surplus revenues may be retained by the corporation or distributed to owners as dividends. Funds also can be distributed to "participating providers" through shared savings and other "incentive" plans. However, a major disadvantage of the for-profit

¹⁹ Of note, a health center that contributes grant-related funds, resources or other in-kind services must document that the contribution furthers the health center's tax-exempt purposes and broad Section 330 objectives. Further, the ability to share or donate assets purchased or enhanced with Federal funds, in whole or in part, is subject to 45 CFR Part 74, which is discussed more fully in Chapter 4, Section B of this manual.

²⁰ Should the parties decide to allocate profits/risk (and/or voting rights) in a manner that is not proportionate to ownership, a careful analysis under the Federal anti-kickback statute is advisable.

structure stems from its greatest advantage: the ability to realize a profit and distribute this profit to the organizational owners. Because organizational profits are taxed at the corporate rate, while dividends are taxed at the individual level, the result is “double taxation” of the corporation’s distributed profits.²¹

Control and decision-making – With respect to control, a Board of Directors governs a for-profit entity. Typically, Board seats are allocated to each party in proportion to the amount of equity held (or contributions made) by such party. However, the parties may decide to allocate Board seats in a different manner, such as:

- Dividing the Board seats equally among the parties, so that each founding organization enjoys equal rights and powers – one vote per organization – notwithstanding disproportionate equity ownership (or contributions made).
- If the entity includes non-health center partners, apportioning Board seats to ensure health center control.²²
- Determining the Board membership through democratic vote of the current Board members (i.e., a self-perpetuating Board).

Often, the parties will distinguish between shareholder powers and Board powers, leaving certain critical decisions (i.e., reserved powers) to shareholder determination. For example, a change in corporate structure or a decision to transfer or sell to another organization all or substantially all of the entity’s assets may require the affirmative vote of the shareholders, rather than that of the Board. Typically, shareholder-voting rights are allocated proportionate to the number of shares. In this respect, critical decisions impacting the identity and structure of the entity and its ability to conduct business will be determined in accordance with each party’s investment in the entity.

²¹ Where the owners/founders of the new organization are themselves tax-exempt entities, individual taxation of dividends would be avoided if, as in most situations involving health-center controlled organizations, participation in the entity is consistent with and furthers the health center’s tax-exempt purposes. However, the new organization’s income will still be taxed at the corporate level.

²² The parties also can ensure health center control through the parties’ voting rights. For example, the parties could (i) grant the health center(s) supermajority or veto authorities, (ii) require, in addition to a majority vote of the full Board, a majority vote of the Board members representing health centers in order to take action, or (iii) distinguish voting power between different classes of ownership (where one class would be comprised of the health center members).

2. Non-Profit Entities

Nonprofit organizations have a more limited scope in that they must be organized to serve a charitable or public purpose, and organizational actions and uses of funds must be consistent with these purposes. The primary advantage of structuring as a nonprofit, tax-exempt organization is the ability to retain funds that would otherwise be lost to taxes. In general, surplus revenues generated by the activities of a nonprofit, tax-exempt entity that are in furtherance of the entity's exempt purpose are not taxed at the corporate level. In addition, tax-exempt organizations often are eligible for government and private foundation grants, and organizations that are charitable (i.e., Section 501(c)(3) organizations) may accept tax-deductible contributions. Tax-exempt organizations, such as health centers, can also contribute funds to other tax-exempt entities (e.g. a network or other integrated entity), if the contribution furthers the health center's charitable purposes.

If the collaborators choose to form a nonprofit entity, the following considerations apply:

Tax-Exempt status – Should the health center and its partner(s) decide to establish a nonprofit corporation, consideration should be given at the outset as to whether the new entity will be able to secure tax-exempt status under Section 501(c)(3) or 501(c)(4) of the Internal Revenue Code. Further, if the new entity secures such status, but engages in revenue-generated activities that are not in furtherance of its exempt purpose (i.e., unrelated business income), the parties should consider whether there could be potential adverse tax consequences. If the unrelated business income becomes substantial in relation to the entity's exempt activities, its tax exemption may be jeopardized.

Capitalization – If the founding organizations choose to form a nonprofit organization, financing may be secured through cash or in-kind contributions, fees, loans, and/or grants, and typically will depend on the type of resources that each founder can bring to the entity. Regardless of the type of financing, factors that may influence the specific amounts contributed by each founder are similar to those discussed above with respect to for-profit entities.

Ownership and distributions – Nonprofit entities cannot be “owned” by any private party(ies) and, inasmuch as funds may only be used for charitable purposes, profits generated by the nonprofit entity may not be distributed to the founders or to anyone else for any private purpose. Accordingly, a nonprofit organization may not distribute surplus earnings to founding parties unless it can document how such distribution (e.g. in the form of grants) furthers the organization's purposes. However, similar to for-profit organizations, nonprofit entities can repay arms-length loans made by founders, can return surplus funds to participating providers through shared savings, performance bonuses and other incentive mechanisms, and can make unrestricted gifts to other nonprofit entities in furtherance of their charitable mission.

Control and decision-making – Similar to for-profit entities, the parties must agree as to the allocation of Board seats. If the new entity is formed as a membership corporation, the founders also must agree on the number and identity of members. As with the reserve powers of shareholders, the parties may reserve certain powers to the members.

3. Limited Liability Companies (LLCs)

LLCs are statutorily created entities that are now recognized in every state and the District of Columbia. An LLC is a business organization that combines the key features of a partnership and a corporation. Specifically, LLCs offer the same protection from personal liability offered by corporations (*i.e.*, members/owners are generally only at risk to the extent of their capital investment). At the same time, LLCs offer the tax benefits of a partnership – the net income of an LLC, unlike a corporation, is not taxed at the entity level. Instead, the income is only taxed when it is distributed ("passes through") to the LLC members/owners. Where LLC members/owners are themselves tax-exempt entities, taxation of an LLC's income may be avoided entirely if, as in most situations involving health-center controlled LLCs, participation in the LLC is consistent with and furthers the health center's tax-exempt purposes.

If the collaborators choose to form an LLC, the following considerations apply:

Organizational documents – In contrast to corporation formation (where Articles of Incorporation and Bylaws are typically the organizing documents), the parties forming an LLC enter into an operating agreement which sets forth agreed upon provisions regarding such matters as capital contributions, allocation of profits and losses, rights/obligations of members, admission and withdrawal of members, transferability of a member's interest, and the appointment of manager(s) (rather than a Board of Directors) of the LLC.

4. Scope of the New Entity's Activities and Other Collaborations

Once a new entity is established and capitalized, the ability of that entity's governing body to make decisions may greatly enhance the speed with which joint activities can be initiated and problems can be resolved. The scope of joint activities undertaken by the new entity may be extremely broad or narrow, according to the parties' goals and objectives (which, in turn, may determine the type of entity formed).²³ Additional considerations include:

Section 330-related benefits – To preserve eligibility for certain Section 330-related benefits, certain activities should remain within a health center's approved scope of project (and outside the entity's scope of activities), such as: hiring of health care professionals, purchase of prescription pharmaceuticals, and other activities that support grantee operations and are paid for by specific health care grants or related program benefits.

Collaborations with other partners -- Of particular importance, the establishment of a new, jointly created entity with one affiliation partner typically should not preclude collaborations with other partners for other purposes. The partners may enjoy a preferential relationship with one another,

²³ Further, health centers may also participate as providers or contractors to the new entity.

as well as the benefits associated with collaboration, while preserving each party's ability to maintain positive relationships and enter into affiliations with other key players in the health care marketplace. These issues may be appropriately addressed through an umbrella affiliation agreement (discussed earlier).

D. CORPORATE PARTICIPATION AND/OR INTEGRATION

In section D:

1. *Cross-Board Representation*
2. *Corporate Integration*

1. Cross-Board Representation

Parties may wish to further extend a "partnership" through the offer of some level of involvement in each other's respective corporate governance (e.g., cross-membership on their corporate Boards of Directors; permitting participation in, but not control of, key Board committees). Health centers and hospitals/health systems and other parties that have chosen to proceed in this manner have been able to pursue similar interests and promote coordination of activities without formally integrating their corporate identities or establishing a new entity (although this approach may serve as part of an affiliation that also includes establishment of a new entity and contractual agreements).

To implement cross-board representation, health centers should consider:

Representatives from the other party – To achieve cross-membership, each party would agree that a certain number of positions on its Board of Directors would be filled by representatives of the other party (i.e., bilateral representation). While such an arrangement impacts the governance of the partners, the level of cross-membership should be structured so that the representative(s) of an affiliation partner(s) will not exercise control over the health center Board's key decisions.²⁴ Nonetheless, cross-Board membership gives each party to an affiliation the opportunity to gain insight into, contribute to, and exert a small amount of influence on (subject to conflict of interest standards), the key decision-making activities (e.g., strategic, operating and capital plan development) of the other party (or parties) to the affiliation.

²⁴ BPHC affiliation policy explicitly prohibits another party from exercising control over, or interfering with, a health center Board's autonomous decision-making vis-à-vis Board authorities and responsibilities required by law or regulation. In particular, no third party may obtain overriding or dual majority approval authority, veto authority, or supermajority power with respect to such requirements. For further discussion of this issue, see Chapter 4, Section A of this manual.

Board resolution and amending the corporate by-laws – In order to implement the arrangement, it may be necessary for the Board of each corporation to pass a resolution adopting the cross-membership agreement and amending the corporate Bylaws. Such a method is relatively less cumbersome to implement than the corporate integration model (see below) and is less likely to raise significant Section 330 compliance concerns.

Conflicts of interest – Since the affiliation partner is likely to be a vendor to the health center, the health center Board should ensure that its Bylaws and/or standards of conduct do not preclude contracts with Board members or their employers or other business associates. Further, the health center should implement (or modify) a conflict of interest policy addressing, among other things:

- Appropriate mechanisms by which the Board member(s) appointed by the affiliation partner will not be involved in the selection, award or administration of any contracts with the affiliation partner (including the affiliation agreement itself).
- The Board member's recusal from, at a minimum, the vote taken on any other matters and decisions involving the affiliation partner (and, possibly from the discussion regarding such matters).

Procurement of goods and services -- Further, it is critically important that the health center's procurement of goods and services from the affiliation partner represent an arm's-length negotiation, preferably the result of a competitive bidding process in accordance with Federal procurement standards set forth in 45 CFR Part 74. For further discussion regarding Federal procurement standards, see Chapter 4, Section B of this manual.

2. Corporate Integration

Less common, perhaps because of Section 330 requirements relative to health center Board autonomy and staffing expectations, are corporate integration approaches, such as mergers or parent-subsidary system formation. Corporate integration involves a change to the corporate structure and identity of one or both of the parties to the affiliation, for example, through consolidation or formation of a parent-subsidary arrangement. BPHC, in its affiliation policy, has stated its grave concerns regarding any affiliation arrangement between a health center and a non-health center entity(s) that would jeopardize the health center Board's autonomy and integrity. See BPHC PIN #97-27, at p. 6. These issues can be addressed relatively easily if two or more health centers are merging with each other (which is discussed in more detail below), or if the health center is becoming the parent of another provider. On the other hand, if it is intended that the health center become a subsidiary of another entity, it is likely that the reorganization would force the health center Board to relinquish powers that Section 330 requires the health center Board to exercise (in turn, making the possibility of maintaining eligibility for Section 330 grant funding remote).²⁵

²⁵ Even corporate integration between health centers requires careful planning and analysis to ensure that the surviving health center remains in full compliance with Section 330 governance and management requirements post-merger.

If the parties choose to pursue an integration option through the formation of a sole corporate member arrangement,²⁶ implementation typically requires the amendment of the health center's Articles of Incorporation and Bylaws to establish the other party as the sole corporate member (i.e. the "parent" corporation) of the health center corporation, and to identify the sole corporate member's rights and responsibilities vis-à-vis the health center's Board. The actual degree of integration is determined by the powers accorded to the sole member as defined in the Articles of Incorporation and Bylaws of the health center.

However, if the health center wishes to maintain its Section 330 grant or FQHC look-alike status, before entering into a sole corporate member (or similar) arrangement, the health center must secure prior approval from BPHC. See BPHC PIN #97-27, at p. 9. Generally, a sole corporate member, either through agreement between the parties or under State law, will have certain powers and authorities that supersede those typically granted to, or reserved by, the health center, e.g., the power to select all or a majority of the health center's Board members, the authority to select the health center's Chief Executive Officer, approval of the health center's budget. In the case of an FQHC, if specific authorities required by Section 330 to be vested in the health center Board are reserved to the sole corporate member, the arrangement may result in the health center's non-compliance with certain Section 330 grant-related requirements (thereby jeopardizing continued receipt of the grant and related benefits). See BPHC PIN #97-27, at pp. 9-10.

For the aforementioned reason, BPHC has indicated that it will not lightly approve a sole corporate member structural model, stating that "[N]o sole corporate member or any other parent-subsidiary approach to corporate integration, or any approach with a different name that appears to be structurally similar, will be deemed to have met all statutory and regulatory requirements unless there is no violation of any aspect of the affiliation policy clarification." See BPHC PIN #97-27, at p. 10 (emphasis added). Accordingly, BPHC scrutinizes proposed sole corporate member affiliations to determine whether the particulars of the sole member relationship impact the health center's compliance with the Section 330 statute and implementing regulatory requirements regarding Board selection, composition, and responsibilities and powers, including, but not limited to, autonomous decision-making of the health center Board in key areas of policy-making.

In general, BPHC will not allow sole corporate members to obtain actual or effective control over those powers and responsibilities that must be exercised by the Section 330 Board.²⁷ For example, a sole corporate member should not obtain power to:

²⁶ These proposals typically have been advanced by hospitals and health systems. On occasion, a dual membership approach has been proposed pursuant to which the health system becomes a member and the health center's non-health system directors are defined as a second member. BPHC has stated that whether the parties propose a sole member or multiple member approach, or, alternatively, if another party assumes powers vis-à-vis the health center Board by creating classes of directors on the Board with health system designees (albeit in the minority numerically) having ultimate authority (or veto power), BPHC will evaluate whether the approach effectively usurps the health center Board's autonomy and, if so, such approach most likely will be disapproved.

²⁷ To secure approval from BPHC for a sole corporate member (or similar) approach, the health center may be required not only to ensure the affiliation's compliance with applicable statutory, regulatory and policy requirements, but also to present justification for the affiliation through legal and/or management analyses. See BPHC PIN #97-27, at p. 10.

- Select a majority of a health center's Board, non-user members, or members of the Executive Committee, or select the Board Chairperson.
- Preclude the selection of, or require the removal of, a Board member not endorsed by the sole corporate member.
- Secure overriding approval authority, veto authority (including through "super-majority" requirements that effectively result in veto authority), or "dual majority" authority (i.e., a requirement that, in addition to the health center Board, the affiliation partner's Board maintains approval authority) vis-à-vis the responsibilities and powers to be exercised by the health center's community-based Board.
- Unilaterally amend the Articles of Incorporation or Bylaws.
- Select or fire the Executive Director.
- Establish and control strategic, operating and capital plans and budgets.
- Adopt the financial management, personnel and health care policies of the health center.

E. PUBLIC ENTITY MODEL

While the vast majority of health centers are private, nonprofit corporations governed by consumer-directed Boards of Directors that meet the specific requirements discussed in Chapter 1 above, Section 330 contains a narrow exception that permits public entities that do not fully meet certain Section 330 governance requirements to qualify for grant funds. Funds available to support such public health centers are limited to no more than five percent (5%) of a particular year's Section 330 appropriation. In recognition of the fact that most public entities are not, and legally cannot, be governed by a consumer-directed Board, Congress amended the statute in 1978 to exempt the governing Boards of public health centers from the requirement that the health center Board establish general policies (e.g., personnel and fiscal policies) for the health center.

The structure of the public health center – Generally, there are two (2) ways to structure a public health center:

- The public entity itself is structured to meet all Section 330 requirements, including those applicable to the consumer-based governing Board of Directors.
- The public entity has a formal arrangement with a “co-applicant” (preferred, but not required to be, a separately incorporated entity) that serves as the public health center's Board of Directors for purposes of Section 330-related oversight responsibilities.

Co-applicant arrangements – Under the co-applicant arrangement, the public entity is the licensed provider of services and receives the Section 330 grant from BPHC (or holds the FQHC Look-alike certification). The co-applicant Board must meet the selection and composition requirements that apply to other health centers' Boards and exercise some, but not all, authorities that other health center boards must exercise. Collectively, the two entities meet all other Section 330 requirements and are referred to as the “health center.”

- Financial and personnel policies – Insofar as the public health center's management team (including the CEO) and staff may be directly employed by the public entity, and it is understood that most public entities cannot legally delegate to another party (i.e., the co-applicant) the authority to establish financial and/or personnel policies applicable to their operations, the public entity is permitted to retain such authorities.²⁸
- Joint decision-making for other authorities – In recognition of the close partnership between the public entity and the co-applicant Board, BPHC guidance set forth in PIN

²⁸ To the extent that the co-applicant Board employs the staff and/or manages the Section 330 grant and related funding, the co-applicant Board should establish applicable personnel and/or financial policies.

#99-09²⁹ offers a significant degree of latitude to public entities and co-applicants to engage in a joint decision-making (although, with the exception of the annual budget, not joint approval) process regarding various matters, which are exercised autonomously by the Boards of private, nonprofit health centers, including:

- Development of the annual operating and capital budgets.
 - Selection, evaluation and dismissal of the health center's CEO.³⁰
 - Approval of the health center's annual project plan and grant applications (or FQHC certifications).
 - Selection of the services to be provided by the health center and the adoption of health care policies, including scope and availability of services, location and hours of services, and quality of care audit procedures.
 - Evaluation of the health center's activities, including service utilization patterns, productivity, patient satisfaction, achievement of program objectives, and development of the process for hearing and resolving patient complaints.
 - Adoption of policies for billing and collection activities, including the policy regarding eligibility for services and criteria for sliding fee discount schedules.
- Co-applicant agreement – The co-applicant Board and the public entity are expected to execute a formal “co-applicant” agreement that describes the delegation of authorities and defines each entity's roles, responsibilities and authorities with respect to oversight and administration of the health center. Typically, the co-applicant agreement will allocate specific responsibilities in key areas consistent with the flexibility granted in PIN #99-09:
- Governance: certain authorities will be subject to joint development, provided that the co-applicant Board retains final and ultimate approval authority.
 - Operations: either party can employ some/all of the management team (subject to the co-applicant Board's ultimate authority to select, evaluate and dismiss the Chief Executive Officer), with substantial flexibility regarding the allocation of finance, clinical and administrative duties.

²⁹ Please note that, while this PIN is specifically addressed to FQHC Look-alike entities, the guidance is equally pertinent to public entity grantees.

³⁰ Under a public health center model, it is permissible for either the public entity or the co-applicant Board to employ the CEO so long as the Board retains the ability to select, evaluate and dismiss such individual.

In addition to the allocation of responsibilities, issues typically addressed in the co-applicant agreement include:

- Cooperation in communicating and/or resolving health center-related issues;
- Treatment of grant-funded property and commitment to operate in a manner consistent with FQHC requirements;
- Record-keeping and reporting obligations;
- Insurance/indemnification requirements (as appropriate, depending on allocation of operational responsibilities);
- Confidentiality protections; and
- Termination (which is usually subject to BPHC approval if the FQHC is Section 330-funded).

Ultimately, the relationship between the public entity and the co-applicant Board, as reflected in the co-applicant agreement, should be structured to comply with all Section 330-related laws, regulations and policies, including the affiliation policies set forth in PIN #97-27 and #98-24.

F. HEALTH CENTER TO HEALTH CENTER CORPORATE AFFILIATIONS

In section F:

1. *Purchase Of Services Arrangements*
2. *Sub-Recipient Arrangements*
3. *Corporate Integration Strategies*

Affiliations between and among health centers have become increasingly more common. The options available are similar to those discussed above, ranging from contractual affiliations to corporate integration strategies. In addition, a grantee health center can enter into “sub-recipient” agreement with another health center that independently meets FQHC-related requirements in order to provide comprehensive services at a site within the grantee’s service area.

1. Purchase Of Services Arrangements

One method by which health centers can integrate operations involves implementation of a contractual affiliation, under which one health center (the purchaser) purchases certain identified services from another health center (the vendor). Under this approach, each health center retains its independent corporate identity and maintains its separate governing Board of Directors. The arrangement itself can be implemented through separate purchase of services agreements or under an umbrella agreement, with specific purchase of services contracts as “add-ons.” For further discussion regarding contractual affiliations, see Section B of this Chapter.

Purchase of services arrangements can be utilized for a variety of reasons, including, but not limited to, reducing costs, maximizing the scope of available services, and filling gaps in expertise/capacity, and can involve a varying degree of integration between the parties. In addition, an affiliation by contract can serve as a prelude to further integration.

Typically, contractual approaches are implemented at the purchaser’s site. For example, the purchaser health center could buy particular clinical, financial and/or administrative services from the vendor health center, which services will be provided at the purchaser’s site. However, to address particular delivery of services issues (e.g., lack of space and equipment, lack of expertise), the purchaser health center could buy services from the vendor health center, which will be provided to the purchaser or its patients at the vendor’s site.

To establish a purchase of services agreement, health centers should consider:

Terms and conditions related to location and oversight -- Regardless of the service location, to implement a purchase of services arrangement, the parties should enter into a purchase of services agreement containing terms and conditions ensuring that: (i) the vendor health center will provide services to the purchaser's patients (or to the purchaser health center, itself) at the specified site, on behalf of the purchaser and in accordance with its policies and procedures; and (ii) the purchaser will maintain appropriate monitoring and oversight of such services and will retain ultimate authority with respect to who provides the services and in the manner by which they are provided.

Terms and conditions related to payment – The purchaser health center should pay the vendor health center an arm's length rate, reflecting fair market value, for the services it provides, and, with respect to clinical services, the purchaser should bill for the services provided to its patients. For additional terms and conditions of typical purchase agreements, see Section B of this Chapter.

2. Sub-Recipient Arrangements

Under a sub-recipient arrangement, one health center is a Section 330 grantee (the prime recipient) and awards a portion of the grant to another health center (the sub-recipient) to carry out a portion of the prime recipients' expanded scope of project, typically to operate a new access point. Similar to a purchase of services arrangement, the parties maintain separate corporate identities and separate governing Boards of Directors. Significantly, the prime recipient is required to: include within its approved scope of project the sub-recipient's facility; as necessary, expand its service area; and expand, or otherwise reconfigure, its Board of Directors in order to include an appropriate number of representatives from the community served by the sub-recipient, based on relative user numbers.³¹

The sub-recipient would be an entity planning to operate as a separate, tax-exempt, nonprofit entity that is fully compliant with, and operates in accordance with, all Section 330-related laws, regulations and policies, including the requirement for a consumer-controlled, autonomous Board representative of the community served by the sub-recipient.³² Accordingly, under a sub-recipient model, both parties would qualify as FQHCs, and be eligible for the benefits available to Section 330-supported FQHCs (including, but not limited to, enhanced reimbursement from the Medicaid

³¹ Although the prime recipient may choose whether to select such representatives from the sub-recipient's Board, it must remain compliant with user majority and other Board composition requirements (see 42 C.F.R. §51c.304). Therefore, the number of seats set aside for representatives from the sub-recipient's community would be roughly proportionate to the number of patients served at the delivery site as compared to the number of patients served at the prime recipient's other site(s).

³² The central requirement for a sub-recipient arrangement is that the sub-recipient entity itself must qualify as an FQHC, e.g., it must fully meet the governance requirements for a Section 330 grantee and provide or arrange for the full scope of FQHC services at its site(s) according to a schedule of charges (based on locally prevailing charges and its costs of operation) and a corresponding schedule of discounts (adjusted based on the patients' ability to pay). In this respect, all Section 330-related requirements apply equally to prime recipients and sub-recipients, including the administrative requirements and cost principles set forth in 45 CFR Part 74.5.

and Medicare programs, FTCA coverage³³, and Section 340B favorable drug pricing).

To establish a sub-recipient arrangement, health centers should consider:

Sub-recipient accountability – Health centers choosing to create a sub-recipient relationship should begin by negotiating a sub-recipient agreement containing terms and conditions ensuring the accountability of the sub-recipient in accordance with Section 330 requirements. Such terms include:

- Provisions that require the sub-recipient to maintain compliance with all grant-related laws, regulations and policies with respect to service provision, financial and operational management, and governance.
- Provisions that allow the prime recipient to maintain oversight and monitoring of the agreement (e.g., site visits, limited scope audits, receipt of programmatic and financial reports from the sub-recipient, as well as the sub-recipient's annual A-133 audit, if applicable).

NOTE: the prime recipient is fully liable to DHHS for its entire scope of project and related expenditures, including the site(s) services and expenditures of the sub-recipient. Because of the prime recipient's exposure in this regard, the sub-recipient may be required to indemnify the prime recipient for its acts and omissions.

- Payment provisions, including provisions requiring the prime recipient to receive and approve an initial budget, as well as modifications, for the expenditure of grant and grant-related funds at the site. Because the budget of the sub-recipient is a subset of the grantee's total budget, the sub-recipient should establish a total budget that includes anticipated funds from Section 330-related program income (i.e., premiums; third party reimbursements; fees) and State, local and other operational funding. In this respect, the Federal sub-grant would equal no more than the difference between the total actual allowable costs incurred by the sub-recipient minus the amount of program income and other revenue received (up to the pledged amount). The prime recipient can give the sub-recipient considerable flexibility regarding the expenditure of program income, including excess program income (revenue greater than the amount pledged), consistent with the flexibility the prime recipient has to spend such funds in furtherance of Section 330 objectives and not for any prohibited purposes.
- Record keeping and reporting requirements consistent with Federal law and regulations.
- Financial and operational performance standards.

³³ A sub-recipient needs to independently pursue deemed status under FTCA, in accordance with BPHC requirements.

- Provisions that permit the recipient to take corrective action if instances of non-compliance, material weakness, or mismanagement are detected.

Other sub-recipient responsibilities – In turn, the sub-recipient would provide a comprehensive scope of services to its patients, in accordance with the policies and procedures established by its own Board of Directors and in the manner required by Section 330. The sub-recipient would operate with its own management team; bill and collect payment for the services it provides in accordance with requirements related to charges and discounts for patients with annual incomes below two hundred percent (200%) of poverty; retain all revenues generated to support the sub-recipient's approved scope of project (again a subset of the prime recipient's scope of project); and establish financial and programmatic management policies in accordance with 45 C.F.R. Part 74 (which are discussed further in Chapter 4, section B of this manual).

3. Corporate Integration Strategies

In this section:

- *Corporate Merger*
- *Asset Purchase*
- *Formation of a Subsidiary Corporation*

Health centers may also choose to affiliate with one another through various corporate integration strategies, including consolidation or merger, asset purchase, or formation of a parent-subsidary relationship.

Corporate Merger

Under a corporate merger approach (subject to State law), one health center (the dissolving health center) would, in effect, be acquired by another (the surviving health center) pursuant to a written "plan of merger" agreement approved by a majority vote (unless either corporation's Bylaws require a supermajority vote) of the governing Boards of both corporations. All of the rights/assets of the dissolving health center would transfer to, and vest in, the surviving health center, subject to Federal, State and/or other third party property interests (including, but not limited to, any reversionary interests retained by the Federal government in the property and equipment that was acquired or improved by the dissolving health center, in whole or in part, with Federal grant funds).

To implement a corporate merger, health centers should consider:

Transfer of assets in which the Federal government retains an interest – Consistent with Federal property standards that govern the transfer, sale and disposition of property and equipment acquired or improved with Federal grant funds, the parties would have to secure prior permission from the Federal government to transfer property and equipment in which the government retains an interest. Upon the transfer, the surviving health center's rights in such assets would be subject

to any interests retained by the Federal government in the assets. Alternatively, the surviving health center could “buy-out” the Federal interests by compensating the Federal government for its share of the fair market value of the assets. For a further discussion of Federal property standards, see Chapter 4, Section B of this manual.

Assumption of liabilities – In addition to acquiring all assets of the dissolving health center, the surviving health center would also assume all of its liabilities (whether known or unknown). The risk associated with assuming liabilities may present a major disadvantage, particularly if the dissolving health center has substantial liabilities, such as major financial problems (which are often the reason for pursuing the merger).

Transfer of Section 330 grant – With respect to transferring the dissolving health center’s Section 330 grant to the surviving health center, Public Health Service (PHS) policy authorizes one health center (in this case the surviving health center) to become the “successor-in-interest” to the prior grantee (the dissolving health center), provided that the surviving health center meets all Section 330-related requirements. The dissolving health center must notify BPHC of the impending change and submit certain documents verifying a proper transfer of assets (e.g., certificate of merger), Board approval of the merger, and the surviving health center’s corporate status. To implement the arrangement, BPHC and both health centers must execute a successor-in-interest agreement under which:

- The dissolving health center releases and discharges BPHC from all claims, demands, and rights against it that the dissolving health center has or may have in connection with the grant (except any allowable costs incurred in the performance of the grant prior to the transfer);
- The surviving health center assumes responsibility for, and agrees to comply with, the terms and conditions of the grant and Section 330-related laws, regulations and policies; and
- BPHC recognizes the surviving health center as the dissolving health center’s successor in interest in and to the grant. As such, the surviving health center becomes entitled to all the interests of the dissolving health center in and to the grant as if the surviving health center were the original party to the grant, and the term “grantee” as used in the grant is deemed to refer to the surviving health center rather than the dissolving health center.

Governance, management, and daily operation – The Board of Directors of the surviving health center would become directly responsible for the governance, management and daily operation of the dissolving health center’s overall operations. The surviving health center would be required to include the dissolving health center’s service area in its scope of project and to expand, or otherwise reconfigure, its Board of Directors in order to include an appropriate number of representatives from the dissolving health center’s service area, based on relative user numbers.

Due diligence investigation and plan of merger – Prior to negotiating the plan of merger, the surviving health center should conduct a due diligence investigation regarding the value of the dissolving health center’s assets and its potential liabilities and/or other third party interests (e.g. Federal interests). As part of the plan of merger, the parties should negotiate terms and conditions, which would define, among other things:

- Assurances that certain services will be continued post-merger.
- The extent to which the dissolving health center's workforce will be transferred to the surviving health center to deliver health care services as either employees or as independent contractors.
- Governance strategies (e.g., granting the dissolving health center one or more Board member seats on the surviving health center's governing Board).

Asset Purchase

As an alternative to merger, health centers could enter into an asset purchase agreement whereby one health center (the purchaser) would acquire the other health center's (the seller) health care operation by purchasing the seller's assets (e.g., equipment and supplies), based on fair market value. The primary advantage of this approach, is that, unlike the merger option, the purchaser can acquire the assets needed to operate the health center but avoid assuming most, if not all, of the seller's liabilities. This may be particularly useful if the seller health center has substantial liabilities (i.e., owes a substantial amount of money to third parties).³⁴ However, the purchaser health center should bear in mind that it must pay fair market value for the assets it intends to purchase.

To implement an asset purchase agreement, health centers should consider:

Sale of assets in which the Federal government retains an interest -- Similar to the merger approach, the sale of assets would be subject to Federal, State and/or other third party property interests (including, but not limited to, any reversionary interests retained by the Federal government in the property and equipment that was acquired or improved by the seller, in whole or in part, with Federal grant funds). Accordingly, once permission for the sale is secured, the purchaser's rights in the acquired assets would be subject to interests retained by the Federal government unless the purchaser "buys-out" the Federal interest.

Transfer of Section 330 grant – With respect to the transfer of the seller's Section 330 grant under an asset purchase agreement, if the seller health center dissolves as a result of the asset purchase, the parties may execute a successor-in-interest agreement (discussed above). If, however, the seller health center remains in existence, as an alternative to implementing a successor-in-interest agreement, the seller may be permitted to transfer to the purchaser health center the legal and administrative responsibility for the grant-supported project prior to the expiration of the approved project period if:

- The original grantee (the seller) has agreed to transfer responsibility to a replacement grantee (the purchaser);
- The need for the grant-supported project that existed when the grant was initially awarded continues to exist at the time of the transfer and there is no significant change in the scope of services provided; and

³⁴ Of note, an asset purchase should not be used as a means to defraud creditors in a bankruptcy situation.

- The transfer is made in a timely manner.

Governance, management, and daily operation – Similar to the merger approach, the purchaser's Board of Directors would become directly responsible for the governance and operation of the seller's health care operations. The purchaser would be required to include the seller's service area in its scope of project and to expand, or otherwise reconfigure, its Board of Directors in order to include an appropriate number of representatives from the seller's service area, based on relative user numbers.

Due diligence investigation and asset purchase agreement – Prior to negotiating an asset purchase agreement, the purchaser should conduct a due diligence investigation regarding the potential liabilities and/or other third party interests (e.g. Federal interests) associated with the particular assets to be purchased. Upon the completion of the due diligence review, the parties would negotiate the asset purchase agreement and the purchaser would acquire the seller's assets, while avoiding assumption of most, if not all, of the seller's liabilities in accordance with the agreement's terms and conditions. The asset purchase agreement should define, among other things:

- The assets subject to the agreement and the assets excluded from the purchase.
- The asset purchase price, based on fair market value.
- The extent to which the purchaser will assume liabilities related to the assets purchased.
- The extent to which the seller's workforce will be transferred to the purchaser to deliver health care services either as employees or as independent contractors.
- Governance strategies (e.g., granting the seller some Board members seats on the purchaser's governing Board; whether the seller will maintain its own Board for non-health care delivery activities).

Continued operations of the seller – The seller could use the money generated from the sale of assets to cover certain outstanding liabilities and then could either dissolve the corporation or continue to operate as a separate corporation. As noted above, if it chooses to continue in existence, its primary health care operations (including its Section 330 grant) would be transferred to the purchaser health center. However, it could deliver a variety of non-health care related services, such as social services and/or fund-raising activities, to support the health care activities of the purchaser. Typically the asset purchase agreement would prohibit the seller from continuing to deliver primary care services.

Formation Of A Subsidiary Corporation

Although very rare in actuality, a third corporate integration approach involves an arrangement under which one health center (the parent) assumes control of the governance of the other (the subsidiary), via sole membership or other methodology, creating a subsidiary corporation of the parent corporation.³⁵ Under this type of affiliation, the subsidiary would continue its corporate existence and would maintain a separate Board of Directors. However, the parent's Board of Directors would gain overall (although not daily) control over the management and operations of the delivery site.

To establish a subsidiary corporation, health centers should consider:

Scope of project, governance, and operations – Similar to a sub-recipient arrangement, the parent *would include* the subsidiary's service area in its scope of project and expand, or otherwise reconfigure, its Board of Directors in order to include an appropriate number of representatives from the subsidiary's service area, based on relative user numbers. However, unlike a sub-recipient arrangement, the subsidiary *would not* have to be fully compliant with Section 330-related governance requirements in its own right. The parent would establish the subsidiary's delivery site as one of its own and, in turn, lease space and, as needed, clinicians from the subsidiary through a purchase of services arrangement. The patients served at the subsidiary's site would be patients of the parent and the parent health center would be responsible for billing and collections.

Assumption of liabilities – Under a parent-subsidary approach, the parent health center *would not* be required to assume the subsidiary's corporate liabilities, although it could arguably be liable for some of subsidiary's liabilities to the extent the parent exerts control over the subsidiary's day-to-day operations.

Amendment of the subsidiary's Articles of Incorporation and Bylaws – Unlike merger and asset purchase options, to implement the parent-subsidary approach, the parent must undertake the relatively simple process of amending the subsidiary's Articles of Incorporation and Bylaws to give the parent the requisite governance authority.

³⁵ A more typical scenario occurs when a single health center corporation establishes a subsidiary corporation to provide services and/or engage in activities that are outside the health center's approved scope of project. Because that type of arrangement involves diversification rather than affiliation, however, it is beyond the scope of this manual.

CHAPTER 3:

Predictable Steps in Negotiating Affiliations

Chapters 1 and 2 of this manual explored:

- various reasons for entering into affiliation arrangements,
- types of potential affiliation partners, and
- the multitude of structural options available to health centers and their partners.

Prior to implementing a plan of affiliation, a number of steps should be taken. This chapter provides a step-by-step approach to execute a successful affiliation agreement.

STEP 1: VALUE ASSESSMENTS

STEP 2: AFFILIATION ALTERNATIVES AND PARTNERS

STEP 3: THE CONFIDENTIALITY AGREEMENT

STEP 4: THE NON-BINDING MEMORANDUM OF AGREEMENT (“MOA”)

STEP 5: THE JOINT PLANNING PROCESS

STEP 6: MUTUAL DUE DILIGENCE

STEP 7: REGULATORY APPROVALS

STEP 8: DEFINITIVE AGREEMENTS

STEP 1: VALUE ASSESSMENTS

As the first step before commencing negotiations, the health center should identify and assess its own strengths and weaknesses in its local marketplace (the health center's "value"). In addition to the obvious sources of value (i.e., property, equipment, supplies, and other tangible assets), the health center may demonstrate value in other ways. For example, the health center may have a long-standing and trusted relationship with the community. This "goodwill" represents a valuable asset, which a potential affiliate might need years to cultivate on its own, but by virtue of its arrangement with the health center, could instantly access.

Compile information to identify and quantify value of health center – To assist the health center in identifying and quantifying its value, certain important information, which will form the basis for the ensuing negotiations, should be compiled. This information includes:

- Number of patients served by type of payor;
- Clinical and administrative capabilities and capacities;
- Array of services offered;
- Experience in providing comprehensive primary care and support services;
- Infrastructure, including facilities, management information systems ("MIS") and equipment;
- Geographic coverage;
- Experience in the implementation of managed care contracts; and
- Existing relationships with other health care and social service providers within the community.

Document financial benefits – In addition, the health center should document (for itself) the considerable financial benefits that it enjoys by virtue of receiving a Section 330 grant or being designated as an FQHC Look-alike entity. As applicable, the health center should quantify the value of:

- The Section 330 operating grant;

- The difference between cost-based or other forms of enhanced reimbursement (Medicare and/or Medicaid) and the amounts that would have otherwise been received for comparable visits;
- Waiver of the Medicare deductible and of co-payments to the extent a patient has an annual income at or below 200% of Federal income poverty guidelines;
- Access to favorable drug pricing under Section 340B of the Public Health Service Act;
- Access to providers through the National Health Service Corps, so long as the health center's service area is designated as a Health Professional Shortage Area (HPSA);³⁶
- Grant support for certain capital improvements and access to facility and network loan guarantees (not applicable to FQHC look-alike entities);
- FTCA coverage in lieu of professional liability insurance (not applicable to FQHC look-alike entities);
- The right to have states outstation Medicaid eligibility workers on the health center site (absent an alternative approved by the U.S. Centers for Medicare and Medicaid Services (CMS); and
- Access to the Federal Vaccine for Children and Pfizer Sharing the Care programs.³⁷

See **APPENDICES 5 AND 6: Value Assessment in Preparation for Negotiation with Potential Partners and Benefits for which Health Centers are Eligible.**

³⁶ Section 332 of the Public Health Service Act (42 USC 254e), as amended by P.L. 107-251, grants automatic HPSA status to health centers, effective upon the date an entity is designated as a health center for a period of not less than six (6) years. Thereafter, each health center will be required to demonstrate that it meets the regulatory definition of a HPSA to maintain such designation.

³⁷ If there are State-level benefits, such as an indigent care pool, these benefits should be documented as well.

STEP 2: AFFILIATION ALTERNATIVES AND PARTNERS

Having assessed the health center's "value" to a potential partner, the health center should think creatively and critically about potential affiliation options and partners. The negotiation and implementation of affiliation arrangements takes time and money, and creates additional obligations, legal and otherwise, for the health center. Such negotiations should not be undertaken lightly.

Conduct a needs analysis and identify options – A “strategic priorities/needs analysis” should be performed and, using the outcome of the analysis as a guide, the health center should identify options regarding potential affiliation partners and the services/items to be provided. Often, health centers have multiple affiliations with different partners. In this regard, consider not only what the health center needs from the potential partner(s), but also what the health center can offer to the partner(s). For example, a health center that initially intended to seek a donation of considerable sums from another provider may, upon further analysis, discover that the sale of excess clinical capacity and/or administrative capacity at fair market value eliminates the need for the gift, while spreading costs and thereby achieving economies.

Develop a “wish list” of potential joint activities – The health center should develop a list of joint activities it wishes to consider, and should define the goals and objectives it wishes to achieve through a potential affiliation or multiple affiliation arrangements. As discussed in the Introduction of this manual, joint activities may range from the health center purchasing administrative support services from a practice management network in the areas of MIS and claims collection, to the health center selling management services to health systems in need of primary care management expertise for the primary care practices they have acquired. Developing clinical linkages among existing sites and services, expanding to new locations, establishing new services and programs, co-locating specialty services, sharing other health care-related resources and expertise, developing integrated protocols and procedures, and establishing teaching programs are also common joint activities.

Construct a list of potential partners – Once an analysis of the center's strengths and weaknesses (based on the value assessment discussed in Step 1) and a carefully constructed "strategic wish list" have been completed, the health center will be able to decide which potential partners are most suitable and for what purposes. It is important to determine early on what the affiliation partner's goals are and whether there is a likely fit, at least on some, if not all, wish list items.

STEP 3: THE CONFIDENTIALITY AGREEMENT

After the parties' initial discussions regarding the goals, objectives, and possible structure of the affiliation suggest a potential fit, thereby making further planning efforts worthwhile, the health center and its affiliation partner(s) should execute a confidentiality agreement. A confidentiality agreement is designed to protect all parties to the negotiation from the unauthorized disclosure and use of confidential and/or proprietary information that may be exchanged during the planning processes, performance of due diligence reviews, and negotiation of definitive agreements.

Avoid unilaterally binding agreements – Typically, confidentiality agreements are relatively straightforward. However, some agreements may contain provisions that unilaterally bind the health center to negotiate exclusively with the potential affiliation partner, while the potential partner remains free to negotiate with others during the same period of time. The health center should not agree to such limitations before the health center has an opportunity to determine the likelihood that an appropriate affiliation with this party will materialize (if at all), and even then, be wary of exclusivity obligations.³⁸

Review all documents and their terms – Consequently, it is important to review every document and all "boilerplate" provisions to make sure that all protections are mutual and that the document does not contain restrictions that would bind the health center prematurely to negotiate and/or collaborate solely with the potential partner.

Provisions common to confidentiality agreements are:

- Definitions of "confidential" and "proprietary" information, as well as information that is not considered confidential/proprietary (i.e., information in the public domain).
- Allowable uses and disclosures of confidential and proprietary information.
- Prohibitions and limitations of all non-specified uses and disclosures without the written consent of the other party(s).

³⁸ Often, a potential partner will attempt to bind the health center to affiliate exclusively with such partner. In general, BPHC discourages relationships that include absolute exclusivity provisions. As such, it is advisable for health centers to qualify any commitment to enter into an exclusive relationship with an affiliation partner so as to retain the right to contract and/or form collaborative relationships with other providers, as required by Section 330 and its implementing regulations.

- The return of confidential and proprietary information promptly, if the parties decide not to affiliate or upon request.
- Remedies for the unauthorized disclosure of confidential or proprietary information by a party, its officers, employees and/or agents, including the right to enjoin the other party(s) from any disclosure of confidential and proprietary information.
- Survival of confidentiality obligations after termination or expiration of the agreement.

STEP 4: THE NON-BINDING MEMORANDUM OF AGREEMENT (MOA)

To establish an orderly negotiation process, as well as to avoid having negotiations break down because of "deal-breakers" that could have been resolved if identified and discussed early on, the parties should reach a non-binding agreement "in principle" regarding the planning process and the key terms of the affiliation, which should be subject to each party's (i) satisfactory due diligence review, and (ii) at least for the health center, Board approval of all definitive agreements.

Common terms for preliminary agreement -- In general, preliminary agreement is important as to:

- The proposed scope of joint activities.
- A time-line for the negotiations.
- Which management and staff members will represent each party in the planning process (i.e., the planning "team").
- What types of consultants (if any) are going to be hired, by which party and at whose expense.
- What types of limitations, if any, will apply during the planning and negotiation period with respect to the ability of the parties to negotiate with others regarding the subject of the MOA.³⁹
- Requirements that the parties will agree on any publicity and/or third party disclosure regarding the collaboration.
- Requirements for disclosure to one another of other pertinent negotiations.
- The parties' financial expectations.
- Other critical terms of the proposed affiliation, including the health center's right to terminate the agreement (as well subsequent negotiations) if the other party affiliates, or is negotiating, with an entity that (i) has a mission that is incompatible with the health center's mission, or (ii) is a competitor of the health center.
- To the extent feasible, all commitments should be mutual, and must be compliant with applicable laws and regulations, including, but not limited to, Section 330, its implementing regulations and related policies and expectations.

³⁹ As the process of planning collaboration arrangements is time consuming and costly, it may be very important for the health center to be assured that the other party is not negotiating with someone else regarding the potential affiliation options.

Clarify expectations on affiliating with other parties – Of particular importance, the agreement should specify expectations concerning negotiations or affiliations with other parties, as well as disclosure of such opportunities to the potential affiliation partner(s). Since health centers have an obligation, as a condition of their Section 330 grants, to make sure they have appropriate collaborative relationships with other local providers, exclusivity provisions must be analyzed carefully. Health centers should qualify any commitment to negotiate (or affiliate) exclusively with one entity so as to permit collaboration with other parties if such collaboration is necessary to insure the provision of, and access to, comprehensive services for the target population, or as otherwise required to fulfill Section 330 requirements and/or implement Board policies and procedures.

STEP 5: THE JOINT PLANNING PROCESS

The parties would be well advised to commit to participate in a joint planning process, as described in the MOA.

Form a planning committee – The planning process generally involves the formation of a joint planning committee to direct the proposed affiliation activities and to represent the parties during the planning process. The planning committee should be comprised of an equal number of appropriate senior-level personnel designated by each party, representing key areas under review, e.g., clinical, finance, etc. Each party should retain sole discretion to designate its respective representatives; however, to maximize the likelihood that the parties' respective decision-making bodies will approve or at least seriously consider the planning committee's recommendations, the representatives selected by each party should be very senior.

Conduct regular planning meetings – The planning committee should meet at regularly scheduled times and dates (preferably, on a monthly basis at the outset) to:

- Review and analyze the specific collaborative options identified during prior discussions and make recommendations with respect to the feasibility of implementing such options;
- Discuss the progress of current affiliation activities, if any, and address and resolve issues related to such activities; and
- Identify new opportunities available to the parties and initiate feasibility studies.

Establish sub-committees or task forces – As necessary, the joint planning committee may establish sub-committees or task forces to perform detailed analyses and to make recommendations to the committee regarding specific issues/matters (e.g., clinical, financial, operational, legal, teaching (as applicable) and other particular matters).

STEP 6: MUTUAL DUE DILIGENCE

In conjunction with the joint planning process, the parties to a potential affiliation arrangement(s) should conduct appropriate “due diligence reviews” in order to enable the health center and the other party (or parties) to make an informed decision regarding whether to proceed with the affiliation and/or to alter the terms of the affiliation. While there is no single “correct” way to conduct a due diligence review, a reasonable level of due diligence (taking into account time and cost considerations and the particular set of facts and circumstances surrounding the proposed transaction) should always be conducted before entering into a binding agreement. Failure to do so could place the health center in a position of discovering, after executing binding agreements, that the other party is not financially, legally or otherwise “fit.”

Investigate all aspects of potential partners – Due diligence may involve an investigation of legal, financial, organizational, management, clinical and/or operational aspects of the potential affiliation partner. This investigation could consist of, among other activities, reviewing various documents, interviewing key personnel, and/or physically inspecting real and personal properties, depending on the nature of the potential collaboration. The information requested should be divided into categories and analyzed by individuals based on their areas of expertise (i.e., the health center's CFO and, possibly, an external financial expert should review the other party's relevant financial information). Because it is as important to understand the historical trends of a potential partner as it is to understand its current situation, the health center typically should request year-to-date information and information for at least the previous three (3) years.

Verify that potential partners can meet obligations – The purpose of conducting a due diligence review is to verify that the potential partner will be legally, and otherwise able to meet all obligations under the definitive agreement. The scope of review should give reasonable assurances that any problems of the potential partner or affiliation arrangement (whether or not previously disclosed), which could adversely affect the health center and/or the likelihood of success of the affiliation, are identified and duly considered.

Assurance to health center's Board of Directors – A reasonable due diligence review also provides assurance to the health center's Board of Directors that the Board has fulfilled its fiduciary duties to ensure that the contemplated affiliation is in the health center's best interests. If the due diligence process reveals information that has negative consequences for the health center, the health center may decide to restructure the transaction, terminate plans to affiliate, or, depending on the particular issue, accept the negative finding as a “cost” of the transaction and proceed with the affiliation (assuming that the negative finding does not pertain to a fundamental legal or financial flaw in the proposed affiliation).

See **APPENDIX 7: A sample due diligence checklist.**

STEP 7: REGULATORY APPROVALS

Prior to the execution of definitive agreements implementing the activities contemplated by the MOA, the health center must satisfy any and all necessary and pertinent statutory and regulatory requirements relevant to the collaboration.

Common regulatory approvals -- Regulatory approvals common to health center affiliations may include:

- Complying with applicable State licensure, certificate of need and credentialing requirements.
- Securing, if necessary, a change in the health center's approved scope of project from BPHC, in accordance with PIN #2002-07, "Scope of Project Policy," (December 31, 2001), attached as **APPENDIX 3**.
- Securing advance rulings, advisory opinions and other regulatory approvals, as may be relevant from other Federal and State regulators (e.g., securing an advisory opinion from the DHHS Office of Inspector General (OIG) regarding the legality of the affiliation arrangement, in whole or in part, under the Federal anti-kickback statute). For further discussion regarding changes in the scope of project and the OIG advisory opinion process, see Chapter 4, Sections B and E, respectively.

Obtaining BPHC approval of the affiliation arrangement -- Each health center contemplating an affiliation should request and obtain from BPHC approval of the affiliation arrangement itself.⁴⁰

- All applicants for New Access Point Section 330 grant funding and entities applying for FQHC Look-alike designation must complete and submit to BPHC the Affiliation Checklist included within the New Access Point or FQHC Look-alike Application. PIN #98-24 also includes the Affiliation Checklist, a copy of which is attached hereto as **APPENDIX 4**.⁴¹ The checklist provides BPHC with information regarding existing and proposed affiliations, which will be used by BPHC to assure that (i) the terms of the affiliation are consistent with

⁴⁰ In addition to Section 330 grant and FQHC-related issues, health centers should be careful to secure a qualified attorney's advice with respect to the arrangement's compliance with Medicare and Medicaid law, anti-kickback statutes, physician self-referral laws, antitrust laws and Federal and State tax issues. There may also be State law antitrust concerns, State corporate practice of medicine, licensing, Certificate of Need ("CON"), zoning and/or other local issues.

⁴¹ Health centers that require a review for compliance of a new affiliation or of significant changes to an existing affiliation during a given budget or project period, can submit the checklist in accordance with BPHC's process for post-award requests, described in BPHC PIN #98-24.

applicable Section 330 governance, administrative and clinical requirements and BPHC expectations, and (ii) the health center organization is in compliance with such requirements and expectations, including BPHC's affiliation policies contained in PIN #97-27 and PIN #98-24. Affiliation approval steps include:

- BPHC either will communicate results with its New Access Point application decision or, in the case of affiliation reviews conducted during a budget/project period, typically will provide feedback within thirty (30) days of its receipt of the request. (FQHC Look-alike reviews will be coordinated with the designation and recertification processes).
- The health center will be afforded an opportunity to resolve outstanding issues.

Health centers that have previously received letters from BPHC approving an affiliation can submit the approval letter along with the completed checklist. For a further discussion regarding BPHC affiliation policies and the affiliation review process, see Chapter 4, Section A of this manual.

STEP 8: DEFINITIVE AGREEMENTS

The final step in the process is the execution of definitive agreements. These may take many forms, including (but not limited to) a contract or multiple contracts, partnership agreement, limited liability company operating agreement, revised Articles of Incorporation and Bylaws for existing entities or new Articles and Bylaws (and possibly a shareholder agreement) for a newly formed entity, or a combination of the foregoing.

Terms of definitive agreements – In addition to the terms and conditions discussed in Chapter 2 of this manual, definitive agreements should include terms that allow the parties to modify the agreements and change the affiliation as may be appropriate over time as well as to terminate the affiliation if the goals of the parties are not being reasonably achieved or if circumstances have substantially changed.

CHAPTER 4:

Legal Considerations Related to Affiliations

There are numerous legal issues that should be addressed in structuring an affiliation arrangement (however “simple” or complex). The types of legal issues depend on the nature and complexity of the affiliation itself. Many of the most common legal considerations are discussed in this chapter.

A. SECTION 330 GRANT-RELATED REQUIREMENTS AND POLICIES REGARDING AFFILIATIONS

B. OTHER SECTION 330-RELATED REQUIREMENTS AND POLICIES

C. FEDERAL TAX CONSIDERATIONS

D. FEDERAL ANTITRUST LAW

E. FEDERAL ANTI-KICKBACK LAW

F. FEDERAL PHYSICIAN SELF-REFERRAL (STARK I & II) LAW

G. FEDERAL FALSE CLAIMS LAWS

H. STATE LAWS AND REGULATIONS

A. SECTION 330 GRANT-RELATED REQUIREMENTS AND POLICIES REGARDING AFFILIATIONS

In section A:

1. *Pin #97-27: Areas of Critical Concern*
2. *Pin #98-24: The Review Process and Good Cause Exceptions of the Direct Staffing Model*

Consistent with Section 330 and the U.S. Department of Health and Human Services (DHHS) implementing regulations, health centers are expected to establish and maintain collaborative relationships with other health care providers in the relevant service area (as reasonable).⁴² However, in 1997, in response to an increasing number of collaborations between health centers and other providers, and a growing concern that such affiliation arrangements might compromise the health center's compliance with legal and policy requirements (thereby jeopardizing its eligibility for Section 330 funds and/or Federally Qualified Health Center [FQHC] status), the U.S. Health Resources Services Administration's (HRSA's) Bureau of Primary Health Care (BPHC) issued a policy information notice (PIN) addressing such arrangements, **PIN #97-27**. The key purpose of the policy is to offer guidance to health centers in forming collaborations that will strengthen their ability to provide comprehensive, cost-effective health care and related services while maintaining the autonomy and integrity of the health center model, as required by Section 330 and DHHS implementing regulations.⁴³

In 1998, BPHC issued a second policy addressing affiliation-related issues. **PIN #98-24** clarifies BPHC's position regarding affiliation arrangements that deviate from BPHC's preference that a health center *directly* contract for certain staff. The PIN addresses arrangements under which a health center contracts with *another entity* for the services of the health center's CFO, CMO, and/or the majority of its primary care clinicians. (For examples of such agreements, see Chapter 2, Section B) PIN #98-24 also sets forth BPHC's review process for determining whether an affiliation

⁴² 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. For additional guidance regarding Federal procurement standards, see Chapter 4, Section B of this manual.

⁴³ It is important to note that BPHC is especially concerned with the potential effects on health center autonomy associated with affiliations with entities not subject to Section 330-related requirements (e.g. a hospital).

arrangement complies with the guidelines described in PIN #97-27, as well as the process by which it will approve a request from a health center for an exception to the direct staffing model.⁴⁴

Key considerations from these policies include:

Autonomy and integrity -- Health centers are expected to maintain a high level of autonomy and integrity as they forge affiliation arrangements with other parties, including meeting requirements and adhering to guidance relating to the selection and composition of the governing Board and the autonomous exercise by the Board of certain authorities and responsibilities.

Structure and operations -- Any health center affiliating with another entity (or entities) should structure the ensuing affiliation agreement(s) to assure that the center's corporate structure and organizational operations remain in compliance with all Section 330-related requirements and expectations.

BPHC review – BPHC will review a number of key areas of each affiliation arrangement to determine:

- Does the affiliation diminish the health center's role/autonomy in carrying out health center activities?
- Does the arrangement result in the health center merely serving as a conduit for passing on a grant award and/or other benefits to a third party?
- Is the affiliating partner vested with inappropriate authority to oversee or approve key aspects of health center activities?

If any of these questions are answered affirmatively, BPHC is not likely to approve the affiliation.

1. Section 330 Affiliation Policy: PIN #97-27

Areas of Critical Concern

In this section:

- *Corporate Structure*
- *Governance*
- *Management and Finance*
- *Health Services and Clinical Operations*

⁴⁴ As noted earlier, the BPHC affiliation policies apply solely to health centers that receive funding under Section 330(e) and/or Section 330(g). However, the considerations discussed therein serve as good guidance for all health centers. Accordingly, it is recommended that all health centers consider these guidelines when negotiating and executing collaborations with other entities.

PIN #97-27 addresses four areas of critical concern: *corporate structure, governance, management and finance, and health services/clinical operations*. BPHC, through the review process specified in PIN #98-24, will determine whether a specific affiliation arrangement impacts the ability of the health center to meet the requirements and/or expectations for each of these areas.

Corporate Structure

BPHC, in its affiliation policy, has stated its grave concerns regarding affiliation arrangements between health centers and non-health center entities that would jeopardize the health center's autonomy and integrity.

BPHC states that it will pay particular attention to corporate integration, which it describes as "structural relationships between the health center and any other entity or entities." Corporate integration typically involves a change to the corporate structure and identity of one or both of the parties to the affiliation, for example, through consolidation or formation of a sole corporate member arrangement or other parent-subsidiary arrangement. These types of arrangements generally will not be approved unless the health center can demonstrate that it remains compliant with all Section 330-related requirements, including Board selection and composition requirements and the exercise of required authorities, and the structure is specifically approved by BPHC. For further guidance on sole member and similar structures and the manner in which they can be structured to comply with BPHC requirements and expectations, see Chapter 2, Section D.

Governance

Board selection and composition requirements – Under all affiliation arrangements, the process for selecting Board members should be designed to ensure that the governing Board complies with applicable regulatory composition requirements (42 CFR §51c.304) and policy expectations. In particular, the health center's governing Board must continue to meet the composition standards described in 42 CFR §51c.304(b) and should also comply with BPHC Program Expectations set forth in PIN #98-23, as follows:

- The Board must be comprised of at least nine (9), but no more than twenty-five (25) members.
- A majority of the Board members must be individuals who have utilized (or, for planning grantees, will utilize) the health center, with a "user" defined in the Program Expectations as an individual who uses the health center as his/her principal source of primary care, and has done so within the last two (2) years. The user members must collectively represent the individuals being or to be served in terms of demographic factors, such as race, ethnicity, and sex.

According to PIN #98-23, a legal guardian of a consumer who is a dependent child or adult, or a legal sponsor of an immigrant consumer, may be considered a user for purposes of Board representation. Further, BPHC expects that, if a health center's Section 330 funding includes both community health center and special population (*i.e.*, migrant, homeless, public housing) grant funding, the consumer representation from the specific special

population(s) should be reasonably proportional to the percentage of health center consumers who are from that special population.⁴⁵

- The remaining members of the Board (“non-user members”) should be representative of the community in which the center's service area is located and should be selected for their expertise in community affairs, local government, finance and banking, legal affairs, trade unions, and other commercial and industrial concerns, or social service agencies within the community.
- No more than one-half of the non-user members of the Board may be individuals who derive more than ten percent (10%) percent of their annual income from the health care industry. For health centers receiving grants only to serve migratory and seasonal farm-workers, the pertinent rules state that two-thirds (2/3) of the non-users may be such individuals.
- No member of the Board should be an employee of the center, or a spouse, child, parent, or sibling (by blood or by marriage) of such an employee.

In PIN #97-27, BPHC identified additional restrictions regarding health center Board member selection and removal processes. Specifically, another party (or parties) should not select a majority of the total number of health center Board members, a majority of the non-user Board members, the chairperson/president of the governing Board, or the majority of Executive Committee members. Further, another party should not limit the selection of certain Board member candidates or, conversely, require the dismissal of any current health center Board members not appointed by that other party.

Board authorities and responsibilities – Section 330, the implementing regulations and BPHC Program Expectations set forth numerous responsibilities that the governing Board of a health center is required or expected to exercise, including:

- Hold regularly scheduled meetings (at least monthly).
- Prepare and approve the health center's overall plan, including its strategic and operational plans.
- Prepare and approve the health center's annual budget and project plan submitted as part of any Section 330 grant application.
- Establish, adopt and periodically update personnel policies and procedures, including selection and dismissal procedures, salary and benefit scales, employee grievance procedures, and equal opportunity practices.

⁴⁵ Section 330(l)(3)(H) authorizes the Secretary of DHHS to waive, upon a showing of good cause by the health center grantee, all or part of the health center Board composition requirements for Section 330 (g), (h) and (i) grantees (i.e., migrant, homeless and public housing grantees). HRSA/BPHC policy regarding health center governance specifies that these exceptions are to be made on a case-by-case basis. Health centers requesting such waivers should present a compelling argument as to why the health center cannot meet the statutory composition requirements, and should address alternative strategies for how the health center intends to meet the statutory intent for assuring appropriate consumer representation. See BPHC PINs #98-12, at pp. 5-6; #98-23, at pp. 28-29.

- Establish, adopt and periodically update the health center’s policies for financial management practices, including a system to assure accountability for corporate resources, center priorities, eligibility for services and long-range financial planning.
- Establish, adopt and periodically update health care policies, including scope and availability of services, location and hours of services, and quality of care audit procedures.
- Evaluate center activities, including service utilization patterns, productivity, patient satisfaction, and achievement of project objectives, and develop a process for hearing and resolving patient grievances.
- Evaluate the Corporation's achievements at least annually, and use the knowledge gained to revise its mission, goals, objectives, plans, and budgets as may be appropriate and necessary.
- Evaluate itself periodically for efficiency, effectiveness, and compliance with all Section 330 requirements.
- Assure compliance with applicable Federal, State and local laws and regulations.
- Select an independent auditor and officially accept the annual audit report.
- Maintain a commitment to provide services to the medically underserved.
- Select, directly employ and, if necessary, dismiss the health center’s CEO or Executive Director.

See 42 C.F.R. §51c.304(d); BPHC PIN #98-23 at p.24.

BPHC affiliation policy states that, in the context of affiliation arrangements, the governing Board of the health center must maintain all authorities and responsibilities required by law or regulation.⁴⁶ Accordingly, other parties (e.g. affiliation partners) should not secure overriding approval authority, veto authority (including through "super-majority" requirements that effectively result in veto authority), or "dual majority" authority (i.e., a requirement that, in addition to the health center Board, the affiliation partner’s Board maintains approval authority) with respect to the Board’s authorities and responsibilities. Such proscription includes authority over the amendment of the health center's corporate documents (i.e., the Articles of Incorporation and Bylaws), which, in turn, may impact the ability of the Board to exercise its prescribed authorities.

⁴⁶ The “public entity” health center model allows for certain exceptions to these requirements. For further discussion regarding the structure and operation of public entity health centers, see Chapter 2, Section E of this manual.

Management and Finance

Taking into consideration the statutory and regulatory requirements related to the health center's management and financial operations, BPHC will review proposed affiliation arrangements to ensure that:

- No other entity has the power to select or dismiss the health center's Executive Director/CEO, without exception.
- No other entity has the power to employ the health center's CFO or CMO, subject to the good cause exceptions discussed below.
- The health center's overall strategic and operational plans, budget, personnel policies and financial management policies are prepared under the direction and control of, and approved by, the health center Board.

Health Services/Clinical Operations

Taking into consideration the statutory and regulatory requirements related to the health center's provision of health services and clinical operations, BPHC will review proposed affiliation arrangements to ensure that:

- The health center maintains its mission of providing care to a medically underserved community/population.
- No other entity has the power to employ the majority of the health center's primary care clinicians, subject to the good cause exceptions discussed below.
- No other entity has the power to preclude, dictate, or otherwise control the health center's relationships with other entities unless such control does not impact (or have the potential to impact) the health center's compliance with statutory and regulatory requirements to collaborate with other local providers and to coordinate care with other Federal, State and local health services delivery projects and programs serving the same population(s).
- The health center's health care policies and procedures are prepared under the direction and control of, and approved by, the health center Board and the health center Board maintains the right to evaluate the health center's clinical activities.

2. Section 330 Affiliation Policy: PIN #98-24: Review Process and Good Cause Exceptions to the Direct Staffing Model

In this section:

- *Compliance Review*
- *Approval of Good Cause Exceptions to the Direct Staffing Model*

As discussed in Chapter 3, Step 7, health centers contemplating affiliations, as well as those operating under existing arrangements that have not been formally presented to BPHC, should request and obtain approval of the affiliation arrangement from BPHC. Approval is also required if a health center intends to contract for certain positions instead of employ directly.

Compliance Review

To obtain approval of an affiliation arrangement,, health centers should send the following information to BPHC for review:

Affiliation Checklist – Applicants for New Access Point Section 330 grant funding and entities applying for FQHC Look-alike designation must complete and submit to BPHC the “Affiliation Checklist” included in the New Access Point or FQHC Look-alike Applications, respectively. Those health centers that require a review for compliance of a new affiliation (or for changes to an existing affiliation) during a given budget/project period can submit the Affiliation Checklist in accordance with BPHC’s process for post-award requests, described in BPHC PIN #98-24.

Other relevant documents – In conjunction with the Affiliation Checklist, health centers should submit relevant reference documents such as:

1. Organizational documents,
2. Affiliation agreements, and
3. Other contractual agreements and leases, such as purchase of services/capacity agreements, management and administrative services agreements, and others.

These documents should demonstrate the health center’s continued compliance with Section 330 grant-related requirements and the requirements discussed in PIN #97-27. For example, submission of the health center’s Bylaws may sufficiently demonstrate the Board’s compliance with selection and composition requirements, as well as its autonomous exercise of prescribed authorities, although note that a contract, lease, grant or other arrangement may contain terms that independently transfer to the other party powers that could jeopardize the health center’s continuing compliance. Consequently, BPHC expects the health center to provide all relevant documents and

to fill out the Affiliation Checklist with references to all documents that define the affiliation agreement(s).

Approval Of Good Cause Exceptions To The Direct Staffing Model

Often, an affiliation with another provider may include the health center's purchase of certain personal services and/or professional capacity from the other organization. Each health center is required to employ its Executive Director/CEO directly (with no exceptions). Further, BPHC states a preference that health centers directly employ other key management staff (e.g., CFO, CMO) and the majority of primary care providers. BPHC recognizes, however, that there are circumstances under which the purchase of management support and/or clinical services is the most efficient and effective method to maximize access to comprehensive, cost-effective, quality care. Consequently, upon request, BPHC may grant an exception to its preference for the direct staffing model.

BPHC review – If, pursuant to the affiliation arrangement, the health center proposes to contract with another party for the services of the health center's CMO, CFO or the majority of primary care clinicians, in addition to a compliance review, BPHC will review the arrangement, as a whole, to determine whether (i) it results in sufficient programmatic benefit, and (ii) the health center maintains responsibility and accountability with respect to the operation of the grant-approved project and the expenditure of grant funds in accordance with applicable rules.

Programmatic benefit – In determining whether programmatic benefit will result from the arrangement, BPHC asks the following questions:

- Is there continued or improved access (i.e. increased capacity evidenced by additional services provided and/or more people served)?
- Does the arrangement provide improved expertise (i.e. management, financial, and/or clinical)?
- Does the affiliation result in an increase in capital (i.e. increased working capital, improved infrastructure, more efficient use of available resources)?
- Will the affiliation maintain or improve quality of care to health center patients (i.e. improved services, as measured through patient satisfaction, and/or improved care, as measured through improved health outcomes)?

Responsibility and accountability – To ensure that the health center is maintaining sufficient accountability with respect to its arrangements with other parties, BPHC will also review the affiliation to determine whether:

- The health center has reserved sufficient rights and control to maintain overall responsibility for direction of the project.

- The health center has provided justification for the performance of the work by another party, showing that the work cannot be more efficiently and effectively performed directly by the center.
- The health center has appropriate systems/processes to assure satisfactory performance in accordance with Section 330.
- The health center has a written agreement with the contractor that complies with DHHS administrative requirements with respect to:
 - a. Establishing the specific services covered by the arrangement, the manner in which they will be performed and the maximum amount of compensation;
 - b. Implementing financial, program and property management systems and records;
 - c. Submitting financial and programmatic reports;
 - d. Complying with Federal procurement standards; and
 - e. Terminating the agreement for contractor breach.

B. OTHER SECTION 330-RELATED REQUIREMENTS AND POLICIES

In section B:

1. *Scope of Project*
2. *Property and Equipment Acquired with Federal Funds*
3. *Federal Procurement Standards*
4. *Federal Tort Claims Act Coverage*
5. *Section 340B Discount Drug Pricing Program*

In addition to the aforementioned requirements and policies that specifically relate to a health center's affiliation agreements, other Section 330-related laws, rules and policies may have an important effect on the scope and structure of affiliation arrangements. This section explores several of those requirements and policies, in particular, BPHC's scope of project policy, Federal property standards, Federal procurement requirements, Federal Tort Claims Act coverage and the Section 340B discount drug pricing program.

1. Scope of Project Policy

In this section:

- *When is BPHC Approval Required?*
- *How to Request a Change in Approved Scope of Project*

The health center's scope of project defines:

- The five core elements (sites, services, providers, service area(s), target population(s)) supported by Section 330 grant funds and grant-related resources;
 - The scope of coverage under FTCA, with certain exceptions⁴⁷;
 - Eligibility for the Federal discount drug pricing program under Section 340B; and,

⁴⁷ The following providers may be part of the health center's approved scope of project but are not covered under FTCA: volunteer providers; physicians contracted with the health center for less than 32 ½ hours per week and not practicing in one of the following areas: obstetrics/gynecology, family practice, pediatrics, adult medicine; physicians contracted under a professional corporation or employed by another corporation; physicians acting as the CMO of a network; interns/residents/students not employed by the health center; physicians supervising non-health center employees, unless done as part of an on-call arrangement.

- The service delivery sites eligible for cost related reimbursement under the Medicare and Medicaid programs. See BPHC PIN #2002-07 – **APPENDIX 4**.

The five core elements should be described specifically in the approved grant application in order to ensure inclusion in the approved scope of project. Exceptions include:

- a. Limited service arrangements of a certain type, provided at multiple locations (e.g., immunizations provided at various day care centers) may be listed by type or category of location.
- b. Locations for off-site activities required by the health center and documented as part of an employment agreement (e.g., coverage at hospital emergency rooms or participation in on-call for unassigned patients) do not need to be listed as sites for the services to be included within the approved scope of project.
- c. Locations where the services provided do not generate encounters (e.g., filling prescriptions, taking x-rays, street outreach, health education, administrative offices) should not be listed as sites, but should be described in the scope and grant application narrative.

Because the scope of project controls how the health center is permitted to utilize Section 330 grant funds and grant-related benefits, it is particularly important for health centers to define their respective scopes appropriately, both initially and through requests to change the approved scope. In addition to the services, sites and providers that are furnished, operated or employed by the health center directly, health centers should include those elements provided under affiliation arrangements for which the health center maintains control. Accordingly, if a health center changes its approved scope of project by adding services through an affiliation with another provider (e.g., adding behavioral health services by contracting with a behavioral health provider), or by opening a new access point (e.g., by assuming responsibility for a site previously operated by a hospital), failure to secure prior approval for the change in scope could have very serious consequences, including:

- a. No FTCA malpractice coverage for the employed or certain contracted health center practitioners providing the additional services, or for the health center itself vis-à-vis such services/sites.
- b. Rejection of Medicaid/Medicare billings for cost-related FQHC reimbursement.
- c. Allegations that the health center has diverted Section 340B drugs by providing them to individuals who are not “health center patients.”

The process to obtain a change in scope is discussed below. Please note, however, that BPHC’s approval of a new access point and/or expanded services grant application results in automatic approval of a change to the submitting health center’s scope of project with respect to the new site and/or the expanded service(s).

When Is BPHC Approval Required?

If, pursuant to an affiliation arrangement, a health center seeks to change its scope of project by (i) changing the number of sites, (ii) adding or deleting services, or (iii) re-locating a site in a manner that will impact the budget, the services provided, the number of patients served, and/or the number and type of providers available at the re-located site, it must secure approval from BPHC prior to implementing the change.⁴⁸ The request will generally be approved if it:

- Does not require any additional Section 330 funding;
- Does not shift resources away from the provision of services to the underserved and vulnerable populations currently served by the health center;
- Furthers the health center's mission by increasing or maintaining access/quality of care to such populations;
- Is fully consistent with Section 330 legislation and BPHC Program Expectations;
- Does not eliminate or reduce access to a required services;
- Does not result in a lower level or quality of health services currently provided to vulnerable populations; and
- Continues to serve a Medically Underserved Area ("MUA") or Medically Underserved Population ("MUP").

Note that a health center may add a site that is not itself in or serving a MUA/P, as long as the health center continues to operate one or more sites in or serving a MUA/P.

⁴⁸ Changes affecting target population, providers or service area that are not linked to changes in sites or services and that do not impact the budget, and re-locations that do not impact the factors listed above, do not require prior approval. For example, re-location to a new facility within the same service area and of the same size as the old facility would not require prior approval if the scope of services remains unchanged. However, health centers are advised to keep their project officers apprised of all changes as they occur and, to ensure eligibility for grant-related benefits, should inform BPHC of all changes either as part of their continuation grant applications or by submitting a letter in the interim.

How to Request a Change in Approved Scope Of Project

PIN #2002-07 – **Appendix 4** – provides comprehensive guidance regarding the process for obtaining approval for a change in scope. To request a change in scope, the health center must prepare and submit (preferably, electronically) a change of scope request as specified in PIN #2002-07, which should include: grantee information; requested documentation (*i.e.*, an updated Exhibit B, a one year budget specific to the change, a one year total budget); if applicable, the Assurance Checklist contained in BPHC PIN #2002-07; and a brief narrative describing the change in scope, prepared in accordance with the requirements set forth in PIN #2002-07. All requests for a change in scope must be submitted separate from the continuation grant application.⁴⁹ However, all approved changes should be described in the subsequent continuation application to ensure eligibility for all grant-related benefits.

The effective date of an approved change (and the date upon which coverage for grant-related benefits begins) will be the date that BPHC receives a complete request. PIN #2002-07 does not provide for retroactive coverage for changes that are implemented prior to receipt of the complete request. Accordingly, if a health center implements a change prior to the date BPHC receives an approval request, the health center will be at risk for the specific service/site for the period of time beginning with the date of implementation until the date the complete request was received by BPHC and, of course, is more generally at risk for disapproval by BPHC.

2. Property and Equipment Acquired with Federal Funds

In this section:

- *Title and Reversionary Interest Requirements*
- *Use and Disposition Requirements*
- *Intangible Property Requirements*

Circular A-110 – Health centers contemplating affiliation arrangements under which they intend to transfer or sell health center assets should be mindful of Federal property requirements and standards contained in Circular A-110, Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals and Other Non-Profit Organizations, issued by OMB (November 19, 1993, as amended August 29, 1997), as promulgated in regulation by DHHS at 45 CFR Part 74.⁵⁰ The purpose of these requirements is to establish uniform standards to govern the use and disposition of real property and equipment furnished or supported by DHHS.

Title and Reversionary Interest Requirements

⁴⁹ Change in scope requests that require additional funding must be submitted in response to competitive funding announcements.

⁵⁰ Throughout this manual, we refer to the uniform administrative requirements pertaining to grants and cooperative agreements with non-profit entities as contained in 45 C.F.R. Part 74. Please note that DHHS has announced that, at some point in the next several months, it will move those administrative requirements from title 45 of the Code of Federal Regulations to title 2, subchapter B of the Code of Federal Regulations. There is no indication, however, that DHHS plans to make any substantive revisions to those requirements when it effectuates that move.

The Federal property standards provide that the Federal government retains a reversionary interest in all real property and equipment acquired (or, regarding real property, improved), in whole or in part with Federal funds, including Section 330 grant funds.⁵¹ Accordingly, such property and equipment generally may not be encumbered, put to a different use or disposed of without BPHC approval. Despite this limitation, title to the real property and equipment vests in the health center grantee, subject to the health center's continued use for the authorized purpose.⁵² As such, health centers are required to obtain insurance as if it wholly owns the property or equipment. See 45 CFR Part 74.31. Further, with respect to real property, the health center should file a notice in the local land records office regarding any Federal reversionary interest in its real property.

Use and Disposition Requirements

In general, health centers must continue to use real property and equipment obtained, in whole or in part, with Federal funds for the specific purposes authorized by the grant award for as long as such property/equipment is needed for the grant project (or, in circumstances under which grant support ends, for as long as the health center is operational). Upon disposition, however, different rules apply to real property versus equipment.

Real Property – If a health center determines that real property is no longer needed for the original project and it desires to use such property in any other project, including other Federally-sponsored projects, or to transfer or dispose of the property (*i.e.*, transfer or sell to a provider collaboration or network in which the health center participates), the health center must first obtain from BPHC either its approval for the other use or written disposition instructions. Disposition instructions will either:

- Permit the health center to retain title to the property;
- Direct the health center to sell the property; or
- Instruct the health center to transfer the property to the Federal government or a third party.

If the health center retains title or sells the real property, it must compensate the government for that proportion of the fair market value attributable to the “Federal share” in the acquisition or improvement cost of the property. If, on the other hand, the health center is instructed to transfer the real property to the Federal government or another party, the health center is entitled to compensation for that percentage of the current fair market value attributable to the health center's

⁵¹ Under the provisions of Part 74, “real property” is defined as land, including improvements, structures and appurtenances thereto (but excluding movable machinery and equipment); “equipment” is defined as tangible nonexpendable personal property having a useful life greater than one year and costing more than \$5000 per unit, unless, in accordance with the grantee's internal property policies, a lower limit is established (*e.g.*, for accounting purposes, the grantee may define as equipment any property with a unit cost greater than \$1000).

⁵² It is important to note that, with respect to equipment acquired with Federal funds, the health center may not use such equipment to provide services to non-Federal organizations (*e.g.*, a new entity formed by the health center and its affiliation partner) for a fee that is less than what private companies charge for equivalent services, unless specifically authorized. The same would apply to supplies acquired with Federal funds, so long as the Federal government retains an interest in the supplies.

share in the acquisition or improvement cost.

Equipment – Contrary to the use and disposition requirements for real property, if the health center determines that equipment is no longer needed for the original project, it may use the equipment in another Federally-sponsored project (in accordance with a list of priorities set forth in regulation) without BPHC approval. If the health center grantee no longer needs equipment that has a current per-unit, fair market value of \$5000 or more, for any Federally-sponsored project, it can request from BPHC either (i) approval to retain title to the equipment for other uses (i.e., as part of an affiliation arrangement), provided that the health center compensates the Federal government for the Federal share of the fair market value, or (ii) disposition instructions, which must be issued no later than 120 days after the request is made. These instructions will direct the health center either to sell the equipment or to transfer the equipment to the Federal government or a third party. If disposition instructions are not issued within the 120-day period, the health center can proceed with the sale of the equipment. Rules similar to those applicable to real property vis-à-vis the proportion of the fair market value attributable to either the Federal government or to the health center will be applied.

Intangible Property Requirements

Over the course of the last few years, various affiliation arrangements between and among health centers (e.g., through the Integrated Services Delivery Initiative) and between health centers and other parties (e.g., through the Healthy Communities Access Program) have resulted in the development of intangible (intellectual) property. In general, a health center and/or other grantee may copyright any work that is subject to copyright and was developed (or for which ownership was purchased) with grant support. However, the Federal government retains a royalty-free, nonexclusive and irrevocable right to reproduce, publish or otherwise use the work, as well as data first produced under a grant award, and to authorize others to do so. Accordingly, if a health center (or an affiliation 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 re-sale), to ensure exclusive rights to such property, Federal funds should not be expended to support the costs of development, management and/or operation.

3. Federal Procurement Standards

In this section:

- *Standards of Conduct*
- *Open and Free Competition and Procurement Procedures*
- *Procurement Records*
- *Contract Administration*
- *Contract Provisions*

Health centers that intend to enter into affiliation arrangements that include contracts for goods and/or services that will be paid for by Federal funds, in whole or in part, are subject to the administrative requirements and cost principles contained in 45 CFR Part 74, incorporating Circular A-110. The purpose of the Federal procurement standards is to ensure that goods and services are obtained in an effective and efficient manner. In general, the procurement standards contain provisions requiring health centers to:

- Establish and maintain written standards of conduct for all employees, contractors, agents and directors, including a conflict of interest provision;
- Provide for, and maximize, open and free competition;
- Establish and maintain written procurement procedures;
- Maintain procurement records; and
- Maintain a contract administration system to ensure conformance with the terms and conditions of the contract, including procedures to monitor and oversee the contractor's performance.

Standards of Conduct

Standards of conduct should provide that no employee, officer⁵³ or agent of the health center may participate in the selection, award or administration of a contract in which Federal funds are used and in which such individual, or an immediate family member or partner, has a financial interest (e.g., ownership or employment) or with whom such individual is negotiating or has any arrangement regarding prospective employment. In addition, health center officers, employees and agents should not solicit or accept any gratuities or favors from contractors.

⁵³ While 45 CFR Part 74 refers to "officer," we recommend extending the standards of conduct to all health center Board members.

Open And Free Competition And Procurement Procedures

Initial determination to contract for goods/services – Prior to entering into an affiliation involving a grant-supported purchase of goods and/or services from another party, a health center should first determine that it is more efficient and effective to contract for the particular item/service, as opposed to providing it directly. See PHS Grants Policy Statement, at page 8-16. The contract price must be reasonable and should generally reflect fair market value to the health center, with reference to what other similar health centers or primary care practice groups would reasonably pay for the same or comparable items/services.

Procurement procedures – Health centers should establish procurement procedures that contain provisions designed to assure that they obtain the best quality goods and services at the lowest possible cost. Procurement procedures should also contain provisions to ensure that the health center will (i) avoid purchasing unnecessary items, (ii) award contracts to capable vendors (taking into account factors such as vendor integrity, past performance, and resources available), who have not been debarred or suspended by the Federal government, and (iii) analyze lease versus purchase alternatives to determine which would be most economical and practical.

Maximization of competition – Of particular importance as health centers negotiate the purchase of goods and/or services is the requirement to maximize competition. Unless a particular vendor (in this context, a potential affiliation partner) is uniquely qualified, or sole source procurement can be otherwise justified, health centers should seek competing bids in response to clear and accurate requests for proposals.⁵⁴ The requirement to maximize competition applies to all health center vendors, including affiliation partners. However, the health center can guarantee its affiliation partner (i) an opportunity to bid on future contracts to provide additional services and (ii) if the partner's bid is competitive and equal to (or better than) the bids received from other vendors, the first opportunity to contract for the services (or a right of first refusal).

Contractor selection -- In selecting a contractor, health centers should, in general, evaluate bidders based on the following criteria: (i) the estimated total cost/price of the submitted bid (including travel expenses); (ii) the appropriateness and accuracy of the bidder's response to the specific description of the services sought and the other elements of the health center's Request for Proposal; and (iii) the bidder's qualifications/experience, or in the case of goods, the quality of the goods.

⁵⁴ Section 330 and DHHS implementing regulations emphasize the establishment of collaborative relationships with other health care providers. As discussed in Chapter 2, Section B of this manual, these requirements have been interpreted to discourage arrangements between health centers and other providers under which a health center is precluded from contracting with other parties and/or is required to grant affiliation partners absolute rights to provide other services to the health center (i.e., exclusivity clauses), particularly if Federal grant money will support contract payments. It is difficult to reconcile exclusivity commitment with Federal procurement standards that require Federal grantees (including health centers) that intend to use Federal funds to support payments under the contract to maximize competition

Procurement Records

In maintaining procurement records and establishing a procurement file, a health center should maintain, at a minimum, the following information:

- A detailed description of the scope of the contracted services/activities;
- The justification for contracting for such services;
- The health center's solicitations, if any, for bids and relevant responses⁵⁵; and
- The basis for selection of the chosen contractor, as well as justification and analysis of the contract price or cost.

Contract Administration

Since the Federal procurement standards do not make the Federal government a party to the contract, the contract will not affect a health center's overall responsibility for the grant-supported project or its accountability to the Federal government for the proper use of Federal grant funds. Accordingly, each health center should establish a contract administration system to assure the contractor's compliance with all terms and conditions of the purchase agreement, and should require the contractor to submit progress and financial reports as necessary to maintain responsibility and accountability.

Contract Provisions

Provisions for all procurement contracts – Procurement requirements specify provisions that must be included in contracts funded or supported by Federal funds, in whole or in part. In general, all contracts must include provisions that define a “sound and complete” contract. Further, all procurement contracts should include:

- The contractor's record-keeping and reporting responsibilities.
- Requirements that the contractor notify and receive prior approval from the health center in the event that there is a material change in the approved scope work or the approved budget for such services.
- The contractor's compliance with certain specified laws:

⁵⁵ If a health center intends to procure grant-supported services from its network or any affiliate on a “sole source” basis, the procurement must be justified in terms of price and contractor qualifications. Consultation with BPHC may also be advisable.

- a. Non-Discrimination/Equal Employment Opportunity requirements found in Executive Order 11246, as amended by Executive Order 11375, and as supplemented by regulations at 41 C.F.R. Part 60, "Office of Federal Contract Compliance Programs, Equal Employment Opportunity, Department of Labor;"
- b. Copeland "Anti-Kickback" Act (for construction or repair projects over \$2000);
- c. Davis-Bacon Act (if required by the authorizing statute); and
- d. Rights to Inventions Made Under Contract or Agreement.

Contracts in excess of the "small purchase" threshold – In addition to the aforementioned provisions, contracts that exceed the "small purchase threshold" amount (currently set at \$100,000), must include the following⁵⁶:

- The remedial actions available to the health center (administrative, contractual or legal remedies) in instances where the contractor violates or breaches the terms of the contract.
- The circumstances under which the health center can terminate the contract, including for default and circumstances beyond the control of the contractor.
- A provision stating that the health center, DHHS, the U.S. Comptroller General, and any of their duly authorized representatives, shall have access to any of the contractor's books, documents, papers, and records which are directly pertinent to a specific program for the purpose of making audits, examinations, excerpts and transcriptions.
- The contractor's compliance with certain specified laws:
 - a. Contract Work Hours and Safety Standards Act (for construction projects);
 - b. Clean Air Act and Federal Water Pollution Control Act;
 - c. Byrd Anti-Lobbying Amendment;
 - d. Debarment and Suspension provisions⁵⁷; and
 - e. Minimum bonding guarantee standards (for construction projects).

⁵⁶ While not required for contracts under \$100,000, we recommend including provisions regarding remedial actions, termination and access to records in all negotiated contracts.

⁵⁷ While not required for contracts under \$100,000, we recommend that health centers receive assurances from each contractor with which they conduct business that neither the contractor nor any of its principles or employees have been debarred or suspended from participating in Federally-supported contracts or from participating in Federal health care programs.

4. Federal Tort Claims Act (“FTCA”) Coverage

In this section:

- *Deeming Process Requirements*
- *Scope of Coverage*

FTCA coverage is one of several grant-related benefits available to health centers that receive funds under Section 330 and that are “deemed” eligible for such coverage. In general, Section 224 of the Public Health Service Act provides FTCA medical malpractice coverage for Section 330 health center grantees, their officers, directors, employees and certain contractors, if and when the health center successfully applies for and is deemed FTCA-covered by BPHC.⁵⁸ The intent of the legislation was to increase the availability of Federal grant funds for the provision of primary care services by allowing health centers to substantially reduce their costs for medical malpractice insurance premiums.⁵⁹ As such, FTCA coverage is available only to the health center (and its directors, employees and certain contractors); with limited exceptions described below, it cannot be extended to a health center’s affiliation partner (and/or the partner’s employees/contractors).

Deeming Process Requirements

Deeming application and requirements – As noted, to attain FTCA-covered status, health centers funded under Section 330 must complete a “deeming” application that demonstrates that the health center (i) has conducted thorough credentialing of its providers (including contracted providers); (ii) has implemented appropriate policies and procedures to reduce the risk of malpractice; and, (iii) will cooperate fully with the Department of Justice in the event that a malpractice suit is brought against the health center and/or its practitioners. See BPHC PIN #99-08, at p. 2 (April 12, 1999). Moreover, health centers are required to have clinical protocols, tracking systems, medical record review, and a quality assurance program.

Confirmation of and change to FTCA coverage – In response to a complete and satisfactory deeming application, the health center will receive a “deeming letter” from BPHC confirming that the health center and its employees/eligible contractors are covered by FTCA. For continued eligibility, health center grantees must submit a re-deeming application on an annual basis. See BPHC PIN #2002-23. Once deemed, FTCA coverage for any new service or site operated and controlled by the health center, whether added through internal corporate expansion or implementation of

⁵⁸ Extensive discussion of the legal basis for health center FTCA coverage, as well as the legal requirements and limitations to such coverage, can be found in BPHC PIN #99-08 (April 12, 1999), BPHC PAL #99-15 (April 12, 1999), and BPHC PIN #97-6 (January 13, 1997) (See also BPHC PIN #2002-07 (December 31, 2001) regarding Scope of Project policy).

⁵⁹ If a health center patient decides to bring a malpractice lawsuit against the health center, its employee, covered contractor, etc., it must do so by first filing a claim for administrative remedies with the Public Health Service and, if the claim is denied (or remains unsettled), the patient can only pursue legal action against the Federal government in Federal court.

affiliation arrangements, will depend, in part, on BPHC approval of a request to change the health center's scope of project, as discussed above.

Impact of health center to health center affiliation arrangements on FTCA coverage – With respect to health center-to-health center affiliation arrangements, if two or more health centers merge to form a new separate legal health center entity, the new corporation will not be FTCA-covered simply by virtue of the two health centers having been deemed FTCA-covered. The new health center corporation must itself receive Section 330 grant funding and would have to apply for FTCA coverage. No employee, contractor or officer of the new corporation would have FTCA coverage until a deeming application from the new corporation is approved. If a deemed health center absorbs a non-deemed health center through merger or consolidation, the staff of the non-deemed health center that become staff of the deemed health center will be covered under the FTCA (assuming all other FTCA-related requirements are met); whereas if the legal entity surviving after the two health centers merge is the non-deemed health center, then the staff from the deemed corporation - which have now presumably become employees or contractors of the non-deemed health center - would no longer be covered by the FTCA. See BPHC PAL #99-15 at p.1 (April 12, 1999).

Scope of Coverage

A health center that enters into an affiliation agreement may have to consider the extent of FTCA coverage of contracted personnel, new services and/or new sites. As discussed above, FTCA provides medical malpractice coverage for the health center entity, as well as certain health care providers who are practicing within the health center's scope of project and within the scope of the provider's employment agreements or contracts.

Coverage for employees and individual contractors – Specifically, FTCA coverage extends to all health center employees, whether full-time or part-time. In addition, FTCA coverage extends to individually contracted clinicians who provide services to health center patients served at the health center site for at least 32 ½ hours a week (i.e., on a full time basis). An exception to this "full-time" requirement exists for individually contracted clinicians who provide services in the fields of general internal medicine, family practice, general pediatrics, and obstetrics and gynecology.

Coverage for contractual arrangements – For contract arrangements to be eligible for FTCA coverage, the agreement must be directly between the health center and the individual health professional providing services to the health center's patients. An agreement between the health center and a physician practice, a separately incorporated physician corporation, or a hospital will not extend FTCA coverage to the individual health professional that is an employee of that practice and/or corporation (rather than an employee of the health center). Accordingly, employees of an affiliation partner, such as a health system, hospital or incorporated group practice, would not be eligible for FTCA coverage, unless the particular employee contracts with the health center on an individual basis.

If an affiliation entails the health center's health professionals delivering services to non-health center patients, there are some circumstances where FTCA coverage is available. See 60 Fed. Reg. 49417-18 (September 25, 1995). These include, but are not limited to, periodic hospital call

conducted by health center health professionals, if required for hospital privileges, and formal after hours coverage arrangements.

No coverage for network entities – Of note, should multiple deemed health centers form a network (i.e., under the Integrated Services Delivery Initiative), the network entity itself would not be eligible for FTCA coverage. Accordingly, health centers are advised not to transfer to the network responsibilities that might result in malpractice exposures (unless private insurance is secured).

Billing and FTCA coverage – Typically, the health center must be responsible for billing for the services provided by its employees and contractors in order for the provision of the services to be FTCA covered. However, PIN #2001-11, issued by BPHC on April 24, 2001, appears to close a potential gap in FTCA malpractice coverage when health centers have arrangements with their employees/contractors in which the employee/contractor bills Medicaid, Medicare, or other third party payors directly for services. Specifically, the PIN extends FTCA coverage to services delivered at or away from the health center site by otherwise covered health center providers as long as:

- The provider reports those billings to the health center.
- The provider remits to the health center the payments he/she received for the specific billing within a “reasonable period of time.”
- The provider’s employment contract authorizes the billing arrangements described above, that is, it provides for direct billing by the provider and requires that the provider turn the funds over to the center.

However, HRSA/BPHC policy provides that FTCA protection will not cover service delivery arrangements under which the provider retains the direct billings as part of a “balance billing” agreement with the health center.⁶⁰ Consequently, if a provider receives direct payment for services from third party payors, the provider must turn it over to the health center, with the health center paying the provider an appropriate amount for the service delivery capacity he or she provides to the health center per their agreement.⁶¹

5. Section 340B Discount Drug Pricing Program

In this section:

- General Requirements for a Section 340B Program

⁶⁰ Under such arrangement, the health center subtracts the amount of direct billing received by the provider from the total payment owed to the provider by the health center, and pays the “balance” to the provider.

⁶¹ Please note that, pursuant to Federal anti-kickback law, any payments from the health center to a provider should represent an arm’s length negotiated, fair market value rate for the services/service delivery capacity provided. The health center should not agree simply to pay any provider (whether employed by, or contracted to, the health center) the enhanced reimbursement rates paid to the health center under the Medicare and Medicaid programs (i.e., its FQHC rates). The Office of Inspector General may consider such enhanced payment a “benefit” furnished to the provider in exchange for referrals or other business provided to the health center, which, if paid for (in whole or in part) by Federal health care programs, may be problematic under the Federal anti-kickback law.

- *Requirements for an In-House Pharmacy Managed by an MSO or Other Affiliation Partner*
- *Requirements for a Contracted Pharmacy*

Another Section 330-related benefit available to both health center grantees and FQHC Look-alike entities is eligibility to participate in the discount drug pricing program under Section 340B of the Public Health Service Act. Section 340B requires drug manufacturers to enter into agreements with DHHS to provide covered outpatient drugs to covered entities, including FQHCs, at discounted prices designed to be, at a minimum, as low as the prices paid by State Medicaid Agencies. See 42 U.S.C. 256b, as amended by Section 602 of P.L. 102-585 (11/11/92). The health center's ability to purchase drugs at discounted prices could potentially result in significant cost savings, which, in turn, provides the health center with an effective means to lower drug prices for its uninsured patients. Accordingly, while not mandatory, participation in Section 340B is strongly recommended.⁶²

Health center options to establish a 340B program – Under the terms of Section 340B, the health center is entitled to purchase and pay for covered drugs at favorable prices. The 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 (“MSO”) or other affiliation partner. Alternatively, the health center may enter into a contractual affiliation with a licensed retail pharmacy (such as a free-standing pharmacy, a retail pharmacy located in a medical building, or a pharmacy located in and operated by a hospital that is available to persons other than hospital patients) to dispense discounted drugs that have been purchased by the health center. In either case, the drugs purchased under the 340B program may be dispensed only to the health center's patients. As such, the health center cannot supply 340B drugs to individuals who are not registered health center patients, but rather are patients of (i) an affiliation partner(s), (ii) a new entity jointly established and controlled by the health center and another provider(s) (e.g., an entity established under the Healthy Communities Access Program, or other participating providers), or (iii) a health center-controlled network or entity (e.g., a network established under the Integrated Services Delivery Initiative).⁶³

Application to participate – If a health center chooses to purchase Section 340B drugs, it must first fill out an “Acknowledgement of Entity Participation” Form indicating the health center's intent to purchase drugs at PHS prices, and submit the form to the Office of Pharmacy Affairs (“OPA”). Included with the form should be information regarding Medicaid billing arrangements (as well as the health center's pharmacy or all-inclusive Medicaid number, if applicable) to ensure that there

⁶² HRSA has added a statement in the Notice of Grant Award for grantees, which, in short, requires health centers to assess their drug procurement practices and participate in the Section 340B Drug Pricing Program, and the Prime Vendor program, if either appears to be the most cost-effective approach. Factors other than price (e.g., vendor performance, cost analysis) should be considered in a health center's assessment including, as appropriate, the factors and standards used to evaluate contractors' bids to provide goods and services, as set forth in the Federal procurement regulations at 45 CFR Part 74.

⁶³ 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 the pharmaceutical manufacturers, and an obligation to pay the 340B discount differential back to the pharmaceutical manufacturers.

are no 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). If the health center intends to utilize a contracted licensed retail pharmacy (rather than an in-house pharmacy) to dispense drugs to health center patients, the center must fill out a Self Certification of Contracted Pharmacy Services form and submit the form to OPA.⁶⁴

General Requirements for a Section 340B Program

As a first step, regardless of whether the health center operates an in-house pharmacy or contracts with a licensed retail pharmacy, a health center must establish and maintain the following:

- A tracking system (or an alternative system approved by the OPA) to ensure that the drugs purchased under the Section 340B program (“covered drugs”) are not resold, transferred or diverted to non-health center patients.⁶⁵
- A schedule of reasonable fees for the covered drugs, taking into account sliding fee discounts for health center patients eligible for such discounts (*i.e.*, patients under 200% of the Federal income poverty guidelines).
- A system to record purchases of covered drugs and any claims for reimbursement submitted for such drugs under Medicaid for the purpose of audits required by DHHS and/or the respective manufacturer with respect to compliance with the prohibitions against (i) drug resale, transfer or diversion and (ii) duplicate Section 340B discounts and Medicaid rebates.

⁶⁴ In general, for contracted pharmacy arrangements, the health center will most likely indicate on the Acknowledgement of Entity Participation Form that it does not bill Medicaid for prescriptions covered under the contract arrangement.

⁶⁵ Health center “patients” are defined in “HRS Notice Regarding Section 602 of the Veteran’s Health Care Act of 1992 Patient and Entity Eligibility,” 61 Fed. Reg. 55156 (October 24, 1996).

Requirements for an In-House Pharmacy Managed by an MSO or Other Affiliation Partner

A health center may choose to contract with an MSO or another affiliation partner (the contractor) to manage the health center's in-house pharmacy. Under such circumstances, there are a number of additional considerations that the health center should review.

- The health center must hold the license or permit to operate the pharmacy and it should be clear that the contractor is managing the pharmacy on behalf of the health center (rather than operating the pharmacy under the health center's license). The contractor must meet any State licensure requirements for MSOs or Pharmacy Benefits Managers, as applicable.
- The contractor must comply with all Section 340B requirements, including procedures to ensure that:
 - a. Covered drugs are not resold, transferred or diverted to non-health center patients;
 - b. The health center maintains responsibility for purchasing covered drugs and the inventory of drugs is kept and managed in an accountable manner;
 - c. Billing of covered drugs dispensed to Medicaid patients is conducted properly (i.e., no duplicate discounts/rebates, and billing only an amount equal to the actual acquisition cost plus a reasonable dispensing fee established by Medicaid);
 - d. The health center and DHHS have reasonable access to the contractor's financial records pertaining to the services provided under the contract;
 - e. The contractor will cooperate with an audit initiated by the health center, DHHS or a drug manufacturer.
- The health center should retain the right to establish prices charged for covered drugs (as well as the corresponding schedule of discounts, if any) and to establish the hours of operation of the pharmacy.
- The health center should maintain proper oversight and monitoring of pharmacy services (similar to other contracted services), e.g., right to approve and, if necessary, replace contracted personnel; receipt of records and reports; right to terminate the contract based on, at a minimum, the contractor's breach and/or non-compliance with Section 340B requirements.

Requirements for a Contracted Pharmacy

As noted above, health centers that do not have a licensed pharmacy may participate in the 340B program by contracting with a licensed retail pharmacy for pharmacy services. Under a contract pharmacy arrangement, the Section 340B requirements as discussed above, including prohibitions against diversion and “double discounts,” apply. To ensure compliance with all requirements, the contract with the pharmacy should, among other things, specify:

- The health center will assume responsibility for establishing the list of drugs purchased by the health center under the Section 340B program and their prices.
- The health center will purchase and be billed for covered drugs directly from the manufacturer/wholesaler (although the drugs may be shipped directly to the contract pharmacy, rather than the health center).⁶⁶
- The pharmacy will not resell, transfer or divert covered drugs to non-health center patients, and if it should do so, the pharmacy will repay the health center an amount equal to the price discount the health center received from the manufacturer.
- The pharmacy will establish a tracking system to ensure that covered drugs are used solely for health center patients and not diverted to non-health center patients, and the health center will have reasonable access to the pharmacy facility and records to monitor the tracking system.
- The pharmacy will not use covered drugs to dispense prescriptions paid for by Medicaid unless the pharmacy and the Medicaid agency have established an arrangement to prevent duplicative discounts/rebates from manufacturers for the same drug.
- The pharmacy will develop and submit to the health center financial and programmatic records and reports deemed necessary by the health center to monitor the services provided under the agreement, will retain such records and reports for a period not less than three (3) years, and will permit access to such records and reports for audit and inspection.
- The pharmacy will cooperate with audits required by DHHS and/or drug manufacturers with respect to the pharmacy services provided under the agreement, and, in particular, compliance with the prohibitions against (i) drug resale, transfer or diversion and (ii) duplicate Section 340B discounts and Medicaid rebates.

⁶⁶ For administrative purposes, the pharmacy should establish a system by which it will monitor the dispensing of covered drugs and submit to the health center dispensing and usage reports, as well as projections of estimated future usage, for the purpose of ordering covered drugs.

C. FEDERAL TAX CONSIDERATIONS

In section C:

2. *For-Profit versus Nonprofit Structures*
3. *Criteria for Federal Income Tax Exemption*
4. *Affiliations Involving For-Profit Organizations*
5. *Unrelated Business Income Tax*
6. *Intermediate Sanctions (IRC Section 4958)*

Because health centers are nonprofit entities, there are Federal tax issues that must be considered whenever a health center affiliates with another entity. The tax considerations are particularly important when health centers are affiliating with for-profit entities.

Examples of health center affiliations that may give rise to tax concerns:

- Affiliations under which the health center invests in a for-profit corporation (e.g., practice management network, MSO, managed care organization) if the investment (i) is not prudent and reasonable, (ii) is substantial in relation to the amount of health center assets that remain devoted to the center's tax-exempt purposes, and/or (iii) does not further the health center's tax-exempt purposes.
- Affiliations with for-profit entities under which the health center's assets come under the control of the for-profit partner (and, therefore, cease to be dedicated to a tax-exempt charitable purpose).
- Affiliations with for-profit entities under which the joint venture results in constraining the health center's ability to act exclusively in furtherance of its tax-exempt purposes.
- Affiliations under which the health center participates in a for-profit partnership or LLC whose activities are not related to the health center's charitable health care mission and are typical of activities customarily carried on by for-profit businesses (e.g., an MSO) if the unrelated activities become substantial in relation to the health center's health care activities.

1. For-Profit Versus Nonprofit Structures

The advent of managed care and the increasingly competitive health care environment have spurred the development of provider networks and integrated service delivery systems that often are comprised of both for-profit and nonprofit corporations owned or controlled by a nonprofit parent

corporation(s).⁶⁷ Key considerations when determining whether to form a for-profit or nonprofit entity include:

- The purpose of the corporation (if not charitable, it will not be possible to obtain §501(c)(3) tax-exempt status);
- The likely source(s) of capital to finance the entity's operations;
- The parties' intent regarding the distribution of surpluses.

It should be noted that the for-profit form is neither inherently improper nor in conflict with a health center's mission. A tax-exempt organization may own (or be part owner of) a for-profit entity, in whole or in part, ordinarily without jeopardizing its income tax exemption, so long as ownership of the for-profit entity will further the tax-exempt purposes of the nonprofit entity.⁶⁸ Moreover, a for-profit entity owned by a nonprofit entity may distribute net income to the nonprofit owners. However, the for-profit entity's "profits" will be taxed before any surpluses are paid to the nonprofit owners, typically in the form of dividends. Regardless of the form, any affiliation with another party, whether for-profit or nonprofit, should be carefully structured so that it does not adversely impact the health center's tax-exempt status under Federal law.

2. Criteria for Federal Income Tax Exemption

There are two types of tax-exempt organizations that are likely to be appropriate for most health center affiliations.

Section 501(c)(3) Exemption – Section 501(c)(3) of the Internal Revenue Code ("IRC") provides for the exemption from Federal income tax of organizations organized and operated exclusively for charitable purposes. No part of any such organization's net earnings may inure to the benefit of any private shareholder or individual.⁶⁹ Federal income tax regulations provide that an organization will be regarded as operated exclusively for one or more tax-exempt purposes only if it engages "primarily" in activities that accomplish one or more of the exempt purposes specified in Section 501(c)(3). An organization will not be regarded as engaging primarily in charitable activities if more than an insubstantial part of its activities is focused on activities that do not further an exempt purpose. See 26 CFR §1.501(c)(3)-(c)(1). In short, the organization cannot substantially benefit private interests as opposed to broader interests.

The income tax regulations further provide that an organization may meet the requirements of Section 501(c)(3) although it operates a trade or business as a substantial part of its activities if the operation of such trade or business is in furtherance of its exempt purpose or purposes and if the

⁶⁷ For further discussion regarding various corporate structures, see "Chapter 2, Section C of this manual.

⁶⁸ For example, tax-exempt organizations can invest charitable assets in a for-profit venture. However, if there is a for-profit partner in the venture, health centers should be particularly careful that their contribution is fairly valued and that it does not come under the control of the for-profit partner.

⁶⁹ Virtually all health centers are Section 501(c)(3) organizations.

organization is not organized or operated for the primary purpose of carrying on an unrelated trade or business.⁷⁰ All of the circumstances must be considered in determining whether an organization is organized and operated for the primary purpose of carrying on an unrelated trade or business. These circumstances include the size and extent of the trade or business and the size and extent of the activities that are in furtherance of one or more exempt purposes. See 26 CFR §1.501(c)(3)-1(e)(1).

Section 501(c)(4) Exemption – Tax exemption also is available under IRC Section 501(c)(4) for “social welfare” organizations. Sections 501(c)(3) and 501(c)(4) organizations are very similar in that both must be organized and operated exclusively for some public “good.” The major differences between the two (2) types of organizations are as follows:

- Section 501(c)(4) organizations may engage in an unlimited amount of legislative advocacy (i.e., lobbying) while the allowable lobbying activities of a Section 501(c)(3) organization are limited to an “insubstantial amount.”
- Donors may make tax-deductible contributions to a Section 501(c)(3) organization, but contributions to a Section 501(c)(4) organization are not tax-deductible as a charitable contribution.
- Some, but by no means all, private foundations may be less inclined to make a grant to a Section 501(c)(4) organization.
- Section 501(c)(3) organizations must apply to the IRS to have their tax-exemptions recognized; Section 501(c)(4) organizations have only to be organized and operated consistent with applicable regulations to be recognized as tax-exempt (although it certainly is advisable to obtain a written exemption ruling from the IRS). In that regard, it is sometimes easier to obtain an IRS ruling recognizing an organization’s exemption under Section 501(c)(4) than under Section 501(c)(3).

Accordingly, the advantages and limitations of exemption under Sections 501(c)(3) and 501(c)(4) must be addressed in considering affiliation options and potential organizational structures for a new entity. Further, it should be kept mind that the fact that a nonprofit entity is controlled by a health center, or a health center and another organization that is tax-exempt under Section 501(c)(3), or that the entity benefits a tax-exempt organization (such as by producing revenues or reducing costs) is not alone sufficient for the new entity to qualify for tax exemption. The new entity must demonstrate that it independently meets the organizational and operational tests for tax exemption under Sections 501(c)(3) or 501(c)(4).

3. Affiliations Involving For-Profit Organizations

In this section:

- Investment in a For-Profit

⁷⁰ Section 513(a) of the IRC provides that the term "unrelated trade or business" means any trade or business the conduct of which is not substantially related (aside from the need of such organization for income or the use it makes of the profits derived) to the exercise or performance by such organization of its charitable purpose or other purpose constituting the basis for its exemption under Section 501 of the IRC.

- Partnership with a For-Profit

Because the assets of an organization that is tax-exempt under Section 501(c)(3) must be dedicated to a tax-exempt charitable purpose, affiliations between a Section 501(c)(3) organization and a for-profit entity must be carefully structured to ensure that the assets of the Section 501(c)(3) organization do not come under the control of the for-profit member. If that were to occur, private inurement or an impermissible amount of private benefit could result which would jeopardize the Section 501(c)(3) organization's income tax exemption. Section 501(c)(4) organizations are subject to similar restrictions on inurement and private benefit.

Investment in a For-Profit

The IRS has long recognized that a tax-exempt organization can capitalize and provide services and assets to a for-profit entity without jeopardizing its tax-exemption. See IRS Priv. Ltr. Rul. 199938041. Accordingly, a Section 501(c)(3) health center's investment in a for-profit corporation (e.g., practice management network, managed care negotiating network, multi-purpose network, MSO, managed care organization, provider-sponsored organization) poses little tax risk, assuming that the investment is prudent and reasonable, takes into account the amount of the investment in relation to the amount of assets devoted to tax-exempt purposes, and, preferably, furthers the center's tax-exempt purposes. This is true even if some or all of the other owners of the for-profit entity are themselves for-profit organizations. Further, such ownership poses little threat to the health center's continued receipt of Section 330 grant funds as long as the health center does not relinquish autonomous decision-making vis-à-vis the health center's governance and operation.⁷¹

Partnership with a For-Profit

From the IRS's perspective, the situation changes drastically if the entity formed by an affiliation with a for-profit organization is a partnership, limited partnership, LLC or similar non-corporate joint venture. These types of joint ventures are also called "pass through" entities whose activities, unlike those of a corporation, are attributed automatically to the members. The IRS is concerned that a joint venture arrangement with a for-profit partner or partners might constrain the ability of the venture's tax-exempt member(s) to act exclusively in furtherance of its tax-exempt purposes.

Rev. Rul. 98-15 – The IRS addressed the tax consequences of a joint venture between a Section 501(c)(3) health care provider and a for-profit partner in Rev. Rul. 98-15, 1998-12 IRB 6. In Rev. Rul. 98-15, a Section 501(c)(3) hospital and a for-profit partner formed a for-profit entity and the tax-exempt hospital contributed all of its assets to the joint venture entity. The IRS ruled that the hospital no longer qualified for income tax exemption because, under the facts described in the ruling, it had ceded control of its assets to its for-profit joint venturer. Rev. Rul. 98-15 clearly indicates that charitable organizations must retain control of charitable assets and continue to operate in a manner consistent with their charitable purpose in joint ventures with for-profit entities.

2002 CPE text considerations – The IRS's position on joint ventures between tax-exempt and for-profit entities continued to evolve after Rev. Rul. 98-15. In its Continuing Professional Education

⁷¹ In fact, BPHC has awarded Integrated Services Delivery Initiative grant funds in support of for-profit networks, so long as the network is majority owned and controlled by health centers and furthers the purposes of the health center owners.

(“CPE”) text⁷² for fiscal year 2002, the IRS stated that the charitable organization does not necessarily have to own the majority interest in the joint venture or control its governing body in order to remain exempt. However, if the charity does not control a majority of the governing board, it must have another effective mechanism to ensure that the venture furthers the exempt organization’s purposes. Fifty percent control is the minimum necessary to maintain exemption. The CPE text contains a non-exhaustive checklist of factors to be considered in evaluating compliance with Rev. Rul. 98-15. These factors include:

- The exempt organization receives an ownership interest in the joint venture proportionate to the value of its contribution.
- The exempt organization has voting control over the joint venture’s board with respect to activities and policies that affect the exempt organization’s tax-exempt purposes.
- The exempt organization’s representatives on the joint venture board are representative of the community.
- The joint venture operates its health care services for charitable purposes.
- The joint venture agreement explicitly requires that charitable purposes override any duty to operate for the financial benefit of the members.
- The terms of the agreement are reasonable and similar or comparable to similar arrangements in the marketplace.
- The joint venture agreement does not have non-compete provisions limiting the charitable organization’s ability to compete with the for-profit partner.
- The venture is not managed by an entity related to the for-profit partner.
- The exempt organization has the unilateral right to terminate the joint venture’s management company and/or the joint venture’s CEO if the manager is not acting to further, or is acting contrary to, the exempt organization’s purposes.

Testing the IRS position – The IRS position on control of joint ventures with for-profit organizations was tested in *St. David’s Health Care System, Inc. v. United States of America*, 2002 WL 31477560 (W.D. Tx). In that case, St. David’s did not retain majority control of the joint venture’s governing body as required by Rev.Rul. 98-15, and the IRS revoked its income tax exemption. In court, St. David’s argued that there were numerous provisions in the joint venture agreement that assured that St. David’s charitable assets would be used for charitable purposes, notwithstanding the absence of majority control of the governing body. Among other things:

- The organizational documents of the joint venture clearly articulated its charitable purposes.
- The joint venture agreement required that the venture be operated in accord with the “community benefit standard” applicable to charitable, tax-exempt hospitals.

⁷² The CPE text is written to assist IRS field agents to better understand various issues involving tax-exempt organizations. Although the CPE text is not binding on the IRS and cannot be cited as precedent, it does illustrate how the IRS is likely to view certain issues.

- St. David's had the unilateral right to terminate the venture if the hospital failed to meet that standard.
- St. David's had the right to appoint the chair of the governing body and had the unilateral right to remove the joint venture's CEO.

The U.S. District Court agreed with St. David's and ruled in its favor. However, the U.S. Fifth Circuit Court of Appeals overturned the District Court's decision and sent the case back to court for a jury trial on the question of whether St. David's had, in fact, retained sufficient control to retain its tax exemption. The jury found in St. David's favor, and the IRS later settled the case allowing St. David's to retain its tax-exemption while preserving, for the time being at least, the IRS's ability to take the position it set out in Rev. Rul. 98-15. In at least one case, the IRS approved a joint venture with a 50/50 control structure where there were adequate other protections to ensure that the joint venture operated for tax-exempt purposes. These included binding charitable purpose provisions, preferable rights upon dissolution, and policies that required the joint venture to provide specific community benefits. It is clear that control, in some form, by the exempt organization assuring that the joint venture promotes the exempt organization's tax exempt purposes will continue to be an important factor in affiliations with for-profit entities.

Ancillary Joint Ventures - Rev. Rul. 98-15 addressed the situation in which virtually all of an exempt organization's assets were committed to a joint venture with a for-profit entity. It did not address the situation in which a tax-exempt entity contributes only some of its assets to a joint venture with a for-profit entity, which is a much more likely scenario for a health center engaging in a joint venture with a for-profit entity. This type of arrangement typically is referred to as an "ancillary joint venture."

The IRS issued guidance with regard to ancillary joint ventures for the first time in Rev. Rul. 2004-51, 2004-22 I.R.B. (June 1, 2004). This ruling involved a tax-exempt university that formed an LLC with a for-profit video production company to produce teacher training seminars at off-campus locations. The tax-exempt and for-profit members of the LLC made equal capital contributions, shared equally in profits and losses, and shared equally in control of the LLC. The IRS ruled that participation in the LLC did not jeopardize the university's tax exemption.

However, unlike Rev. Rul. 98-15, the IRS did not focus on control issues. Rather, the IRS held that because participation in the for-profit LLC did not amount to a substantial part of the university's activities, its tax exemption would not be adversely affected. Moreover, because the university controlled the content of the educational seminars and set the standards for student participation, the IRS held that participation in the LLC promoted the university's tax exempt activities. Therefore, profit distributions from the LLC would not be subject to the unrelated business income tax. (See below).

Although Rev. Rul. 2004-51 does not involve health care providers, it is widely viewed as being generally applicable to all types of ancillary joint ventures.

4. Unrelated Business Taxable Income

Organizations otherwise exempt from tax under Section 501(c) of the IRC (including organizations exempt under Sections 501(c)(3) and 501(c)(4)) are subject to tax on their "unrelated business taxable income" ("UBTI"), i.e., income not generated in furtherance of an exempt purpose. See IRC Section 511(a).⁷³ Passive dividend income, regardless of the amount, is not taxable as unrelated business income. However, to the extent that more than an insubstantial amount of the exempt organization's activities (as determined by the totality of the circumstances) involve operating the "subsidiary" organization, such dividend income may not be considered "passive."

Example – For example, net income from a health center operating a management service organization or providing practice management services probably would be subject to the unrelated business income tax. These types of activities are not related to a health center's charitable health care mission and are typical of activities customarily carried on by for-profit businesses. Although the income would be taxable, the unrelated activities would not threaten the health center's tax exemption unless they become substantial in relation to the health center's health care activities. If that were to become problematic, the health center could form a for-profit subsidiary to conduct the unrelated business activities.⁷⁴

In addition, other types of passive income such as interest, rents, and royalties generally are not taxable as unrelated business income, except for certain income derived from debt-financed property. See Section 512(b). However, income from interest, rents, and royalties from any entity that the tax-exempt organization deriving such amounts controls is considered to be unrelated business income. See IRC Section 512(b)(13).⁷⁵

5. Intermediate Sanctions (IRC Section 4958)

Private inurement – The fact that individuals sometimes use their positions as "insiders" of a tax-exempt organization to their own benefit, by drawing excessive salaries or other "perks," has been of concern to the IRS for many years. Technically, such conduct results in "private inurement." Since the presence of **any** private inurement means that an organization will no longer qualify for income tax exemption, private inurement should be avoided at all costs. However, because the

⁷³ Section 512(a)(1) of the Code defines the term "unrelated business taxable income" as gross income derived from any unrelated trade or business regularly carried on by it less allowable deductions directly connected with the carrying on of such trade or business. Unrelated business taxable income is subject to the prevailing corporate income tax rate.

⁷⁴ In such a situation, the health center's income (in the form of after-tax dividends) would not be subject to tax, as long as the health center did not become involved in the day-to-day operation of the subsidiary. If that were to occur, the activities of the subsidiary would be attributed to the health center and potentially could threaten its tax-exempt status.

⁷⁵ For purposes of the unrelated business income tax, "control" is defined as 50% ownership.

penalty in cases of private inurement is so drastic, the IRS historically has been reluctant to challenge possible cases of inurement, except in the most egregious cases.

Intermediate sanction rules – That situation changed in 1995 with the enactment of IRC Section 4958. IRC Section 4958 provides the IRS with two tiers of "intermediate sanctions" (sanctions short of revocation of income tax exemption) allowing the IRS to tax "excess benefits" (i.e., excessive (unreasonable) compensation) received by a "disqualified person" in transactions occurring after September 14, 1995.⁷⁶ The first tier provides for a tax in the amount of 25% of the excess benefit (and correction of the transaction, i.e., return of the benefit with interest). The second tier is a tax in the amount of 200% of the excess benefit if the transaction is not corrected before the IRS sends a notice of deficiency. In addition, "organization managers", who authorized the transaction, may be liable for a tax in the amount of 10% of the excess benefit (up to \$10,000).

Word of caution – Board members and senior health center staff should keep the requirements of IRC 4958 in mind when negotiating affiliation agreements, if they are likely to receive additional compensation or derive other benefits from the affiliation. For example, if the health center CEO will receive additional compensation as a result of the affiliation, it will be important to assure that the CEO's overall compensation is "reasonable," taking into account any additional duties required on account of the affiliation. Similarly, Board members should be careful not to obtain a personal benefit as a result of an affiliation, e.g., stock in a for profit subsidiary of the health center. These principles are not new. However, because the IRS now has a very effective weapon to use in cases of private inurement, i.e., "an excess benefit transaction," it intends to pursue cases vigorously.

Definitions –

- A *disqualified person* is anyone who, within a 5-year period prior to the date of the transaction, was "in a position to exercise substantial influence over the affairs of the organization" and any immediate family member of a disqualified person. Officers or employees of a related entity controlled by the parent exempt organization can be "disqualified" persons, as can other business entities (except for other Section 501(c)(3) organizations) with which the exempt organization does business. Under the Section 4958 regulations, a person automatically is considered to be "disqualified" if:
 - a. he or she serves as a voting member of the organization's governing Board;
 - b. he or she has the power or responsibilities of the President, CEO, or Chief Operating Officer of the organization or;⁷⁷

⁷⁶ The IRS still may seek to revoke an organization's exemption in cases of private inurement. However, correction of the transaction and imposition of the appropriate tax are likely to be the remedies in most cases involving "unreasonable" compensation. Since the IRS views intermediate sanctions as a revenue enhancement law, revenue agents are likely to be aggressive in reviewing compensation arrangements.

⁷⁷ A person who has managerial control over a discreet segment of an organization (e.g., the CMO) *may* be a disqualified person.

- c. he or she has the power or responsibilities of treasurer or CFO of the organization.

However, a person receiving less than \$90,000 per year in compensation (subject to annual cost-of-living adjustments) is not a disqualified person unless he or she is in one of the above categories. Otherwise, whether or not a person is a "disqualified person" is determined on the basis of "all relevant facts and circumstances."

- An *excess benefit transaction* is one in which the value of the benefit provided to a disqualified person exceeds the value of the consideration received by the organization, including:
 - a. Unreasonable compensation, i.e., compensation that exceeds the value of the employee's services. All items of compensation, including bonuses, fringe benefits, vested deferred compensation, and liability and other insurance premiums, must be considered.⁷⁸
 - b. Gifts or other perquisites provided to disqualified persons who are not employees, i.e., persons who are not compensated for their services.⁷⁹
- There is a presumption that a compensation arrangement is *reasonable* if:
 - a. The compensation arrangement was approved by the Board of Directors (or a committee of the Board) composed entirely of individuals who do not have a conflict of interest with respect to the transaction.
 - b. The Board obtained and relied upon appropriate data in determining compensation comparability.⁸⁰
 - c. The Board adequately documented the basis of its compensation decision at or before the time the compensation is made and properly reported it (e.g., IRS Form W-2 or Form 1099).
- An *organization manager* is any officer, director, or trustee or an individual having powers or responsibilities similar to those of officers, directors, or trustees, regardless of title, if:
 - a. The person is so designated in Articles of Incorporation or Bylaws.

⁷⁸ The Section 4958 regulations provide that the reasonableness of compensation is to be determined as of the time that the contract for services was made. If reasonableness cannot be determined as of that time, then all of the facts and circumstances up to and including the date of payment are to be considered.

⁷⁹ The regulations provide that an organization can pay reasonable travel expenses for board members to attend board meetings, not including luxury travel or a spouse's expenses.

⁸⁰ A written offer from an organization competing for a person's services can be used to establish comparability, as can compensation paid by a comparable for-profit organization.

- b. The person regularly exercises general authority to make administrative or policy decisions on behalf of the organization.

Organization managers are liable for sanctions if they knowingly participate in an excess benefit transaction, unless their participation was not willful and was due to reasonable cause. An organization manager can rely on a reasoned, written opinion of an appropriate professional (i.e., legal counsel, as well as accounting firms, certified public accountants, and individual valuation experts who meet certain criteria), after full disclosure of the facts, that a transaction is not an excess benefit transaction.

D. FEDERAL ANTITRUST LAW

In section D:

1. *Per Se And Rule Of Reason Analysis*
2. *Relevant Safety Zones*
3. *The Messenger Model*
4. *Other Permissible Activities*
5. *State Antitrust Laws and Healthcare Collaboration Statutes*

The Federal antitrust laws⁸¹ prohibit anti-competitive activities that unreasonably restrain trade or that create or attempt to create monopolies. Their purpose is to promote competition and protect consumers against competitors who engage in collective and concerted conduct that results in excessive “market power” in “relevant markets.”⁸² Accordingly, the Federal antitrust laws are designed both to regulate and to encourage competition. As they apply to the health care industry, the antitrust laws ensure that high quality health care services are accessible and affordable for the consumer.

Examples of health center collaborations that may give rise to antitrust concerns:

By their very nature, most health care provider affiliations are designed to promote collective and concerted actions by actual or potential competitors and, therefore, can give rise to antitrust concerns. Such actions do not have to be intentionally anti-competitive to violate the antitrust laws. Examples of collaborations common to health centers that may give rise to antitrust concerns include:

- Agreements between the health center and other providers to negotiate jointly with managed care organizations and other third party payors.
- Affiliation agreements with multiple competing hospitals to create a coordinated primary, secondary and tertiary care delivery system.
- Affiliation arrangements with other providers (e.g., other primary care providers, hospitals) to share the responsibility for the provision of certain health care and related services (e.g., immunizations, health education, outreach), with each shared service to be provided by one of the affiliation providers.
- Affiliation agreements with other providers to develop (i) joint reporting systems under which certain competitively sensitive information (e.g., price-related terms) may be shared, (ii)

⁸¹ The Sherman Act, 15 U.S.C. §§1-7 and the Clayton Act, 15 U.S.C. §§ 12-27.

⁸² Market power takes into account both product market (i.e., the services offered), and geographic market (i.e., the service area).

coordinated fee schedules, and/or (iii) patient tracking and referral systems (which could result in the allocation of patients).

The justifications for entering into such arrangements typically include enhancing the quality and continuum of care, increasing access to and efficiency of services, reducing costs and allocating scarce resources in an effective manner. However, there could be antitrust exposure for the affiliation partners if the desired outcomes do not outweigh any anti-competitive harm that may result. Thus, it is crucial that all potential affiliations between health centers and other health care provider(s) in the center's market be evaluated to determine whether the activities contemplated by the affiliation could result in an antitrust violation.

Government enforcement – The government agencies that enforce the antitrust laws, the United States Department of Justice (DOJ) and the Federal Trade Commission (FTC), have generally viewed joint ventures in the health care arena favorably. However, collaborative activities that are either anti-competitive by nature (e.g., price fixing, boycotting, market allocation agreements) or viewed as such when measured against the potential anti-competitive harm that could result from performance of the activities, may expose the affiliation partners to liability under the antitrust laws. Accordingly, both agencies have issued various policy statements and guidelines, explaining the factors they consider when analyzing the validity of health care provider arrangements.⁸³ Additionally, if health centers and their affiliation partners are unsure as to whether a proposed arrangement and/or activity passes muster under antitrust analysis, they can request a Business Review Letter or an Advisory Opinion from either DOJ or FTC, respectively, in connection with the specific proposed arrangement.

1. Per Se and Rule of Reason Analysis

There are two primary analyses used to determine whether an arrangement among actual or potential competitors complies with the antitrust laws – the “per se” and the “rule-of-reason” standards.

Absolutely anti-competitive – Some arrangements, such as price fixing, group boycotts, and market allocation agreements, have been deemed inherently, or per se, anti-competitive. With these types of arrangements, there is no need to inquire as to the purpose of the arrangement or to consider the arrangement's pro-competitive benefits or its overall effects. These arrangements are simply deemed anti-competitive by nature and, consequently, should be avoided.

Rule of reason test for “gray areas” – Other arrangements, such as mergers, consolidations, joint ventures and other collaborative agreements, are analyzed under a fact-based “rule of reason” test to determine the overall competitive effect. These arrangements generally fall within a gray area; they could possibly constitute an antitrust violation, but require further analysis.

⁸³ DOJ and FTC issued joint Statements of Antitrust Enforcement Policy in Health Care Affiliations (“Policy Statements”), first in 1993, and again in 1996. In April 2000, DOJ and FTC issued their Antitrust Guidelines for Collaborations Among Competitors (“Guidelines”), which, unlike the Policy Statements, are not limited to the health care industry. This past July (July 2004), DOJ and FTC issued a report examining anticompetitive barriers to health care access (“Improving Health Care: A Dose of Competition”). Both sets of guidelines, the report, and other guidance can be found on each agency's website: www.usdoj.gov and www.ftc.gov.

As a first step, DOJ and FTC examine the nature of the agreement to determine (i) what the underlying business purposes are, and (ii) what, if any, anti-competitive harm and pro-competitive benefits could result.⁸⁴

- If little or no anti-competitive harm is found, the agencies will not challenge the arrangement.
- If there is an identified potential for anti-competitive harm and there are no overriding benefits offsetting the harm, the agencies may challenge the arrangement with no further analysis.
- If, however, the arrangement produces both a potential for anti-competitive harm as well as pro-competitive benefits, the agencies will conduct a further market analysis before deciding to challenge the arrangement.⁸⁵ Upon further analysis, if (i) the pro-competitive benefits outweigh the anti-competitive harm, and (ii) any implementing agreements that would otherwise be deemed per se illegal, such as price agreements, are reasonably necessary to realize those benefits, the arrangement will be deemed appropriate under antitrust law.

2. Relevant Safety Zones

In this section:

- *Integrated Provider Networks*
- *Other Safety Zones for Providers Lacking Substantial Integration*

The DOJ and FTC Policy Statements describe a number of “safety zones” for certain collaborative arrangements (and the activities conducted under these arrangements) that, absent extraordinary circumstances, will be protected from antitrust enforcement. To be afforded protection, the arrangement and/or activity must satisfy all criteria of the relevant safety zone.⁸⁶

Integrated Provider Networks

The safety zone for integrated provider networks allows a network to negotiate and contract with third parties as a single entity on behalf of its participants and to engage in other activities typically considered anti-competitive, if the participants are sufficiently integrated. Examples of activities that may fall within this safety zone include:

- Exchanging information related to current or future fees, costs, wages, salaries, benefits, credit terms, bids or negotiations with third party payors or purchasers, or other financial

⁸⁴ The analytic steps for the rule of reason test are set forth in detail in the Policy Statements.

⁸⁵ Examples of pro-competitive benefits include: greater cost-effectiveness and efficiencies, and improvements or enhancements in goods and services (*i.e.*, improved quality, innovative and new services). Examples of anti-competitive harms include: more costly goods and services; reduction in output, quality, service and/or innovation; limitation of, or control over, independent decision-making (thereby reducing the ability to compete); and facilitation of practices that result in collusion (*i.e.*, exchange/disclosure of competitively sensitive information).

⁸⁶ It is important to remember that an arrangement or activity that fails to meet the precise requirements of a safety zone may still be permissible if the agencies conclude under the rule of reason analysis that the arrangement is likely to provide benefits to consumers that outweigh any potential anti-competitive effects.

information, including the development of reporting systems that result in the exchange of such information.

- Developing and implementing joint pricing strategies for payors and patients, including standard fee schedules for patient billing.
- Allocating services, markets or patients, including, but not limited to, agreements to eliminate duplicative services, agreements to refer patients to one another (subject to a provider's independent professional judgment), and the development of a patient tracking system that results in the allocation of patients.
- Jointly negotiating and contracting with third party payors, vendors, purchasers or providers or agreeing not to deal with certain payors, vendors, purchasers or providers.

Financial integration – In order to satisfy the requirements of the integrated provider safety zone, participants must be financially integrated at a sufficient level. To be considered “sufficiently integrated,” the following criteria must be met:

- The participants share substantial financial risk, i.e., capitation payments, global fee arrangements, fee withholds, cost or utilization based bonuses or penalties⁸⁷; and
- The participants demonstrate other indicia of financial integration, i.e., make substantial capital investments in the arrangement and/or execute a participating provider contract that provides for capitation.

In addition, if the collaboration is non-exclusive, it must be comprised of no more than 30% of the primary care or specialty physicians in the relevant market OR if the collaboration is exclusive, it must be comprised of no more than 20% of the primary care or specialty physicians for the relevant market.

Clinical integration – A non-exclusive collaboration that is unable to demonstrate sufficient financial integration may still be able to obtain safety zone protection by demonstrating sufficient clinical integration. Clinical integration can be evidenced by the implementation of an active and ongoing program to evaluate and, as necessary, modify the practice patterns of the participating providers, and to create a high degree of interdependence and cooperation to control costs and ensure quality. Specific indicia of clinical integration in a provider network include:

- Implementing utilization control mechanisms to control costs and assure quality of care.
- Establishing information systems to gather aggregate and individual data in order to measure performance of the group and of the individual participating providers, and to ensure exchange of all relevant patient data.

⁸⁷ In the recently released report entitled “Improving Health Care: A Dose of Competition” (July 2004), DOJ and FTC indicated that, in determining whether a physician network is sufficiently financially integrated, the agencies will also consider the extent to which a particular “payment for performance” arrangement (i.e., an arrangement under which financial incentives are used to reward quality of care) constitutes the sharing of substantial financial risk among the participants.

- Monitoring patient satisfaction with the participating providers.
- Establishing reporting systems to provide payors with detailed reports on the costs and quantity of the services delivered, and on the collaboration's success in meeting its goals.
- Employing centralized staff.
- Investing significant time and money in the development of necessary infrastructure, including practice standards and protocols and care management protocols, and actively monitoring the care provided through the collaboration.
- Monitoring the participating providers' compliance with network's standards and protocols, and taking remedial action against those individuals who fail to adhere to them.

Networks that (i) have established sufficient clinical integration, and (ii) can demonstrate that joint price negotiations are reasonably necessary to achieve the substantial efficiencies arising from the clinical integration, may be afforded safety zone protection. However, neither FTC nor DOJ have specifically defined the parameters of "sufficient clinical integration." Further, the agencies have not determined a uniform manner by which to measure whether collective negotiations are reasonably necessary to accomplish the goal of the clinical integration.

In 2002, the FTC issued its first advisory opinion permitting the establishment of a non-exclusive network based solely on clinical integration. The network, which was comprised of (and owned by) competing primary and specialty care physicians, proposed to coordinate and integrate certain health care services provided by its members with a clinical resources management program that would include (i) a web-based electronic clinical data record system, clinical practice guidelines and measurable performance goals, and (ii) a centralized Medical Director (and other staff, as necessary). Additionally, all network members had to commit to participate in the network's programs and adhere to the network's protocols.

With respect to fee-related issues, the network proposed to offer its members' services to payors, negotiate price and other terms, and enter into fee-for-service contracts, provided that fee proposals were developed by a consultant who would not share competitively sensitive information among the physicians. Further, the members were not precluded from contracting independent of the network and payors were not precluded from negotiating and contracting with a member individually.

The FTC determined that the proposed program facilitated and increased communication among the members, creating both significant integration among their practices and certain efficiencies that could not be achieved by the members acting independently. Further, the price agreement was deemed ancillary to the operation of the venture because it was reasonably related to the integration of the members and reasonably necessary to achieve the desired pro-competitive benefits.⁸⁸

Although this opinion appears to provide FTC support for clinically integrated arrangements, in the recently released report entitled "Improving Health Care: A Dose of Competition" (July 2004), DOJ and FTC declined to describe particular network structures under which providers would be able to achieve sufficient clinical integration to justify joint negotiations. The agencies stated their belief

⁸⁸ Similarly, an unreported FTC action indicated that the agency closed an investigation into a collaboration that created a substantial degree of market concentration because the collaboration created considerable efficiencies, including quality of care improvements.

that listing specific structures could run the risk of channeling market behavior, rather than encouraging market participants to develop structures that are responsive to their own goals and the particular market conditions they face. To assist providers in self-analyzing whether their particular structures would pass muster, the agencies provided, by way of example, a list of questions that the agencies themselves would ask when analyzing whether a particular arrangement is sufficiently clinically integrated, including:

- What do the participating providers plan to do together from a clinical standpoint (i.e., the specific activities, the desired results, how the activities differ from what each provider does individually)?
- How do the providers expect to accomplish these goals (i.e., necessary infrastructure and investment, specific implementing mechanisms, specific evaluation measures)?
- What basis is there to think that the individual provider will actually attempt to accomplish the goals (i.e., individual incentives, specific mechanisms to change and re-align incentives)?
- What results can reasonably be expected from undertaking these goals (i.e., evidence to support the goals, potential for success)?
- How does joint contracting contribute to accomplishing the goals (i.e., is it reasonably necessary and in what ways)?
- To accomplish the goals of the collaboration, is it necessary for providers to affiliate exclusively with one network, or can they effectively participate in multiple networks and continue to contract outside of the network?

Other Safety Zones for Providers Lacking Substantial Integration

Provider networks that are not sufficiently integrated can still conduct certain collaborative activities, so long as appropriate safeguards regarding the distribution and use of information (i.e., no exchange of competitively sensitive information) are included in the arrangement. In particular, DOJ and the FTC have developed safety zones for the following activities:

- Jointly purchasing supplies, equipment and services used to execute and manage the collaboration, provided that the arrangement does not result in the collaborators effectively exercising market power and does not facilitate price fixing or reduction of competition.
- Collecting and sharing fee-related information (i.e. factual information pertaining to historical data and reimbursement methods currently in use by providers), provided that the information:
 - a. is collected by a third party consultant;
 - b. is more than three months old;
 - c. is presented in an aggregate form that cannot be used to identify a particular provider; and

- d. does not represent the collective communication of information or views with respect to prospective fee-related issues.
- Collecting, sharing and generally discussing non-fee-related information (i.e. medical and other service-related data; practice parameters), with respect to developing potential business strategies and prospective operational issues, provided that neither the collaborators collectively, nor the representative of the collaboration, uses the information for purposes of boycotting (or threatening to boycott) a payor, vendor or purchaser.
- Participating in price and cost information surveys (i.e. surveys of historical prices of health care and related services or historical salaries, wages or benefits), provided that the information:
 - a. is collected by a third party consultant;
 - b. is more than three months old;
 - c. is shared in an aggregate form that cannot be used to identify a particular provider; and
 - d. is not an exchange of information regarding future prices of services or staff salaries, wages or benefits, or of price or cost information culminating in an agreement as to the prices of services or staff salaries, wages or benefits.

3. The Messenger Model

If the collaboration lacks adequate integration (or if the adequacy of integration is questionable), the participating providers should use the messenger model for negotiating and contracting with third parties. Under the messenger model, a “messenger” (e.g. a network) serves as a negotiator-intermediary between individual providers and purchasers. Although there is no safety zone covering this type of arrangement, the DOJ and FTC recognize use of the “messenger” model and have stated that such an arrangement “when properly designed and administered, rarely present substantial antitrust concerns.”

Limited messenger activities – Under the messenger model, individual providers must make independent, unilateral decisions regarding acceptance or rejection of contractual terms (including, but not limited to, fee schedules) offered by a third party and must remain free to conduct negotiations independent of the messenger (“non-exclusivity”). In this regard, the activities that can be performed by the messenger are very limited; in the absence of an applicable safe harbor, the messenger cannot:

- Divulge or share with the participating providers the price or other competitive terms and conditions of any contract negotiated for (or with) any one provider; however, the messenger can facilitate the drafting of minimum contract terms and conditions, which are compiled and obtained separately from, and for, each provider, and that, individually, each provider is willing to accept, and can communicate such guidelines to payors.
- Disseminate to any of the providers the views and intentions of other providers (or of the

messenger) regarding a proposal(s); however, the messenger can facilitate each provider's understanding of the proposed contract terms and conditions by providing objective and/or empirical information about such terms.

- Collectively negotiate and contract for the providers or coordinate their responses to a proposal(s); however, the messenger can communicate to each provider individually the contract offers from payors, and communicate to each payor the independent, unilateral decisions obtained from each provider regarding such offers. Note that, because the messenger does not have the power to reject any offers on its own volition, it/he/she must convey all offers to the providers, not just those that meet the pre-determined minimum terms.
- Bind an individual provider to a contract, unless terms fall within a previously determined acceptable range, and the messenger has the explicit and specific authority to do so by that provider. The parties to the contract should be the individual provider and the payor.

Recent enforcement actions – Recently, both DOJ and the FTC have focused much of their enforcement efforts on non-integrated provider networks that purported to engage in actions under messenger model arrangements, but, in actuality, served as their respective members' *de facto* exclusive bargaining agents with payors. In general, each of the networks entered into an agreement with their respective members to (i) fix prices and price-related terms, (ii) negotiate uniform fees and other contracting terms, (iii) execute contracts containing such terms, and/or (iv) refuse to deal with payors except on the collectively agreed upon terms. Further, the members asserted that they would deal with payors only through their respective network, and the networks used coercive tactics with third parties (e.g. health plans) to induce higher fees for members (including refusal to transmit price offers deemed insufficient and, in some cases, threats to terminate pre-existing contracts). Of note, none of the networks and their respective members engaged in any coordinated joint activity that could justify such collective actions.

The agencies determined that, under these scenarios, the illegal concerted actions effectively restrained prices and other competition among the members, by inflating fees and fixing other competitively significant terms of dealing with health plans (which ultimately resulted in harm to consumers). In the resulting settlement agreements, the networks and their members were prohibited from (i) entering into, participating in or facilitating any agreements to negotiate collectively, to deal (or refuse to deal) with specific payors, or to deal only through the network, or to fix the terms of dealing, and (ii) exchanging any information regarding an individual member's willingness to deal. Often the agencies also required the network, for a specific number of years after the settlement, to provide the respective agency with prior notice before entering into any arrangements with providers where it would act as a messenger on behalf of those providers.⁸⁹

Of note, the networks were not prohibited from engaging in conduct reasonably necessary to operate a "qualified risk-sharing joint arrangement" or a "qualified clinically integrated joint arrangement." However, in one settlement, the network was required to provide the agency with prior notice before negotiating or entering into any agreement related to price or other terms of dealing under a qualified clinically-integrated joint arrangement. Accordingly, despite the previous

⁸⁹ While the majority of networks were permitted to continue limited operations under the guidelines of the settlement agreements, one of the networks examined by DOJ was forced to cease all operations and disband completely and permanently.

approval of a network primarily based on the network's clinical integration (see Section 2 above), networks and their participating members should be cautious in relying solely on clinical integration as a basis to implement joint activities involving price and other competitively sensitive information, without specific agency approval.

Contrary to the arrangements describe above, in another recent enforcement action, FTC approved a network that intended to operate under a true messenger model arrangement. Unlike the arrangements previously disapproved, the network proposed to:

- Operate as a non-exclusive network, permitting its members to participate in other networks and to contract with payors directly (including those payors that contract with the network).
- Convey payor offers to its members on an individual basis, and communicate to each payor which members will accept the particular payor's offer.
- Collect from each member individually information regarding the minimum payment level that member will accept, which information will not be disclosed to other members.
- Contract with any payor on behalf of members whose minimum payment requirements are at or below the payment offered by that payor.
- Notify any member whose minimum payment requirement is greater than the payor's offer that he/she may unilaterally decide to "opt in" to the contract at the lower payment level or negotiate and to contract individually with such payor.
- Provide certain administrative services in connection with the payor contracts, including credentialing, dispute resolution, and transmitting information between the payors and the members.

Of note, the network represented that it would not (i) negotiate price or price-related terms on behalf of its members, (ii) coordinate or facilitate agreements among the members in responding to payors or to specific terms, (iii) recommend the acceptance or rejection of any offers or terms, or (iv) give or suggest an opinion on the appropriateness of the price or other competitive terms of any payor.

4. Other Permissible Activities

Although not specified in a safety zone, non-integrated provider collaborations may conduct certain other activities that are narrowly tailored to further only collaborative activities and that do not involve the sharing and discussion of competitively sensitive information. These activities include:

- Discussing the form and structure of a potential collaboration arrangement, as well as historical data about the participants, which, in turn, would enable the parties to determine whether to proceed with the arrangement.
- Developing protocols for shared services and personnel.

- Developing and establishing shared information and clinical and administrative management systems, mechanisms, practices and procedures necessary to execute and manage the affiliation.
- Establishing joint patient tracking systems, provided that this does not result in patient allocation among participating providers.

5. State Antitrust Laws and Healthcare Collaboration Statutes

Under the judicially established “State action immunity doctrine,” State agencies, municipalities, other types of local government agencies and private parties may be immune from Federal antitrust liability for certain anti-competitive conduct, if they are acting within the scope and purview of a State statute or regulation.⁹⁰ Specifically, the State action immunity doctrine sets forth a two-pronged legal test that must be satisfied if Federal antitrust immunity is to be granted:

- The anti-competitive conduct must be “clearly articulated and affirmatively expressed as State policy.” The expression of a clear State policy should be based on specific, detailed legislative authorization and, further, should reflect some affirmative expression that the State has reasonably foreseen the potential anticompetitive effects.
- The State policy must be “actively supervised” by the State. State officials must, therefore, have and exercise the power to review and regulate the particular acts of private parties and to disapprove anti-competitive acts that fail to accord with State policy. The State must also exercise sufficient independent judgment and control so that the anti-competitive conduct is a product of deliberate State intervention.⁹¹

State immunity statutes – For provider collaborations, a State “Health Care Collaboration Statute” may provide the clear State policy and active supervision necessary to establish State action immunity from Federal antitrust laws. Approximately half of all States have enacted Health Care Collaboration Statutes to encourage voluntary cooperative agreements among physicians, hospitals and other health care providers.

In general, State immunity statutes allow hospitals, physicians, and other health care providers to enter into joint venture/merger agreements that result in lower health care costs, higher quality and increased accessibility. Procedurally, these statutes contemplate significant government involvement in reviewing and monitoring the proposed collaborative arrangement. If the arrangement is approved, the parties to the arrangement are granted State action immunity for conduct that is otherwise regarded as a potential violation of State and/or Federal antitrust laws. Health centers and their collaboration partners contemplating activities that may run afoul of the antitrust laws may wish to consider the requirements and potential protections afforded under a

⁹⁰ The actions of the Federal government and of State legislatures are generally immune from Federal antitrust prosecution; however, the actions of State agencies, cities and local governments are not automatically immune.

⁹¹ Unlike private parties that must satisfy both prongs of the legal test, State agencies, municipalities and other local government need only satisfy the first prong to be granted immunity under Federal antitrust law.

specific State Health Care Collaboration Statute and determine whether it makes sense to avail themselves of the process.

E. FEDERAL ANTI-KICKBACK LAW

In section E:

1. *The Federal Anti-Kickback Statute*
2. *Pertinent Safe Harbors*
3. *Special Fraud Alerts, Advisory Bulletins and Other Guidance*
4. *Advisory Opinions*

The Federal fraud and abuse laws (which include the Federal anti-kickback statute, “Stark I & II physician” self-referral prohibitions and False Claims legislation) are designed to prevent fraudulent or abusive use of Federal health care programs.⁹² All providers participating in Federal healthcare programs have the responsibility of complying with the various Federal fraud and abuse statutes.⁹³ These statutes present particular challenges to health centers and their potential affiliation partners in the context of developing and implementing collaborative relationships, as these relationships and the manner in which they are structured may result in exposure under the fraud and abuse laws.

1. The Federal Anti-Kickback Statute

The main purpose of the Federal anti-kickback statute is to prevent abusive arrangements that could result in higher costs to the government or compromise the quality of care provided to beneficiaries of Federal health care programs. In summary, the statute prohibits arrangements under which any entity or person:

- Knowingly or willfully
- Solicits or receives (or offers to pay)
- Anything of value (“remuneration”)
- Directly or indirectly, overtly or covertly, in cash or in kind

⁹² The term "Federal health care program" includes, among others (i) the Medicare program, (ii) other health care programs administered by Federal agencies, including the Public Health Service, (e.g. the Section 330 program) the Department of Veterans Affairs and the Department of Defense, and (iii) certain Federal/State health care programs, including the Maternal and Child Health program, Medicaid, certain block grant programs and the Child Health Insurance Program (CHIP) (Titles V, XIX, XX, and XXI of the Social Security Act, respectively)).

⁹³ The Medicare and Medicaid Patient and Program Protection Act, including its Medicare and Medicaid anti-kickback, false claims, civil monetary penalties and safe harbor provisions is codified at 42 USC §§1320a-7, 7a, and 7b, and the Stark Physician Self-Referral Prohibitions are set forth in 42 USC §1395nn.

- In exchange for making or inducing patient referrals or the purchase or lease of goods, services or equipment (other business generated between the parties)
- Any of which are paid for, in whole or in part, by Federal health care dollars.

The implications of the anti-kickback statute may be particularly important for health centers and their affiliation partners, in that collaborations often include cost-effective methods to increase access to, and availability of, services provided to the uninsured or underinsured individuals and families served by the health center. As such, many health centers consider entering into affiliation arrangements under which other local providers furnish donations or no-cost or low cost goods/services to the health center, thereby assisting the health center in expanding and enhancing the range of services available to its patients while stretching scarce resources (that, in turn, can be used to support otherwise uncompensated care).

Examples of health center arrangements that may give rise to anti-kickback concerns:

- Arrangements under which the health center’s affiliation partner agrees to provide to health center patients certain services that the health center is obligated to provide under its Section 330 grant (e.g., diagnostic lab and x-ray, ob/gyn services, pediatric care) and to subsidize all or a portion of the costs of the services it provides by furnishing the services to the health center and its patients at no charge or at a discounted (i.e., below market) rate.
- Arrangements under which the health center rents clinic space and/or equipment from (or to) its affiliation partner at no charge or at a discounted rate (or at an above market rate).
- Arrangements under which the health center’s affiliation partner donates to the health center information systems, personnel, or other resources at no charge or at a discounted rate.
- Arrangements under which the health center’s affiliation partner agrees to provide to the health center a monetary donation (or a below market loan, which may be forgiven at a later date) to assist the health center in defraying a portion of its otherwise uncompensated costs of providing health care and related services.
- Arrangements under which the health center enters into a purchase agreement with an existing physician practice to purchase the practice in hopes of converting it into a health center satellite site.
- Arrangements under which the health center’s affiliation partner offers to cover a portion of the costs associated with the health center’s recruitment of a new provider/employee (e.g., travel and moving expenses, signing bonuses).

While these arrangements may be well meaning, they could be problematic under anti-kickback law if the benefits (e.g., donated or low cost goods/services) provided to the health center by the affiliation partner are furnished with the intent of inducing the health center to refer patients to, and/or to generate other business with, the affiliation partner, which would be paid for, in whole or in part, by Federal health care dollars.⁹⁴ If the Office of the Inspector General (OIG -- the

⁹⁴ Although the more common scenario involves the health center receiving the “benefits” or remuneration, there could be instances in which the health center provides benefits to the affiliation partner with the intent of inducing the affiliation partner to refer patients to, and/or generate business with, the health center (such as an arrangement under which the health center purchases an existing physician practice or rents space in the health center facility to

office within DHHS that enforces the Federal fraud and abuse laws) determines that the requisite intent exists, both the health center and its affiliation partner(s) could be exposed to civil and/or criminal liability, including the imposition of civil monetary penalties; exclusion, suspension or debarment from Federal health care programs; criminal fines, and/or imprisonment.

To minimize exposure – To minimize exposure, health centers and their affiliation partner(s) should ensure that:

- Any “remuneration” flowing between the parties is not an unlawful incentive for prohibited referrals or other business.
- As applicable, all arrangements between the parties satisfy, or come as close as possible to satisfying, the requirements of applicable safe harbors (which are discussed in more detail below).
- Communication between the parties does not indicate or infer a prohibited intent, thereby “tainting” the relationship.

Terms – There are a few key terms of the statute with which health centers should be familiar:

Knowingly or willfully: The anti-kickback Statute is an intent-based statute. In order to convict a person or entity of a violation of the statute, the Government must show that the person or entity knows or has reason to know (i.e., should know) that (i) the activity or transaction violates the anti-kickback statute, and (ii) regardless, the person or entity engages in the arrangement.

Remuneration: Remuneration is interpreted broadly to include anything of value (or inducement) exchanged for referrals or other business generated between the parties to a transaction, including donations and monetary savings from free or below market (discounted) goods/services. For example, if a health center accepts monetary donations or donations of equipment from a hospital with which the health center does business, both parties may be in violation of the anti-kickback provisions, provided the requisite intent is established.

Inducement: As used in this statute, inducement means to influence, in any way, the reason or judgment of the provider or other individual responsible for making referrals or purchasing goods and services. Inducement to refer or generate other business between the parties does not have to be the primary or sole purpose for the arrangement. The mere element of influence is sufficient.

Use of Federal Health Care Dollars: Although the statute requires that Federal health care dollars be used to pay for all or part of the activities in question, this provision has been construed very broadly to encompass anything that may have been paid for in any degree by Federal funds. The statute does not require a direct connection between Federal health care funds and illegal payments.

its partner at above market rates). Such arrangements would be equally prohibited by Federal anti-kickback law, if entered into for the purpose of inducing such referrals.

2. Pertinent Safe Harbors

In this section:

- *New Statutory Safe Harbor for Health Center Grantee Transactions*
- *Personal Services and Management Contracts*
- *Space and Equipment Rental*
- *Discounts*
- *Referral Agreements for Specialty Services*
- *Sale of Practice*
- *Investment Interests in Underserved Areas*
- *Practitioner Recruitment in HPSA*
- *Obstetrical Malpractice Insurance Subsidies*
- *Managed Care Safe Harbor for Risk-Sharing Arrangements*
- *Waiver of Beneficiary Co-Insurance and Deductible Amounts*
- *Other Safe Harbors*

Because the anti-kickback statute is worded very broadly, and could be interpreted to preclude certain appropriate arrangements, Congress and the OIG established a series of statutory and regulatory exceptions (safe harbors), which protect from prosecution certain business arrangements and practices believed to pose a minimal risk of fraud or abuse of Federal health care programs. See 42 C.F.R. §1001.952. In order to be protected under a specific safe harbor, the arrangement must meet all requirements of that rule. Further, if an arrangement requires protection under two or more safe harbor rules, it must completely comply with all of the requirements of each of the relevant rules.

Securing safe harbor protection – Ideally, health centers and their affiliation partner(s) should strive to meet all of the elements of the specific safe harbor(s) that cover their arrangements. Arrangements that do not satisfy all of the requirements of a specific safe harbor(s), however, may still be permissible; such arrangements will be judged on a case-by-case basis to determine whether:

- An impermissible intent exists, and
- The arrangement will result in a high risk of fraud or abuse and/or compromise the quality of care.

If not protected under a safe harbor – If the parties cannot secure safe harbor protection, they should still make a concerted effort to meet as many requirements as possible (and to document the business reasons why they cannot fully comply with safe harbor requirements) in an effort to establish and maintain a compliant arrangement and minimize liability under the anti-kickback statute. At a minimum, health centers and their affiliation partners should strive to ensure that arrangements include terms that reflect an arm's length negotiation (and, with respect to price terms, fair market value), preserve independent provider judgment and patient freedom of choice regarding referrals, and are not tied to purchase or lease decisions.

The following are safe harbors that are particularly pertinent to health center affiliation arrangements.

New Statutory Safe Harbor for Health Center Grantee Transactions

On December 8, 2003, President Bush signed into law the Medicare Prescription Drug, Improvement and Modernization act of 2003, which included the long-awaited “health center safe harbor” to protect from prosecution under the Federal Anti-kickback law certain arrangements between health center grantees and other providers/suppliers of goods and services that support or expand accessibility, availability, and/or quality of services provided to health center patients. Specifically, the safe harbor exempts from the definition of remuneration that is prohibited by Anti-kickback law:

any remuneration between a health center entity. . . and any individual or entity providing goods, items, services, donations, loans, or a combination thereof, to such health center entity pursuant to a contract, lease, grant, loan or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center entity.⁹⁵

The legislation provides that the Secretary of DHHS will establish standards relating to the safe harbor no later than one year from the date of the legislation’s enactment. Accordingly, OIG at DHHS has a deadline of December 8, 2004, to publish final regulations establishing such standards. In establishing the standards, the legislation requires that DHHS consider the following factors:

- Whether the arrangement between the health center and the other party results in savings of Federal grant funds or increased revenues to the health center;
- Whether the arrangement between the health center and the party restricts or limits an individual’s freedom of choice; and
- Whether the arrangement between the health center and the other party protects a health care professional’s medical judgment regarding medically appropriate treatment.

Further, DHHS may consider and include other standards and criteria that are consistent with Congress’ intent in enacting the health center safe harbor legislation.

On March 1, 2004, an OIG official informally advised NACHC that, in her opinion, the statutory safe harbor for health centers was effective as of the date of enactment of the statute (*i.e. as of **December 8, 2003***). However the OIG official indicated that her views would not be binding on the Department of justice. Further, the OIG official was unclear as to the type or extent of regulatory standards (other than those specified in the legislation) that the OIG’s office will establish to implement the statutory provision.

As such, until the regulations are issued, it is advisable that health centers proceed with caution when developing and implementing written affiliation agreements with actual or potential referral sources. In particular, health centers and their affiliation partners should:

⁹⁵ Section 431 (a) of H.R. 1, the Medicare Prescription Drug and Modernization Conference Agreement.

- Be mindful of the aforementioned statutory standards and, as necessary, consult with qualified counsel to minimize Anti-kickback exposure.
- Leave room to modify agreements as may be appropriate to secure safe harbor protection once the OIG issues the implementing regulations.

Personal Services and Management Contracts

The safe harbor for personal services and management contracts protects arrangements under which a health center contracts for personal or management services with an affiliation partner(s) with whom the health center may have a referral relationship (e.g., physicians contracted from private practices or hospitals; part-time CMO or financial support services provided by a hospital; information technology services provided by a hospital or health system), or vice-versa, provided that all of the following requirements are met:

- The parties enter into a signed, written contract;
- The contract specifies the services to be provided;
- If services are to be provided on a sporadic or part-time basis, the contract specifies the schedule and the exact charge for such intervals;
- The term of the contract is not less than one (1) year. If the contract can be terminated “for cause” prior to the expiration of a one (1) year term, the contract cannot be re-negotiated for the duration of the initial term;
- The aggregate compensation to be paid under the contract is set in advance (i.e., compensation cannot fluctuate or vary based on “per use, “per patient,” or other similar methodology), is consistent with fair market value in an arms-length transaction, and does not vary based on volume or value of referrals or business generated;
- The services performed under the contract cannot involve the counseling or promotion of a business arrangement/activity that violates any State or Federal law; and
- The aggregate services cannot exceed those that are the reasonably necessary to accomplish the commercially reasonable business purpose of the contract.

Space and Equipment Rental

The space and equipment rental safe harbors protect arrangements under which a health center leases space and/or equipment from an affiliation partner(s) with whom the health center may have a referral relationship, or vice-versa, provided that all of the following requirements are met:

- The parties enter into a signed, written lease agreement;
- The lease covers all of the premises/equipment to be leased in specific detail;
- If the lease provides access to the premises/equipment on a sporadic or part-time basis, the lease specifies the schedule, length and exact rent for such intervals;

- The term of the contract is not less than one (1) year. If the contract can be terminated “for cause” prior to the expiration of a one (1) year term, it cannot be re-negotiated for the duration of the initial term;
- The aggregate rental charge to paid under the lease is set in advance (*i.e.*, compensation cannot fluctuate or vary based on “per use, “per patient,” or other similar methodology), is consistent with fair market value in an arms-length transaction, and does not vary based on volume or value of referrals or business generated; and
- The aggregate space/equipment cannot exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the contract.

Discounts

In general, “discounts” may be disguised kickbacks in that they provide a benefit to the entity or individual receiving the discount, in the form of “savings,” which may induce such entity or individual to refer patients or business to the entity/individual providing the discount. The discount safe harbor may protect arrangements under which the health center receives certain discounts on items or services from its affiliation partner(s). The term “discount” is defined as “a reduction in the amount a buyer (who buys either directly from a “seller” or through a wholesaler or a group purchasing organization functioning as an “offeror”) is charged for an item or service based on an arms-length transaction.”

- **Discount requirements for buyers** – The Federal regulations provide very detailed standards that must be met by the buyer, the seller and the offeror of the discount. Typically, under such arrangements, the health center will be the buyer of goods or services.⁹⁶ As such, all of the following requirements would apply:
 - a. The discount must be earned based on purchases of that same good or service bought by the health center within a single fiscal year;
 - b. The health center must claim the benefit of the discount in the fiscal year in which the discount is earned or in the following year;
 - c. The health center must fully and accurately report the discount in the applicable cost report so as to ensure that the Federal (or State) health care program gets the benefit of the discount; and
 - d. The health center must submit, upon request by the Secretary or a State agency, certain information regarding the discount that the seller/offeror provides to the health center.
- **Discount requirements for sellers that could impact buyers** – In order for the buyer to meet its reporting obligations, the seller/offeror is required to report the discount to the buyer in the manner proscribed by the safe harbor. Further, the seller/offeror is required to refrain

⁹⁶ If the health center is the seller or offeror of the discount, the safe harbor regulations provide other requirements to ensure compliance with the discount safe harbor.

from doing anything that would impede the buyer from meeting its reporting obligations. If a seller/offeree does not comply with applicable requirements, it is possible that a buyer health center will lose safe harbor protection, even if the health center has complied with all of the requirements applicable to buyers. Accordingly, health centers should include in any agreement with a seller/offeree language requiring compliance with applicable safe harbor requirements.

- **Not “discount” transactions** – Of note, the rule lists certain transactions that would not qualify as a “discount” such as:
 - a. Warranties;
 - b. Cash payments (or cash equivalents);
 - c. A reduction in price applicable to one buyer but not to Medicare or Medicaid;
 - d. Services provided in accordance with a personal or management services contract; and
 - e. Other remuneration (in cash or in kind) not explicitly described in a safe harbor.

Referral Agreements for Specialty Services

The OIG recognizes that practitioners and providers must be able to refer patients to specialists for certain services that they themselves cannot provide, with the understanding that the specialists will refer the patients back to the initial provider at a later date. Technically, a reciprocal referral arrangement such as this may be considered a violation of the anti-kickback statute. The safe harbor for referral arrangements for specialty services protects arrangements under which a health center agrees to refer patients to its affiliation partner(s) for the provision of specialty services in return for an agreement by the affiliation partner(s) to refer such patients back to the health center at a mutually agreed upon time (or circumstance)⁹⁷, provided that all of the following requirements are met:

- The mutually agreed upon time or circumstance for referral back to the health center must be clinically appropriate;
- The service for which the referral is made must not be within the medical expertise of the health center, but must be within the specific expertise of the practitioner receiving the referral;
- The parties must not receive payment from each other and must not split a global fee from any Federal health care program for the services covered by the safe harbor; and

⁹⁷Typically, the health center would be the entity referring patients to a specialty provider for the provision of services that the health center does not provide directly. If, however, the health center is the health care provider receiving the referral for specialty services (e.g. certain behavioral health therapies), the safe harbor can still protect the arrangement provided that the applicable requirements are satisfied.

- Unless both the health center and the practitioner receiving the referral belong to the same group practice, the only exchange of value between the parties can be the remuneration the parties receive directly from third-party payors or from the patient for the services furnished by the particular party.

*Sale of Practice*⁹⁸

The safe harbor for the sale of a practice protects arrangements under which one practitioner (e.g., a health center) purchases the practice of another practitioner, provided that all of the following requirements are met:

- The period from the date of the first agreement pertaining to the sale to the completion of the sale is not more than one (1) year; and
- After one (1) year from the date of the first agreement pertaining to the sale, the practitioner who is selling his or her practice will not be in a professional position to make referrals to, or otherwise generate business for, the health center for which payment may be made in whole or in part under Medicare or Medicaid. In other words, the selling practitioner is selling or moving away from his or her patient base. This section of the safe harbor would not protect a health center that purchases a physician practice and employs the physicians.

Investment Interests in Underserved Areas

The safe harbor for investment interests protects payments to health centers that constitute a “return on investment” for an investment interest held by the health center in a health care entity (e.g., a radiology center; a birthing center) that is located in Federally-designated MUA or that serves a Federally-designated MUP, provided that all of the following requirements are met:

- During the prior fiscal year or twelve (12) month period, no more than 50% of investment interests of each equivalent class of investments were held by interested investors (investors who are in a position to make or influence referrals, furnish items or services or otherwise generate business for the entity);
- The terms for all passive investors (interested and non-interested) are the same;
- The terms offered to interested investors are not related to the previous or expected volume of referrals, items or services or business otherwise generated;
- There is no requirement that passive investors make referrals, furnish items or services or otherwise generate business;

⁹⁸ The OIG has also issued a safe harbor applicable solely to the sale of a practice by a practitioner to a hospital or other entity when the practice is located in a HPSA. However, to qualify for this safe harbor, the purchasing entity must diligently and in good faith engage in commercially reasonable recruitment activities that “may reasonably be expected to result in the recruitment of a new practitioner to take over the acquired practice” and that will satisfy the practitioner recruitment safe harbor. As such, it is unclear whether this safe harbor would apply to situations in which the new practice is absorbed into the health center’s scope of project.

- The entity or any investor does not market or furnish the entity's items or services to passive investors differently than to non-investors;
- 75% of the dollar volume of the entity's business for the prior fiscal year or twelve (12) month period was derived from providing services to persons who reside in the MUA or are members of an MUP;⁹⁹
- Neither the entity or an investor loans funds to a prospective investor; and
- The amount of payment to an investor is directly proportional to the investment interest.

Practitioner Recruitment in Health Professional Shortage Area (HPSA)

When a provider (e.g., hospital) assists a practitioner with the fees and/or expenses associated with such practitioner's re-location, the arrangement could be a potential anti-kickback problem in that the practitioner may be obligated to refer patients or other business to the provider "footing the bill." The practitioner recruitment safe harbor protects arrangements under which a practitioner receives payment or other benefits from an entity to induce the practitioner to relocate into the area served by the entity and that is designated as a HPSA for the practitioner's area of practice, provided that (among other requirements):

- The practitioner and the entity enter into a signed agreement, which specifies the benefits the entity will provide to the practitioner for a period of no more than three (3) years;
- The benefits will not vary based on the volume or value of referrals to, or business generated for, the entity;
- The arrangement will not restrict the practitioner's professional judgment or require the practitioner to make referrals to, or generate business for, the entity; and
- The practitioner agrees to treat Federal health care program beneficiaries in a nondiscriminatory manner.

Typically, if a health center's affiliation partner(s) desires to subsidize a portion of the health center's practitioner recruitment costs, it would provide such subsidy to the health center, not to the practitioner recruited by the center. Under such circumstances, it is unclear whether the OIG would consider the health center entity "the practitioner" for purposes of satisfying the aforementioned safe harbor.

Obstetrical Malpractice Insurance Subsidies

When a hospital or other entity offers malpractice insurance subsidies to a practitioner, it could raise

⁹⁹ If the area loses its MUA/MUP designation, there is a grace period of three (3) years.

a potential risk of a kickback violation, because the subsidies may be viewed as an inducement to the practitioner to refer patients or other business to the entity paying the subsidies.¹⁰⁰ The safe harbor for obstetrical malpractice insurance subsidies protects arrangements under which a hospital or other entity subsidizes the cost of malpractice insurance for a practitioner (including a certified nurse midwife) engaging in an obstetrical practice as a “routine” part of his or her practice, which is located in a HPSA or MUA or that serves an MUP, provided that (among other requirements):

- The entity paying the premiums and the practitioner enter into a written agreement that sets out the payments to be made and other terms under which the payments are provided;
- The amount of the subsidy will not vary based on the volume or value of past or expected referrals to, or business otherwise generated for, the entity;
- The arrangement will not restrict the practitioner’s professional judgment or require the practitioner to make referrals to, or generate business for, the entity; and
- The practitioner agrees to treat obstetrical patients who are enrolled in a Federal health care program in a nondiscriminatory manner.

Similar to the concern raised under the practitioner recruitment safe harbor, if a health center’s affiliation partner(s) desires to subsidize a portion of the malpractice premiums for a health center’s practitioner, it would provide such subsidy to the health center, not to the practitioner. Under such circumstances, it is unclear whether the OIG would consider the health center entity “the practitioner” for purposes of satisfying the aforementioned safe harbor.

Managed Care Safe Harbor For Risk-Sharing Arrangements

Arrangements under which a provider contracts with a managed care organization to provide services to enrollees in exchange for payment amounts that could put the provider “at risk” for the provision of services (i.e., full or partial capitation payments) may be problematic under the Federal anti-kickback law, in that the managed care organization receives a benefit in the form of savings generated by making reduced or fixed (regardless of the true cost of furnishing services) payments to the provider in exchange for referring its enrollees to the provider. The safe harbor for managed care risk sharing arrangements protects such arrangements.

Under the safe harbor, arrangements between eligible managed care organizations (“EMCO”) and the providers or entities with whom they directly contract for the provision of Federal health care program services (such as Medicaid and Medicare) are protected, provided that the providers or entities do not seek additional payments from Federal health care programs for the services provided under the arrangement. To ensure that this proviso will not prevent health centers from seeking wrap-around payments from State Medicaid agencies (to which health centers are entitled by law), the safe harbor exempts wrap-around payments from the term “supplemental payments”

¹⁰⁰ Typically, this safe harbor would not apply to health centers deemed eligible for FTCA coverage, to the extent that they do not purchase separate malpractice coverage for their providers. However, health centers that have not been deemed eligible or that carry gap insurance for contracted providers and circumstances not covered by FTCA may want to consider this safe harbor if, as part of an affiliation arrangement, an affiliation partner subsidizes the cost of malpractice coverage for health center obstetrical practitioners.

for purposes of satisfying the safe harbor. In short, if a health center contracts with an EMCO to provide services to Medicaid enrollees and also seeks payment from the State Medicaid agency for supplemental payments for these services, the arrangement can be protected from Federal anti-kickback prosecution (so long as the other elements of the safe harbor are met).

Of importance to health center affiliation arrangements, the safe harbor does not exempt wrap-around payments in situations under which an EMCO contracts with a network, which, in turn, contracts with a health center for the provision of services to Medicaid enrollees. NACHC has requested that the OIG modify its position to protect wrap-around payments made in connection with arrangements under which health centers contract with networks rather than the EMCOs. To date, a clarification has not been issued; accordingly, wrap-around payments are not exempt from potential exposure under the aforementioned circumstances.

Waiver of Beneficiary Co-Insurance and Deductible Amounts

In general, the waiver of beneficiary cost-sharing amounts by a health care provider may be problematic from an anti-kickback perspective in that it may induce patients to utilize such provider for the provision of services payable under a Federal health care program. However, safe harbor regulations permit certain entities, including health centers, to waive beneficiary cost sharing amounts owed by Medicare and Medicaid beneficiaries, if those patients qualify for discounts from the health center's established schedule of fees due to their low income status (i.e., their annual income is below 200% of the Federal poverty level).¹⁰¹

Health centers must keep in mind that, under this safe harbor, protection from anti-kickback scrutiny is available only to the health center entity. The health center cannot "pass-through" its ability to waive co-payments and deductibles to its affiliation partners. Accordingly, an affiliation partner cannot waive cost-sharing amounts under an affiliation arrangement unless it independently qualifies for the safe harbor or, consistent with guidance issued by the OIG vis-à-vis gifts and inducements provided to beneficiaries, the affiliation partner makes an individualized determination of need to justify the waiver of cost-sharing amounts.¹⁰²

Other Safe Harbors

In addition to the safe harbors discussed above, the OIG has established safe harbors relating to the following areas:

- Employment relationships.

¹⁰¹ Health centers are still obligated to comply with BPHC requirements, which include attempting to collect a portion of the co-payment based on the health center's schedule of discounts applicable to patients under 200% of the Federal poverty level. For example, if the patient's copayment is \$20 and the patient qualifies for a 50% discount on the fee under the health center charge schedule, according to BPHC guidance, the health center should attempt to collect \$10 as the patient's co-pay.

¹⁰² In 2002, the OIG issued a special advisory bulletin entitled "Offering Gifts and Other Inducements to Beneficiaries," in which it reiterated its position prohibiting providers from waiving beneficiary copayments and deductibles unless the waiver occurs in accordance with specific guidelines. In particular, providers are permitted to make non-routine, unadvertised waivers of cost-sharing amounts based on individualized determinations of financial need (or exhaustion of collection efforts).

- Warranties for products.
- Group purchasing organizations.
- Referral services for practitioners.
- Physician investment interests in certain securities of large, publicly traded corporations and in joint ventures under specifically delineated standards.
- Investment interests in group practices.
- Incentives offered to health plan enrollees by health plans operating pursuant to a contract with HCFA or a State health care program.
- Ambulatory surgical centers.
- Cooperative hospital service organizations.

3. Special Fraud Alerts, Advisory Bulletins and Other Guidance

In this section:

- *Joint Venture Arrangements*
- *Hospital Discounts Offered To Patients Who Cannot Afford To Pay Their Hospital Bills*
- *Rental of Space in Physician Offices by Persons or Entities to Which the Physician Refers*
- *Arrangements for the Provision of Clinical Lab Services*

As discussed above, an arrangement that does not meet the requirements of a specific safe harbor will be evaluated on a case-by-case basis to determine the legality of the particular arrangement. However, on occasion, the OIG issues specific guidance, in the form of special fraud alerts and advisory bulletins, which serve to alert the public to certain practices that may expose the participating parties to liabilities under the anti-kickback statute. While the practices themselves are not prohibited under the anti-kickback statute, certain elements of the practices could be problematic. Accordingly, the guidance provides assistance on how to structure the practices and their elements to avoid potential anti-kickback statute-related liabilities.

In addition to special fraud alerts and advisory bulletins, the OIG may issue specific responses in the form of letters to health care providers to clarify issues regarding common arrangements. Unlike advisory opinions, which address the legality of particular arrangements, these letters provide informal guidance on issues that the OIG believes are of general interest to the health care community. Further, the letters do not bind either the OIG or the party(s) that requested the letter. For additional information regarding advisory opinions, see the next section -- Section 4.

The following alerts, bulletins and letters are particularly pertinent to health center affiliation arrangements. Additional guidance regarding a variety of issues (e.g., prescription drug practices, gifts and inducements to program beneficiaries, practices of business consultants, telemarketing, nursing facilities, home health care, patient anti-dumping prohibitions) can be found on the OIG's website at www.oig.hhs.gov.

Joint Venture Arrangements

Joint ventures in general -- In the area of joint venture arrangements between actual or potential referral sources, the OIG has issued both a special fraud alert and an advisory bulletin. The OIG describes joint ventures in broad terms, ranging from contractual agreements between the parties under which they cooperate in providing services, to the creation of a new legal entity by the parties (such as a limited partnership or corporation) to provide such services. While the OIG acknowledges that many joint ventures are established for legitimate reasons, it is concerned with joint ventures that have the sole purpose of securing a "stream of referrals" for the joint venture partners. According to the OIG, the questionable features of suspect joint ventures occur in three (3) areas:

- The manner in which investors are selected and retained (e.g., investors are chosen because they are in a position to make referrals to one another; the joint venture tracks its source of referrals and distributes this information to investors).
- The nature of the business structure of the joint venture (e.g., the joint venture is a "shell" for referrals).
- The financing and profit distributions (e.g., the amount of capital invested by the physician may be disproportionately small and the returns disproportionately large, physician investors only investing a nominal amount).

Contractual joint ventures -- Recently, the OIG has expressed concern with contractual joint venture arrangements under which a health care provider in one line of business (the purchaser, or typically, the health center) expands into a related health care business through a contractual arrangement with an existing provider of that related service or item (the vendor, e.g., a dentist or a pharmacy) to provide services/items to the health center's existing patients, including Federal health care program beneficiaries. The OIG identified several common characteristics of such arrangements, which together or separately may be problematic:

- The health center establishes a new line of business to provide services/items to its patients. The new business primarily serves the health center's existing patients (i.e., the health center typically does not intend to expand the business to serve new patients).
- The health center neither operates the business nor commits substantial resources (financial, personnel, etc.) to it. Rather, the health center contracts out substantially the entire business to the vendor, who is compensated by the health center to provide services to its patients. The health center's primary contribution to the business is the patients who the health center sends to the vendor to receive services.

- The vendor manages the business and may provide a host of services, including management and billing services, personnel, equipment, space, training, inventory -- the greater the scope of services, the greater the likelihood that the business is a joint venture rather than a simple contract.
- The parties share in the economic benefit. The vendor takes its share under its contract(s) with the health center, and the health center bills insurers and patients in its own name for the services/items provided by the vendor and retains the "profits" from the business. The health center's risk is minimal because of its ability to influence the number of patients served.
- Aggregate payments to both parties vary with volume/value of business generated by the health center – the payments made to the vendor from the health center, as well as payments received by the health center from payors, vary based on the amount services/items provided.
- The parties may agree to a non-compete clause, so that the arrangement is exclusive.
- The vendor is an established provider of the services/items provided and, absent the contractual arrangement, could be a competitor of the health center in connection with the specific services/items (if the health center provided these services directly).

While these types of arrangements may appear to be similar to standard contracted services arrangements, the OIG believes that, if structured as described above, the arrangements may be problematic because they “sidestep” the anti-kickback statute by eliminating the “referral.” By entering into a joint venture (defined for purposes of this bulletin as “a common enterprise with mutual economic benefit”) (i) the health center establishes a new line of business to provide its existing patients with an item or service that the health center would otherwise have to refer to an outside vendor, and (ii) the vendor functions as an agent of the health center (rather than a referral provider) by providing services to the health center’s patients on behalf of the health center – accordingly, the “referral” is eliminated in form but not substance.

NOTE: The aforementioned bulletin does not prohibit the arrangements discussed, but rather provides guidance to parties entering into such arrangements regarding practices that the OIG deems unacceptable. Health centers that enter into agreements with contracted providers to furnish services to health center patients, on behalf of the health center, should ensure (among other things) that:

- The services provided by the contracted provider are under the control and operation of the health center, not the contracted provider.
- The arrangement is structured to effectuate a legitimate business purpose.
- To the extent possible, the arrangement satisfies the requirements of applicable safe harbors, including an arm’s length negotiation between the parties resulting in fair market value compensation.
- The arrangement is non-exclusive (in other words, the health center and the contracted provider are free to compete with one another and enter into similar arrangements with other parties).

Hospital Discounts Offered To Patients Who cannot Afford To Pay Their Hospital Bills

Recently, the OIG issued guidance clarifying that, under certain circumstances, hospitals have the ability to provide financial relief to uninsured and underinsured patients and Medicare beneficiaries who cannot afford their Medicare cost-sharing amounts, without running afoul of the Federal fraud and abuse laws.

In particular, the OIG believes that neither (i) the Federal anti-kickback law, nor (ii) the OIG's authority to exclude from participation in Federal health care programs any provider that submits bills or payment requests that overcharge Medicare or Medicaid, prohibits or restricts hospitals from offering discounts to uninsured patients who cannot afford to pay their hospital bills. In the first instance, the Federal Anti-kickback law prohibits a hospital from giving or receiving anything of value in exchange for referrals payable by a Federal health care program. However, it does not prohibit a hospital from discounting the costs of services provided to uninsured patients who are unable to pay for such services, provided that the discounts are not linked to any business payable under a Federal health care program.¹⁰³

With respect to the OIG's exclusionary authority, the OIG points out that the statute contains an exception for situations in which the Secretary finds "good cause" for any substantial differences between the amounts billed to Medicare/Medicaid and the provider's usual charges. Further, in recently proposed regulations defining key terms in the statute, the OIG clarified that free or substantially reduced charges to uninsured persons (and underinsured patients who are self-paying for the services furnished) should not affect the calculation of a provider's usual charges. It should be noted that the OIG restated its belief that the exclusion provision does not require a hospital to charge everyone the same, nor to offer Medicaid/Medicare its best prices, so long as the hospital does not routinely charge Medicare/Medicaid substantially more than it charges others.

The OIG also believes that Federal fraud and abuse law do not prohibit hospitals from reducing or waiving Medicare cost-sharing amounts for patients experiencing financial hardships.¹⁰⁴ While Federal fraud and abuse law prohibits both (i) the routine waiver of cost-sharing in exchange for business payable by Federal health care programs and (ii) inducements, including waivers of cost-sharing, to Medicare/Medicaid beneficiaries in order to influence their selection of provider (this last prohibition does not apply to uninsured patients), the law also contains an exception to the waiver of cost-sharing obligations based on financial hardship, provided that the waiver is not advertised or routine, and it is determined in good faith that the person is in financial need (or reasonable collection efforts have failed).

Because this guidance speaks only to circumstances under which hospitals are permitted to discount services, the clarifications contained within do not directly apply to or impact the

¹⁰³ On the other hand, the OIG points out that discounts to underinsured patients may give rise to concerns, and, as such, hospitals should exercise care in providing such discounts, ensuring that there is no tie to business for which payment under Medicaid/Medicare is available.

¹⁰⁴ "Reasonable measures of financial hardship" should be used to determine financial need, taking into consideration a host of factors (*e.g.*, cost of living; income, assets and expenses; family size; scope and extent of bills).

internal operations of health centers. However, these clarifications could have a significant impact on health center-hospital collaboration arrangements. In particular, this new guidance could be a useful tool for health centers attempting to negotiate collaboration arrangements with hospitals, under which (among other things) the hospital furnishes discounted services to the health center's patients eligible for sliding fee discounts.

Rental Of Space In Physician Offices By Persons Or Entities To Which The Physician Refers

This alert focuses on the rental of space in “physicians’ offices” (which could include health center facilities) by entities or persons that supply or provide health care items or services (the provider) to patients referred either directly or indirectly by the physician/landlords. The OIG warned that unnecessary or excessive rental payments might be viewed as a “disguised” kickback from the provider to the physician/landlord to induce the physician/landlord to refer patients and/or other business to the provider, thereby violating the Federal anti-kickback law. Specifically, questionable areas may include:

- **The appropriateness of having a rental agreement:** rental payments for space that traditionally has been provided free or for a nominal charge for the benefit of patients (e.g., a closet that houses durable medical equipment) may be inappropriate.
- **The rental amounts:** amounts should reflect fair market value; not take into account the volume or value of referrals or other business; should not exceed amount paid for comparable property; and, except in rare circumstances, should not exceed the rate paid in the primary lease.
- **The actual space rented and the amount of time of the rental:** space and time should be that which is reasonable and necessary for the supplier to achieve a commercially reasonable business purpose.

Arrangements for the Provision of Clinical Lab Services

Arrangements between a provider (such as a health center) and an outside laboratory under which the outside laboratory offers or gives the provider (who is an actual or potential referral sources) services, equipment or supplies at no charge or at a below fair market rate can implicate the anti-kickback statute.

Of particular importance to health centers is the OIG's discussion of circumstances under which a clinical laboratory places in the health center facility a phlebotomist and related equipment (e.g., printers) and supplies to collect specimens from the health center's patients, which specimens will be tested by the outside laboratory. Under such arrangement, the anti-kickback statute is not implicated by the placement of the phlebotomist and the equipment/supplies in the health center, so long as the services provided by the phlebotomist and the use of the equipment/supplies are limited to the collection of specimens.

If, however, in addition to taking specimens, the phlebotomist performs tasks that usually are performed by the health center's medical staff, and/or if the equipment is used for services not integral to the phlebotomist's work, the OIG may determine that the laboratory is providing the

health center with a benefit in exchange for referrals to the laboratory. Accordingly, the health center and the lab should execute an agreement that prohibits the phlebotomist from performing additional tasks (and limits the use of equipment solely in connection with the phlebotomist's services) and should rigorously enforce the agreement.

4. Advisory Opinions

In this section:

- *"Community Benefit" Transactions*
- *"Public Benefit" Transactions*

In addition to issuing specific guidance, the OIG will respond to specific requests from individuals or entities for the OIG's opinion as to the legality of an existing arrangement or an arrangement that the individuals or entities may be considering. Seeking an OIG advisory opinion allows health centers and their affiliation partner(s) to insulate themselves from future liability as the advisory opinion is binding as to that arrangement (but only as to that particular arrangement). Advisory opinions are limited only to the particular requesting parties and bind only the OIG (and not other governmental agencies); accordingly, unlike safe harbors that protect any arrangements that satisfy applicable requirements, advisory opinions have no precedential value. It is important to note, however, that advisory opinions can offer reasonable guidance in interpreting statutory provisions, as well as demonstrate the OIG's enforcement intentions with respect to particular arrangements, in whole or in part.

In general, OIG advisory opinions are available with respect to:

- What constitutes prohibited remuneration.
- Whether an arrangement falls within a statutory exception.
- Whether an arrangement falls within a safe harbor.
- What constitutes inducement to reduce or limit service.
- Whether certain activity is grounds for penalties.

Note that advisory opinions will not opine on whether an arrangement is "fair market value" or whether a person is a bona fide "employee."

There are a few disadvantages in seeking an advisory opinion. First, the OIG charges the requestor for certain costs involved in preparing an advisory opinion. Second, the OIG has a "reasonable" period of time to answer a request for an advisory opinion. In most cases, it takes many months, during which the underlying transaction can go stale. Moreover, if the opinion rejects the proposed arrangement, the health center and its partner(s) will be bound by that conclusion. Nevertheless, health centers entering into an affiliation may wish to consider seeking an advisory opinion if the proposed affiliation raises serious questions of exposure under the anti-kickback statute.

“Community Benefit” Transactions

Over the past few years, the OIG has approved a variety of arrangements that have conferred a “community benefit” to, and served the community interests of, underserved populations. The participants in the arrangements typically were charitable mission-driven entities (e.g., health centers, a nonprofit hospital, a supporting foundation). Each of the proposed arrangements between actual or potential referral sources included transactions that traditionally have been viewed by the OIG as problematic (e.g., the provision of monetary donations, free or discounted goods or services, loan forgiveness). Notwithstanding, the OIG determined that each of the arrangements, as described, were permissible under the anti-kickback statute because they demonstrated certain “low risk” factors. Such factors included:

- Bona fide charitable donations that furthered the respective missions of the entities involved, resulting in benefits to the community as a whole, as well as to the specific populations served (i.e., increased quality and/or access to services).
- Minimal risk of abuse of Federal health care programs (i.e., the arrangement did not present a high risk of over-utilization of services or increased costs to the programs).
- Certain safeguards (either contractual or in practice) that protected against prohibited referrals or the generation of other business.
- No limitations or restrictions on a patient’s freedom of choice and the provider’s professional judgment.
- Narrowly tailored terms so that the benefit did not exceed what is necessary to accomplish the stated purpose.

Community benefit grant -- Of particular importance to health centers, in Advisory Opinion #01-09, the OIG approved an arrangement between a health center and a local community-based hospital under which the health center assumed financial and operational responsibility for certain services provided at an outpatient clinic previously operated (at a substantial loss) by the hospital, in order to avoid either closing the clinic or significantly curtailing the services provided. However, to do so, the health center required a grant from the hospital to defray a portion of the costs of providing otherwise uncompensated health care services to patients served at the clinic (including an expected increase in uninsured patients).

In approving the arrangement, the OIG recognized that charitable donations are essential in “sustaining and strengthening the health care safety net for the insured and uninsured.” Further, the OIG determined that the arrangement would not result in a high risk of abuse of Federal health care programs, based on the following factors:

- The proposed grant furthered the shared charitable missions of the parties by ensuring the continuity of care for current clinic patients and the availability of services for all underserved residents of the community.

- Because the costs covered by the proposed grant would otherwise be covered by other health center funds, including Section 330 dollars, the proposed grant “indirectly relieves the burden on the Federal fisc (treasury).”
- The grant agreement did not contain any restrictions or limitations (other than to expend the funds to pay for the costs of uncompensated care); the amount of the grant was fixed and would not vary based on the volume or value of referrals or other business generated between the parties; at the end of the grant year, the parties would perform a reconciliation between the amount of funds awarded and the actual costs of uncompensated care and any funds in excess of costs would be returned to the hospital; and the funds themselves did not include any discount, rebate or reduction in charge.
- Because the hospital agreed to accept all referrals of health center patients regardless of the patient’s ability to pay, additional uninsured referrals would offset any potential benefit obtained by the hospital due to the parties’ business relationship.
- The arrangement contained other safeguards and low risk factors (as discussed above) and the ancillary agreements necessary to implement the arrangement (i.e., leases for space, equipment, and personnel) complied with applicable safe harbors.

“Public Benefit” Transactions

Recently, the OIG issued several advisory opinions related to “public benefit transactions.” The opinions appear to acknowledge the importance of arrangements between health care entities that provide services to underserved populations, and to protect such arrangements from prosecution under the Federal anti-kickback statute.

In the first opinion, a medical center proposed to contract with a county-owned women’s health clinic serving primarily indigent and low-income patients to:

- Provide physician services at the clinic for a below fair market value rate;
- Move the medical center’s obstetrics and gynecological residency program to the clinic; and,
- Provide inpatient hospital services to low income and indigent patients at no charge to the clinic or to the patient.

In the second opinion, an end stage renal dialysis (ESRD) provider proposed to contract with a hospital district to:

- Provide acute hemodialysis services to a hospital district’s inpatients for a fair market rate;
- Purchase the hospital district’s hemodialysis machines at fair market value; and,
- Provide, either directly or through other community ESRD providers, chronic hemodialysis services to certain “grandfathered” patients at no charge to the hospital district or to the patients.

Under both arrangements, the OIG determined that, because there existed the possibility that the provider furnishing the free or discounted care to indigent patients would do so in exchange for receiving referrals of paying business, the proposed arrangement could potentially generate prohibited remuneration under the anti-kickback statute. However, the OIG also found that because the arrangements included certain features that mitigated the risk of fraud and abuse, and lacked other aggravating factors (such as overutilization or increased cost to Federal health care programs), it would not impose administrative sanctions for engaging in the arrangements. In particular, the OIG determined that:

- In the first opinion, although the payment received by the medical center for the provision of physician services was less than fair market value, it was “not unreasonable in the circumstances presented.” In addition to compensating for the costs of the physician services, the payment covered the “additional costs” incurred by the medical center (which would not otherwise be reimbursed) in moving its residency program to the clinic and gave the medical center the opportunity to strengthen its residency program.
- As part of the arrangement in the second opinion, the free chronic services provided to indigent patients by the ESRD provider and other community providers that were not involved in the specific arrangement represented a community effort to share responsibility for indigent care.

Common factors – With respect to the features common to both arrangements, the OIG determined that the following factors minimized the potential for abuse:

- Any potentially prohibited remuneration generated by the county-owned clinic or by the hospital district would inure to the public, not private, benefit (defined as a financial benefit in the form of savings to the “public fisc” (public treasury)).
- The types of business that the medical center/ESRD provider could generate from the clinic/hospital district made it unlikely that the arrangements would result in overutilization of, or increased costs to, Federal health care programs.
- The costs of providing free services to indigent patients would offset, in part, any potential benefits derived from the business generated by the medical center/ESRD provider.
- There was no adverse impact on competition in the health care marketplace because both arrangements followed the “relevant government contracting laws” (i.e., procurement standards).

Difference between “public benefit” and “community benefit” – While the issuance of these “public benefit” advisory opinions appears to signify the OIG’s continued willingness to exempt from anti-kickback prosecution certain arrangements that benefit the community, health centers should not rely on these opinions as a “blessing” from the Federal government to engage in similar arrangements. In addition to the limitation on the use of advisory opinions common to all such opinions, it is unclear whether the OIG’s discussion of the “public benefit” factor is an extension of the reasoning it utilized in approving earlier arrangements that resulted in significant benefits to underserved populations, as well as their respective communities. Rather, the OIG may be making exceptions for arrangements implemented by public entities that benefit the public fisc (the public treasury). In this regard, it is difficult to discern whether the OIG would approve similar arrangements involving private, nonprofit entities (e.g., health centers) without a demonstrated savings of public (e.g., Section 330) funds.

F. FEDERAL PHYSICIAN SELF-REFERRAL (STARK I & II) LAW

In section F:

1. *The Stark Law*
2. *Exceptions to Prohibition On Referrals To Entities With Which Physician Has A Compensation Arrangement*

Similar to the Federal anti-kickback statute, the Stark law focuses on arrangements between referral sources that could adversely impact Federal health care programs. However, unlike the anti-kickback law, which is an intent-based statute, in most cases, the Stark statute is a strict-liability law (i.e., if the elements of the Stark law prohibitions are present, unless the arrangement fits squarely within an exception to the Stark law, a violation has occurred).

1. The Stark Law

The purpose of the Stark law and its corresponding regulations is to prevent over-utilization of a “designated health service” (“DHS”) paid for by Medicare or Medicaid that could occur if a physician were in a position to benefit personally from making referrals for such services. Specifically, the law prohibits arrangements under which

- *A physician*
- *Refers Medicare and Medicaid patients*
- *To an entity*
- *For the provision of a specific DHS*
- *If the physician (or an immediate family member of the physician)*
- *Has a financial relationship with the entity*
- *Unless the relationship meets one of the proscribed exceptions.*

With respect to affiliation arrangements, because of the proscription on physician referrals to an entity with which the physician has a financial relationship (e.g., either a compensation arrangement or an ownership interest), the Stark law may impact the health center’s choice of affiliation partner(s), as well as the structure of the arrangement itself. Accordingly, health centers contemplating affiliations should consider the implications of the Stark law during the initial planning phase.

Examples of health center arrangements that may give rise to Stark concerns:

- The health center employs or contracts with a physician who also has an ownership interest in an imaging center (with which the health center desires to affiliate). The physician (but not the health center's other providers) is prohibited from referring Medicaid/Medicare patients to the imaging center for the provision of a DHS.
- The health center employs or contracts with a physician whose spouse has an ownership interest in a physical therapy clinic (with which the health center desires to affiliate). The physician (but not the health center's other providers) is prohibited from referring Medicaid/Medicare patients to the physical therapy clinic for the provision of a DHS.
- The health center contracts with a podiatrist to provide services to health center patients. The podiatrist is prohibited from referring Medicare and Medicaid patients to the health center for the provision of a DHS, e.g., prosthetics, orthotics and prosthetic devices that the podiatrist does not stock (but that the health center does carry) or radiology services provided by the health center's in-house radiology department), unless the agreement between the parties satisfies the exception to the Stark law for personal services arrangements (for discussion regarding this exception, see Chapter 4, Section F below).
- The health center enters into an agreement with a physician under which he or she rents space/equipment from the health center. The physician is prohibited from referring Medicare and Medicaid patients to the health center for the provision of a DHS (e.g., laboratory services provided by the health center's in-house lab), unless the agreement between the parties satisfies the exceptions to the Stark law for the rental of office space and the rental of equipment (for discussion regarding these exceptions, see Chapter 4, Section F below).
- The health center employs or contracts with a physician and compensates him/her based, in part, on referrals to a hospital. The health center also leases space from the hospital for one of its sites. This is an example of an "indirect compensation arrangement." (For further discussion regarding "indirect compensation" arrangements, see Chapter 4, Section F below). Accordingly, the physician is prohibited from referring Medicare and Medicaid patients to the hospital for the provision of a DHS, unless the compensation paid to the physician by the health center represents the fair market value for his or her services.

Note that, in the example above, if the physician is compensated in a manner that does not take into account the volume or value of business generated for the hospital (i.e., straight salary), the arrangement will not be treated as an indirect compensation arrangement and, therefore, a Stark issue does not arise. **Accordingly, health centers can prevent an actual or potential Stark problem at the outset by avoiding paying compensation to a physician based on the physician's referrals to other health care providers that are or could be potential affiliation partner(s) providing a DHS to health center patients.**

Although the statute is addressed to the referral practices of physicians, it operates by prohibiting (unless certain exceptions apply) the health care entity that provides a DHS for which a prohibited referral was made from billing Medicare (or any individual, third party or other entity) for the service. Effectively, the consequence of a Stark law violation would be a denial of a Medicare claim for a DHS provided pursuant to a prohibited referral. Additionally, the law prohibits payment to a State Medicaid agency of the Federal Financial Participation ("FFP") for the costs of providing a Medicaid-

covered DHS that was provided as a result of a prohibited referral. Copayments or similar amounts collected from patients for the provision of a DHS that was provided as a result of a prohibited referral must also be refunded. Finally, violators of the Stark law may face civil monetary penalties and may be excluded, suspended or debarred from Federal health care programs.¹⁰⁵

Terms – There are a few key terms of the statute with which health centers should be familiar:

Physician: The Stark Law applies only to referrals made by a “physician” as defined in Medicare (*i.e.*, doctors of medicine, osteopathy, dental surgery, dental medicine, podiatry, optometry and chiropractors). The Stark Law does not apply to referrals made by nurse practitioners, physician assistants, and other non-physician health care providers.

Referral: A referral for purposes of the Stark Law includes the request by a physician for, or ordering of, or the certifying or re-certifying of the need for, any DHS for which payment may be made under Medicare Part B, including a request for a consultation with another physician and any test or procedure ordered by or to be performed by (or under the supervision of) that other physician. However, a referral does not include any DHS personally performed or provided by a physician.

Entity: For purposes of the Stark law, health care providers, whether practicing individually or as partnerships, corporations or group practices, are treated as “entities.”

Designated Health Services (DHS): The DHS subject to the Stark Law are: clinical laboratory services; physical therapy services; occupational therapy services; radiology, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices; home health services and supplies; outpatient prescription drugs¹⁰⁶; and inpatient and outpatient hospital services. A referral for “physician services” (*i.e.*, the professional services of a physician) that are unrelated to a DHS is specifically excluded from the definition of a prohibited referral.

Immediate Family Member: The Stark Law applies if a member of the physician’s “immediate family” has a financial relationship with the entity that provides the DHS. “Immediate family member” is defined to include any of the following, by blood or by marriage: spouse, grandparent, grandchild, parent/stepparent (by birth or adoption); child/stepchild or sibling/step sibling; in-laws. (Hereinafter, the term “physician” will be used to mean both the physician and his/her immediate family members, as applicable).

Financial Relationship: For purposes of the Stark Law, a “financial relationship” with a health care entity includes both an “ownership or investment interest” in the entity and a “compensation

¹⁰⁵ Many States have also enacted physician self-referral prohibitions, with sanctions that are apart from, and in addition to, those found in Federal law. Accordingly, in addition to the Federal Stark law, health centers should familiarize themselves with their respective State’s prohibitions (if any).

¹⁰⁶ The Stark Law defines outpatient prescription drugs as those outpatient prescription drugs covered by Medicare Part B. Because the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 added a new Medicare Part D providing for a Medicare prescription drug benefit, CMS may revise the definition of outpatient drugs to include those prescription drugs covered under Part D. This would broaden the reach of the Stark Law significantly.

arrangement" with the entity. The existence of a financial relationship does not have to be a result of the referral for a DHS – any financial relationship will implicate the Stark law.

- **Ownership/investment interest:** The Stark Law applies to ownership or investment interests that a physician has in a health care entity that provides a DHS. The interest can be through equity, secured debt, or other means. Further, the Stark Law reaches investment interests held indirectly, that is, through one or more layers of holding companies (i.e., an ownership or investment interest in an entity that has an ownership or investment interest in the entity providing the DHS).
- **Compensation arrangement:** A compensation arrangement, for purposes of the Stark Law, is "any arrangement involving any remuneration" between a physician and a health care entity that provides a DHS. It is important to note that the Stark law definition of compensation arrangement includes any remuneration between a physician and a health care entity. Thus, it covers remuneration paid by a health care entity to a physician, such as compensation for services, and remuneration paid by a physician to a health care entity, such as rental payments paid by a physician to an entity from whom he/she rents space.

2. Exceptions to Prohibition On Referrals To Entities With Which Physician Has A Compensation Arrangement

This section includes:

- *Personal Services Arrangements*
- *Rental of Office Space and/or Equipment*
- *Indirect Compensation Arrangement*
- *Fair Market Value Compensation*
- *Non-monetary Compensation Arrangements*
- *Compliance Training*

Because the scope of the prohibition on referrals in the Stark Law is very broad, many common health care practices would be impossible if all referrals between physicians and entities with which they have a financial relationship were prohibited. For example, under a literal reading of the statute, a physician employed by a health center (and, therefore, having a compensation relationship with the center) could not refer a patient to the center's in-house clinical laboratory. In order for physicians and entities to continue to enter into legitimate arrangements that do not promote over-utilization, there are several exceptions to the Stark law.¹⁰⁷ To meet a Stark Law exception, an individual/entity must satisfy all of the requirements of the exception.

The following exceptions are particularly pertinent to health center affiliation arrangements:

Personal Services Arrangements

¹⁰⁷ Although not pertinent to health center affiliation arrangements, health centers should be aware that there is an exception to the Stark law that exempts from prohibited compensation arrangements amounts paid by an entity to a physician who has a bona fide employment relationship with the entity to provide services.

Remuneration provided by a health center to a physician who is not a bona fide employee, but rather, provides services to health center patients under a personal service arrangement is not considered a compensation arrangement subject to the Stark law if:

- The arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement;
- The arrangement covers all of the services to be provided by the physician to the health center;
- The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement;
- The term of the arrangement is for at least one (1) year;
- The compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and except in the case of a physician incentive plan, is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties;

With respect to the “set in advance” requirement, a health center can pay a contracted physician on a time-based, per unit of service or “per click” basis (i.e. each time a machine is used), so long as the parties establish a fixed charge for each encounter or “click” (or unit of time) in the initial agreement. Percentage compensation arrangements also may be considered to be compensation that is “set in advance” if certain requirements are met. Specifically, the formula under which percentage compensation is calculated must be: (i) established in an agreement between the parties before the items or services covered are furnished; (ii) stated in sufficient detail so that it can be objectively verified; and (iii) set so that it may not change over the course of the agreement between the parties based on the volume or value of referrals or other business generated by the referring physician. Note, however, that percentage compensation arrangements are not protected under the Anti-Kickback Statute. (See Section E of this manual.)

- The services to be performed under the arrangement do not involve the counseling or promotion or a business arrangement or other activity that violates any State or Federal law; and
- The arrangement meets such other requirements as DHHS may impose by regulation as needed to protect against program or patient abuse.

Rental of Office Space and/or Equipment

Payments made by a lessee to a lessor for the use of office space and/or equipment are not considered a compensation arrangement subject to the Stark law if:

- The lease is set out in writing, signed by the parties, and specifies the premises/equipment covered by the lease;

- The space/equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee. With respect to a lease for space, the lessee may make payments for the use of space consisting of common areas if such payments do not exceed the lessee's pro rata share of expenses for such space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using such common areas;
- The lease provides for a term of rental or lease for at least one (1) year;
- The rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties;
- The lease would be commercially reasonable even if no referrals were made between the parties; and
- The lease meets such other requirements as DHHS may impose by regulations as needed to protect against program or patient abuse.

Indirect Compensation Arrangement

An “indirect compensation arrangement” is an arrangement under which the health center contracts with an entity to which its physicians are likely to refer patients for the provision of a DHS. Specifically, an “indirect compensation arrangement” is defined as an arrangement with all three of the following characteristics:

- Between the referring physician and the entity furnishing the DHS there exists an unbroken chain of any number of persons or entities (but no fewer than one person or entity) that have financial relationships between them (i.e., each link in the chain has either an ownership or investment interest or a compensation arrangement with the preceding link).

For example, a hospital leases space to a health center, which, in turn, employs a physician who refers patients to the hospital for a DHS.

- The referring physician receives aggregate compensation from the entity in the chain with which he or she has a direct financial relationship that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.

In the example above, the health center physician receives incentive compensation from the health center for referring patients to the hospital for a DHS.

- The entity furnishing DHS has knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician receives aggregate compensation that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.

If the compensation paid to the referring physician does not vary based on the volume or value of business generated by the physician for the DHS provider, the arrangement will not be considered an indirect compensation arrangement.

If, however, an arrangement satisfies the aforementioned requirements (and, therefore, is an indirect compensation arrangement), the arrangement will not be subject to the Stark law if:

- The compensation received by the physician from the health center is fair market value for services and items actually provided, and neither the aggregate amount nor the per unit/per click rate takes into account the volume or value of the referrals or the other business that is generated by the referring physician for the entity furnishing DHS.
- The compensation arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement. If the arrangement is a bona fide employment relationship, the arrangement need not be set out in a written contract, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.
- The compensation arrangement does not violate the anti-kickback statute or any laws or regulations governing billing or claims submission.

Fair Market Value Compensation

Compensation that results from an arrangement between a health center and a physician for the provision of items or services by the physician to the health center is not considered a compensation arrangement subject to the Stark law, if:

- The agreement is in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in the agreement;
- The agreement specifies the timeframe for the arrangement, which can be for any period of time and can contain a termination clause, provided the parties enter into only one (1) arrangement for the same items or services during the course of one (1) year. An arrangement made for less than one (1) year may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change;
- The compensation to be provided under the arrangement is set in advance, is consistent with fair market value, and is not determined in a manner that takes into account the volume or value of any referrals or any other business generated by the referring physician.;

- The arrangement involves a transaction that is commercially reasonable (taking into account the nature and scope of the transaction) and furthers the legitimate business purposes of the parties;
- The arrangement meets a safe harbor under the anti-kickback statute, has been approved by the OIG under a favorable advisory opinion, or does not violate the anti-kickback statute; and
- The services to be performed under the arrangement do not involve counseling or the promotion of a business arrangement or other activity that violates a State or Federal law.

Non-Monetary Compensation Arrangements

Compensation that is paid by a DHS provider to a physician (including a physician-employee of a health center) who refers patients to or generates other business for the DHS provider, in the form of items or services (not including cash or cash equivalents) that does not exceed an aggregate of \$300 per year is not considered compensation subject to the Stark law if:

- The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician;
- The compensation is not solicited by the physician or physician's practice (including employees and staff members); and
- The compensation arrangement does not violate the anti-kickback statute.

Compliance Training

Compliance training provided by a hospital to a physician who practices in the hospital's local community or service area is not considered compensation subject to the Stark Law, provided that the training is held in the local community or service area.

"Compliance training" is defined as training regarding the basic elements of a compliance program (e.g., establishing policies and procedures, training staff, internal monitoring, reporting, etc.) or specific training regarding the requirements of Federal health care programs (e.g., billing, coding, reasonable and necessary services, documentation, unlawful referral arrangements).

Professional Courtesy

Professional courtesy provided by a hospital or other health care provider, defined as "the provision of free or discounted health care items or services to a physician or his or her immediate family members or office staff," does not constitute compensation subject to the Stark Law if certain conditions are met. Specifically:

- The professional courtesy must be offered to all physicians on the entity's medical staff or in the local community without regard to the volume or value of referrals or other business generated between the parties;
- The health care items and services provided are of a type routinely provided by the entity;
- The professional courtesy policy is set out in writing and approved in advance by the governing body of the health care provider;
- The professional courtesy is not offered to any physician (or immediate family member) who is a Federal health care program beneficiary unless there is a good faith showing of financial need;
- If the professional courtesy involves the whole or partial waiver of any coinsurance obligation, the insurer is informed in writing of the reduction; and
- The provision of a professional courtesy cannot violate the Anti-Kickback Statute or any billing or claims submission laws or regulations.

G. FEDERAL FALSE CLAIMS LAWS

In section G:

1. *Civil False Claims*
2. *Criminal False Claims*

In general, a false claim is any request or demand for payment for services or supplies that were not provided as presented or for which a health care provider is not entitled to payment. While there are several Federal laws addressing the submission of false claims or the making of false statements, this section will focus on the Federal Civil False Claims Act (FCA), which is codified at 31 USC §3729-3733.¹⁰⁸

Liability for the actions of agents – Under limited circumstances, the FCA may impact affiliation arrangements between health centers and their affiliation partner(s). In general, health centers are legally liable for the actions of their agents, such as outside groups who perform billing services for the health center, and other third parties with whom a health center contracts to perform services on its behalf. As such, in addition to ensuring its own compliance with the FCA, the health center should ensure that its vendors, other contractors, and consultants who perform FCA-related services on behalf of the center comply with applicable FCA requirements. Taking into consideration the substantial penalties that may be imposed for a violation of the FCA, health centers that enter into affiliation arrangements under which another entity (or individual) performs billing services, prepares cost reports, etc. on behalf of the center should:

- Verify that the contractor is qualified to provide the contracted services (i.e., has current knowledge of applicable billing and cost reporting rules, including those specific to health centers).
- Provide appropriate oversight and monitoring of the contracted or outsourced services (i.e., by conducting random spot checks of the billing system/cost reports or requesting summary reports).

Liability for the billing of services performed jointly with affiliation partners – Further, health centers should ensure the correct and proper billing for services provided under an affiliation arrangement where the health center may not exercise full control on a daily basis. For example, many health centers enter into affiliation agreements with the local teaching hospital under which the hospital rotates residents through the health center and the parties share the responsibilities regarding the residency program. Under the typical residency training agreements, the health center bills only for the patient care services provided, while the hospital bills for the costs related to

¹⁰⁸ The focus of the FCA is broader than just Federal health care programs; however, it includes fraudulent claims for the provision of health care services. In addition to the FCA, criminal false claims and criminal false statements are addressed at 18 USC §287 and 18 USC §1001, respectively. False claims provisions under the Social Security Act, which apply solely to health care programs, are codified at 42 USC §§1320a-7, 1320a-7a, 1320a-7b, and 1395nn(g).

training (see Chapter Two of this manual for a more detailed discussion regarding joint residency training agreements). Because such “split” billing arrangements are not fully in the health center’s control, it is prudent for the health center to request assurances that the hospital is billing solely for those costs attributable to the teaching program to ensure that the parties are not double billing the Federal government for patient care services. Further, the health center should ensure that its own billers (whether internal or contracted) are aware of billing rules pertaining to services provided by residents. Listed below are two actual examples of FCA issues that can arise through residency training programs.

- A medical group and physician who ran gynecology residency program at a hospital agreed to pay \$250,000 to resolve a lawsuit alleging that they billed Medi-Cal for services as if they had been provided by attending physicians when they were performed by residents.¹⁰⁹
- The University of California’s five medical schools returned \$22.5 million in an action claiming that the medical centers billed Medicare and Medicaid for services purportedly performed by faculty when services were, in fact, performed by residents alone with little supervision.¹¹⁰

1. Civil False Claims

In this section:

- *The False Claims Act (FCA)*
- *Whistleblower (Qui Tam) Provisions*
- *Civil False Claims under the Social Security Act*

The False Claims Act (FCA)

The FCA prohibits any individual/entity from submitting, or causing the submission of, a false or fraudulent claim for payment to the US government. It also prohibits any individual/entity from making or using (or causing someone to make or use) a false record or statement in order to get a claim approved. The scope of the FCA extends to any request or demand for money or property that the Federal government provides, in whole or in part.

Individual acted “knowingly” – To be convicted under the FCA, the government must prove that the individual/entity acted “knowingly,” meaning they:

- Had actual knowledge of true information and

¹⁰⁹ U.S. and State of Calif. ex rel. Pieszek v. Glendale Medical Center, C.D. Cal. CV98-6501-ABC, 2/8/01. BNA-HLR, Vol. 10, No. 8 (2/22/01), p. 300.

¹¹⁰ U.S. ex rel. Krahel v. Regents of the Univ. of Calif., N.D. Calif., No. C96-1703-WHO, settled 2/2/01; U.S. ex rel. Donald v. Regents of the Univ. of Calif., E.D. Calif. No. 5-99-2406-DFL, settled 2/2/01 BNA-HLR, Vol. 10, No. 6 (2/8/01), p. 221.

- Acted with “deliberate ignorance” (i.e., purposefully or willfully disregarding information that would demonstrate the falsity of the claim) or
- In “reckless disregard” (i.e., failing to supervise billing staff or to ensure that they have requisite knowledge to submit claims)
- Of the truth when submitting the claim.

Common billing problems – The government does not have to prove that the individual/entity intended to defraud the government. However, billing errors, honest mistakes and negligence or mistake do not constitute violation of the FCA. The following list includes common billing problems that may expose health centers to liability under the FCA¹¹¹:

- Billing for services that were not rendered or provided.
- Billing for services that were not “medically necessary” or not defined by the appropriate standards.
- Misrepresenting the service rendered or the product provided by upcoding (billing for a more expensive service than the one that was furnished downcoding) or by billing a non-covered service as a covered service.
- Duplicate billing for the same service, either by the same provider or by separate providers (which results in duplicate payments by the government).
- Unbundling services or products that are required to be billed together at a single (typically reduced) fee.
- Filing false cost reports.
- Knowingly misusing of a provider identification number (submitting a claim showing that services were furnished by one provider when they were actually furnished by another provider).
- Clustering (charging one or two middle levels of service codes exclusively).

Substantial penalties can be imposed upon an individual/entity that violates the FCA, including treble damages (three times the difference between what was paid and what should have been paid), plus an additional penalty between \$5,500 and \$11,000 for each false claim filed after September 29, 1999 (or between \$5,000 and \$10,000 for each claim filed prior to that date). Also, an individual/entity may be liable for the cost the government incurs in bringing a civil action to recoup the false claims.

¹¹¹ Potential false claims may also include claims submitted as a result of the provision of substandard care or claims, which result from activities, which may violate the Federal anti-kickback statute or the Stark law. While the FCA has not explicitly been extended to these potential activities, it can be argued that such activities fall within the theoretical scope of the FCA.

Whistleblower (Qui Tam) Provisions

The FCA also provides an incentive for private citizens to sue violators on behalf of the Federal government. Any individual, known as a “relator,” can bring a legal action, known as a “qui tam” or “whistleblower” action, against a potential violator. Once the suit is filed, the government has the option to proceed with the prosecution itself or to let the relator handle the case. If the government takes over the case and wins, the relator is eligible to receive a 15-25% share of any recovery. If the government lets the relator handle the case, and the relator wins, the relator can claim a 25-35% share of the recovery. Accordingly, it is prudent for a health center to monitor its compliance with the FCA, so as not to become the subject of a whistleblower suit.

Civil False Claims under the Social Security Act

In addition to the FCA, the Social Security Act contains both civil and criminal false claims provisions. Under the Social Security Act, civil penalties may apply if:

- An individual/entity knowingly presents a false or fraudulent claim (or causes someone else to present a false or fraudulent claim) for payment under a Federal health care program and
- DHHS determines that the individual/entity knows or should have known the claim was false or fraudulent.

The standard to prove a violation (i.e., knows or should have known), as well as the areas of concern, are similar to the FCA.¹¹² Sanctions for false claims under the Social Security Act include treble damages, civil monetary penalties of not more than \$10,000 for each item or service falsely claimed, and exclusion from participation in Federal (and potentially State) health care programs.

2. Criminal False Claims

In this section:

- *Criminal False Claims or Statements under the U.S. Criminal Code*
- *Criminal False Claims under the Social Security Act*

Federal criminal false claims provisions exist under both the U.S. criminal code and the Social Security Act. Unlike the civil false claims laws that can subject the health center entity to substantial sanctions, criminal sanctions (including imprisonment and/or fines) can be imposed only on the person who made the false claim or statement.

¹¹² In addition to the areas of concern listed for the FCA, an individual/entity may violate the civil false claims provisions of the Social Security Act if a claim is submitted for items or services furnished during a period of time when the provider furnishing such items or services was excluded from participation in the Federal health care program to which the claim was made.

Criminal False Claims or Statements under the U.S. Criminal Code

Under the U.S. Criminal Code, criminal penalties may be imposed if an individual:

- “Knowingly” makes or presents to the Federal government false, fictitious or fraudulent claims.
- “Knowingly and willfully” makes or presents to the Federal government false, fictitious or fraudulent facts, statements, representations, writing or other documents.
- Enters into any agreement, combination or conspiracy to defraud the Federal government by filing false, fictitious or fraudulent claims with the government.

To obtain a criminal conviction, the government must show, beyond a reasonable doubt, that an individual knew he or she submitted a false claim, statement, representation, etc. With respect to false statements, representations, etc., the government must also prove, beyond a reasonable doubt, that the individual willfully made such statements and representations, meaning that he or she voluntarily and intentionally disregarded a known legal duty.

Criminal False Claims under the Social Security Act

Under the Social Security Act, criminal penalties may be imposed if an individual:

- Knowingly or willfully makes a false statement of material fact in any application for benefits or payments paid for by Federal health care programs.
- Knowingly or willfully submits a claim to the Federal government for payment of physician services knowing that the person who provided the services was not licensed as a physician.
- Knowingly or willfully conceals or fails to disclose an event impacting whether the organization should receive payments, so as to fraudulently secure payments.
- Knowingly and willfully overcharges for a service provided to a Medicaid patient.
- Fails to report any sums received to which he or she is not entitled, with the intent of fraudulently keeping those sums.

Similar to the criminal provisions under the U.S. Criminal Code, to obtain a criminal conviction, the government must show, beyond a reasonable doubt, that an individual knew he or she submitted a false claim or statement, representation, and/or that the individual willfully made such submissions or statements, meaning that he or she voluntarily and intentionally disregarded a known legal duty.

H. STATE LAWS AND REGULATIONS

Health centers should be aware of State law requirements that could affect a potential affiliation. These laws may include:

- Clinic licensure and Certificate of Need (CON) laws.
- Professional licensure, certification and/or other authorization to render services.
- Zoning laws.
- Environmental laws.
- Life and safety codes.
- Corporation/LLC statutes.
- Charitable immunity statutes.
- Charitable solicitation laws.

Health centers seeking to create a managed care organization will need to consider State insurance requirements, including net worth requirements, and/or may require Medicaid agency approvals if an existing managed care organization's structure is altered.

In addition, many States have counterparts to the Federal laws discussed within this manual. Accordingly, health centers should be aware of any State laws pertaining to tax, antitrust, and/or fraud and abuse concerns. Qualified counsel should be consulted to advise regarding which State laws pertain to a particular arrangement, and the means by which to structure the affiliation so as to comply fully with such laws.

CHAPTER 5:

Conclusion

While forming an affiliation can involve complex legal and policy-related issues and limitations and may require extensive negotiation, experience has demonstrated that the benefits of affiliating may be well worth the effort. In particular, health centers should approach an affiliation with the recognition that a successful affiliation is beneficial to all of the participating parties.

As a first step, the health center should (i) clearly define its goals and objectives for entering into a collaboration, (ii) carefully consider and determine the appropriate affiliation vehicle by which to achieve these goals and objectives, and (iii) objectively evaluate its potential affiliation partner(s) to determine whether there is an appropriate “fit.” To achieve the goals and objectives in an efficient and effective manner, health centers and their affiliation partner(s) also should have a clear understanding of the resources that each party can contribute to, and the benefits that they can expect to derive from, the affiliation. Further, to ensure that all issues and considerations are well thought-out and measured, the party’s should engage in a deliberate, step-by-step approach to planning, negotiating and establishing the chosen affiliation approach. Finally, the health center and its partner(s) must consider all legal and policy requirements and ramifications related to establishing the affiliation, to ensure not only smooth implementation, but also a successful future.

APPENDIX 1

BPHC PIN # 97-27

Go to www.bphc.hrsa.gov/pinspals

APPENDIX 2

BPHC PIN # 98-24

Go to www.bphc.hrsa.gov/pinspals

APPENDIX 3

BPHC PIN # 2002-07

Go to www.bphc.hrsa.gov/pinspals

APPENDIX 4

Affiliation Check List

(Attached to end of BPHC PIN 98-24, www.bphc.hrsa.gov/pinspals)

APPENDIX 5

Value Assessment in Preparation for Negotiation with Potential Partners

- The health center serves _____ covered lives.

NOTE: if individuals and families who are currently uninsured were to become insured through Medicaid and/or S-CHIP expansions, as has occurred in other States, the health center might serve _____ additional covered lives.

- The health center collectively employs or contracts with:

_____	primary care physicians
_____	nurse practitioners
_____	nurse midwives
_____	physician assistants
_____	other

- The health center offers "one-stop shopping" for comprehensive, case-managed primary health care and related services, including:

[list services]

- The health center offers coverage of the following geographic area(s):

[describe service areas and attach a map]

- The health center has a strong reputation for high quality and consumer-focused care, including accountability to the consumer through consumer-majority governance.

[describe patient satisfaction surveys, accreditation]

- The health center has demonstrated its commitment to public health, health education, and disease prevention.

[list programs, outreach, etc.]

- The health center provides care in a cost-effective manner.

[describe primary care case management expertise; document cost savings on reduced hospital days and non-urgent emergency room visits]

- The health center has significant infrastructure including:

[describe facilities, claims management, billing systems, MIS, equipment]

[quantify opportunities to co-locate specialists, offer joint residency programs]

[compare the cost of building/expanding on health center's current service capacity versus the cost of buying freestanding practices to provide a comparable scope of services]

- The health center has experience with managed care.

[detail experience, including case management]

- The health center is a "community benefit" partner with successful track record in using Federal/State investments to enhance access for medically underserved populations

- The health center has established relationships with other health care providers in the community, including:

[detail the health center's formal and informal relationships with hospitals, specialists, and other primary care providers and the strength of those relationships]

- The health center is affiliated with or has close relationships with social service providers, including:

[detail the health center's formal and informal relationships with social service providers and the strength of those relationships]

- The health center offers a low-risk partnership opportunity because of its unique entitlement as a "Federally Qualified Health Center" to enhanced reimbursement under the Medicaid and Medicare programs, as well as additional benefits available to the health center as an FQHC (or, in some cases, an FQHC look-alike entity), including, but not limited to, FTCA coverage, drug pricing discounts, and access to federal loan guarantees for the development, operation, and ownership of managed care networks or plans and practice management networks.

Annual Financial Benefits

- ❖ Section 330 Grant \$ _____
- ❖ Enhanced Medicaid rates \$ _____
(i.e. \$ _____ more than average primary care visit to private clinician)
- ❖ Medicaid managed care “wrap-around” payments..... \$ _____
- ❖ Enhanced Medicare FFS rates..... \$ _____
(i.e. \$ _____ more than average primary care visit to private clinician)
- ❖ FTCA malpractice coverage..... \$ _____ savings
- ❖ PHS drug discount program..... \$ _____ savings
- ❖ Vaccine for Children and Pfizer Share the Care programs \$ _____ savings

Additional Benefits

- ❖ Access to Federal capital grants..... \$ _____
- ❖ Access to grants for the planning, development and operation of managed care networks or plans and practice management networks. \$ _____
- ❖ Payment for outstationed Medicaid eligibility activities. \$ _____
- ❖ Access to Federal loan guarantees for capital projects.
- ❖ Access to Federal loan guarantees for loans to develop and operate managed care networks or plans and practice management networks.
- ❖ Medicare deductible waived.
- ❖ Can waive, in whole or in part, Medicaid/Medicare copayments for patients with

income at or below 200% of poverty.

- ❖ Savings from low or no cost transactions, pursuant to the Federal anti-kickback safe harbor for health center grantees.
- ❖ Access to NHSC Providers if the service area is designated as a Health Professional Shortage Area (“HPSA”).¹¹³

This Value Assessment tool was prepared for the National Association of Community Health Centers, Inc. (“NACHC”) by attorneys with the law firm of Feldesman Tucker Leifer Fidell LLP.

¹¹³ Section 332 of the Public Health Service Act (42 USC 254e), as amended by P.L. 107-251, grants automatic HPSA status to health centers, effective upon the date an entity is designated as a health center for a period of not less than six (6) years. Thereafter, each health center will be required to demonstrate that it meets the regulatory definition of a HPSA to maintain such designation.

APPENDIX 6

Benefits for which Health Centers are Eligible

The following list summarizes various benefits available to health centers that receive grants under Section 330 of the Public Health Service ("PHS") Act (42 U.S.C. 254b). Benefits designated by an asterisk are available to Federally Qualified Health Center ("FQHC") "look-alike" entities (*i.e.*, health centers that DHHS designates as FQHCs based on a determination that they meet all Section 330 requirements, but that do not receive Section 330 grants), as well as to Section 330 grant recipients.

1. Access to Federal grants (*i.e.*, Section 330 operating grant, expansion grants) to support the costs of otherwise uncompensated comprehensive primary and preventive health care and "enabling services" delivered to uninsured and underinsured populations at sites within the Section 330 approved scope of project.
 - FQHC "look-alikes" are eligible to apply for "new start" Section 330 grants when funding is available for such purposes.
2. Access to Federal grants to support the costs of planning, developing, and/or operating a:
 - Managed care network or plan.
 - Practice management network.
3. Access to Federal loan guarantees of the principal and interest on loans made by non-Federal lenders for the costs of developing and operating managed care networks or plans and practice management networks, which are majority owned and/or controlled by Section 330-supported health centers.
4. Access to grant support and loan guarantees for capital improvements.
5. Access to Federal Tort Claims Act ("FTCA") coverage (in lieu of purchasing malpractice insurance) for the Section 330-supported health center and its health care professionals (including certain contracted professionals) who provide services to health center patients within the health center's approved scope of project and the health care professionals' employment/contractor agreements.
6. Safe harbor under the Federal anti-kickback statute for low or no cost transactions between health center grantees and any entity/individual providing goods, services, donations, loans, *etc.* to the health center pursuant to a written agreement so long as the agreement helps to maintain or increase care provided to the underserved population(s) served by the health center.

- *7. Access to favorable drug pricing under Section 340B of the PHS Act, which allows FQHCs to purchase covered outpatient prescription pharmaceuticals for health center patients at substantially discounted prices for distribution either directly by a health center pharmacy or through contract with a licensed retail pharmacy.
- *8. Access to reimbursement under the Prospective Payment System (“PPS”) or other state-approved alternative payment methodology (which is predicated on a cost-based reimbursement methodology) for Medicaid-eligible services, and to cost-based reimbursement for services provided under Medicare. “Enhanced” Medicaid reimbursement is available even if the FQHC is a subcontractor to a managed care plan (*i.e.*, by receiving supplemental “wrap-around” payments from the State).
- *9. Absent an alternative approved by the Centers for Medicare and Medicaid Services (“CMS”), the right to have State Medicaid agencies outstation Medicaid eligibility workers on FQHC site. FQHCs can also contract with State Medicaid agencies for FQHC staff to carry out outstationing activities at FQHC sites (and for the health center to be reimbursed for such activities).
- *10. Reimbursement by Medicare for the "first dollar" of services rendered to Medicare beneficiaries, *i.e.*, waiver of the Medicare deductible.
- *11. Safe harbor under the Federal anti-kickback statute for the waiver of co-payments to the extent a patient is at or below 200% of Federal income poverty guidelines and therefore entitled to a discount based on the health center's application of its schedule of discounts.
- *12. Access to providers through the National Health Service Corps, so long as if the health center's service area is designated a Health Professional Shortage Area (“HPSA”).¹¹⁴
- *13. Access to the Federal Vaccine For Children program, which distributes vaccinations to FQHCs (and other eligible providers) at no charge for either the vaccine or its delivery for the provision of vaccines to uninsured children. FQHCs are also eligible to participate in the Pfizer Sharing the Care Program.

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¹¹⁴ Section 332 of the Public Health Service Act (42 USC 254e), as amended by P.L. 107-251, grants automatic HPSA status to health centers, effective upon the date an entity is designated as a health center for a period of not less than six (6) years. Thereafter, each health center will be required to demonstrate that it meets the regulatory definition of a HPSA to maintain such designation.

APPENDIX 7

Sample Due Diligence Checklist

While negotiating an affiliation, and prior to finalizing the arrangement, the health center should request from its affiliation partners some or all of the following information (as applicable to the particular arrangement and the affiliation partners):

A. Corporate Organization and Governance

1. Articles of Incorporation and amendments thereto (and proposed amendments, if any).
2. Bylaws and amendments thereto (and proposed amendments, if any).
3. Names and affiliations of the members of the Board of Directors and its officers, and minutes from the Board of Directors meetings for the past year (including minutes of the Executive Committee and the Finance Committee).
4. If the affiliation partner is a for-profit corporation, the shareholders agreement, a list of substantial shareholders (*i.e.*, shareholders with 5% or more of the shares in the affiliation partner), and minutes from the shareholder meetings for the past year; if the affiliation partner is an LLC or LLP, the Operating Agreement, list of owners and minutes of owners' meetings for the past year.
5. Any agreements relating to transactions with "insiders" (*i.e.*, directors, officers, key employees), including loans, leases, and purchases or sales of property.
6. Any agreements or documents that limit the affiliation partner's business activities or ability to compete in any market.
7. All documents relating to any major acquisition, disposition, reorganizations or other extraordinary corporate event of material significance.
8. Certificates of Good Standing from State corporate agency (necessary at time of closing).
9. List of current affiliates (*i.e.*, parent, subsidiaries, contractual) and copies of significant contractual affiliations with third parties, as well as disclosure of third parties with whom affiliation discussions are actively underway. Note: the potential affiliation partner may not be able to disclose such other discussions if it is prohibited by a confidentiality agreement.
10. If the affiliation partner is another health center, the most recent Notice of Grant Award.

B. Regulatory Filings and Matters

1. Lists and copies of all material Federal, State and local operating permits, licenses, authorizations, certificates of need, consents and approvals (including, but not limited to, health-care related licenses and accreditations).

2. All tax-exempt determination letters issued by the Internal Revenue Service (IRS), and all inquiries from (and correspondence from or to) the IRS over the last three (3) years that relates to the affiliation partner's tax-exempt status.
3. Form 990 for the last three (3) most recently completed fiscal years.
4. Most recent application for accreditation, and copies of the accrediting body's report even if accreditation was not earned.
5. All inquiries, reports, notices and correspondence received from, or issued by, any Federal, State or local governmental regulatory agency (including, but not limited to, the Office of Inspector General, the State Medicaid Fraud Unit, the Office of Civil Rights, the Equal Employment Opportunity Commission), any entity acting on behalf of such governmental agency, or any professional licensing, certification or accreditation agencies regarding (i) compliance with any and all rules, regulations, guidelines or other requirements (including zoning or building codes, environmental laws or regulations, or occupational safety laws or regulations), and (ii) deficiency reports, responses thereto and plans of correction, during the last three (3) most recently completed fiscal years as well as the current fiscal year.

C. Financial Information

1. Audited financial statements for the last three (3) most recently completed fiscal years, and unaudited year-to-date financial statements for the current fiscal year.
2. Management letters provided to the affiliation partner by its external auditors for the last three (3) most recently completed fiscal years.
 3. Detailed operating results (income statements and balance sheets) and cash flows for the current fiscal year and for the past three (3) years.
 4. Operating and/or capital budgets and plans for the current fiscal year.
5. Financial forecasts, including but not limited to, cash flow statements.
6. Current aging of, and general ledger for, accounts payable and accounts receivable.
 7. List of unrecorded liabilities and/or contingencies which could affect financial statements.
 8. Copies of all notes, loan agreements, guarantees, mortgages, security agreements, capitalized lease agreements and other documents with respect to all outstanding indebtedness of, or indebtedness guaranteed by, the affiliation partner (including but not limited to agreements establishing lines of credit).
9. Contact name for outside accounting/auditing firm.
10. Descriptions of any public or private grant funding awarded to the affiliation partner to support its operation.
11. Analysis of patient and payor mix for the current fiscal year and for the past three (3) years.
12. If the affiliation partner is another health center, the most recent cost report and notice of prospective payment rate.

D. Real Property and Equipment

1. Documents of title for the affiliation partner's real property and equipment (material assets) relevant to this transaction.
2. Summary description of all real estate and/or facilities owned or leased by the affiliation partner or any subsidiary relevant to this transaction, including location and primary use of such property, and an inventory of all equipment owned or leased by the affiliation partner.
3. Any appraisals of relevant real property obtained within the past three (3) years.
4. Liens, encumbrances or third party interests related to all real estate/equipment owned by the affiliation partner, which is relevant to this transaction.
5. All UCC financing statements filed with respect to the affiliation partner's assets, which is relevant to this transaction.

E. Insurance Matters

1. Copies of insurance policies or self-insurance program for general liability coverage and required professional liability and/or errors and omissions coverage for the affiliation partner and its employees (including, as applicable, deeming letters for FTCA coverage).
2. Copies of insurance policies or self-insurance program for directors and officers liability coverage.
3. Copies of insurance policies or self-insurance program for employment-related claims.
4. Description of all claims filed and/or settled during the last three (3) completed fiscal years and the current fiscal year under the insurance policies or self-insurance programs provided pursuant to E(1) or E(2), above.
5. Identification of any policy or self-insurance program pertaining to the coverages provided pursuant to E(1) or E(2), above, that have been cancelled, suspended and/or limited during the past five (5) calendar years.

F. Personnel and Employment-Related Information

1. Copies of all personnel manuals, policies and guidelines, employee job descriptions, and an organizational chart that shows all staff (levels and number of personnel).
2. Names of the key management staff and consultants, and all health care professionals, and copies of their employment/consultant agreements, licenses and DEA numbers, and resumes.

NOTE: If the affiliation involves the merger or acquisition of the affiliation partner, or the transfer of employees to the health center, the affiliation partner's employment contracts may contain provisions that expose the health center to potential financial

liabilities (e.g., non-compete clauses that prohibit the employee from soliciting past clients; language that voids the contract upon a merger or acquisition).

NOTE: If the affiliation involves a lease of services from personnel employed by, or under contract to, the affiliation partner, it is critical to confirm that the employment agreements and/or contracts are not at variance with the terms of the proposed lease of services.

3. Names of contractors for health care services and copies of their contracts.
4. Summary of all disciplinary proceedings, investigations or actions regarding the licensure of any employees, consultants, or contractors.
5. Copies of all severance plans, agreements or documents describing binding obligations of the affiliation partner in the event of a change in control of the partner's organization.
6. Copies of all salary charts and employee benefit plans, including summary plan descriptions and descriptions of all stock options, profit sharing and incentive compensation arrangements, and retirement/pension plans.
7. Description of all current and past employment-related claims brought against the affiliation partner or one of its employees by a former or current employee during the past three (3) years, including disputes involving employee benefits, termination actions and other labor disputes, EEOC charges, material grievances and legal/regulatory claims.
8. Copies of all Form 5500 filed for the three (3) most recently completed fiscal years.

NOTE: If the affiliation involves the shutdown of a single site (or one or more facilities or operating units within a single site) of an affiliation partner with 100 or more full-time employees (or 100 or more full and part-time employees who work, in the aggregate, at least 4000 hours per week, exclusive of overtime hours), which results in a loss during any 30 day period of 50 or more full-time employees, the affiliation partner (and potentially the health center) must comply with the requirements of the Worker Adjustment and Retraining Act (WARN).

G. Operational Information

1. Operating hours for clinics and administrative offices.
2. Copies of all major operating policies and procedures of the affiliation partner.
3. Copies of contracts with entities performing delegated administrative activities (e.g., billing entities, MSOs) and all policies and procedures of such entities with respect to the delegated activity.
4. Copies of contracts for equipment, leases and other agreements which (a) have a term of more than one (1) year; (b) have an annual expense greater than \$2500; (c) are short-term contracts with unusual or significant restrictions (such as "output" or "requirements" purchase order/contracts); (d) are shared service agreements; or, (e) are asset disposition agreements.
5. Copies of contracts with third party payors, including Medicare and Medicaid provider agreements and contracts with managed care organizations, and any

- correspondence from payors alleging the affiliation partner's failure to comply with terms and conditions.
6. Written strategic or long term business plans or reports commissioned from consultants regarding future business operations.
 7. Descriptions of billing systems, as well as information systems capabilities with respect to: (a) day-to-day management and long term planning; (b) data collection and reporting vis-à-vis contractually required reports, HEDIS and/or other clinical, financial and administrative reporting requirements; (c) internal quality assurance programs; and (d) electronic medical records capabilities.
 8. Description of all marketing and advertising campaigns currently being planned, implemented, or completed during the current fiscal year.
 9. Description of statutory and contractual insolvency plan(s).

H. Clinical Information

1. Copies of all clinical policies and procedures, medical staff bylaws, utilization management and quality assurance procedures and policies, claims management procedures, patient grievance policies, peer review activities and credentialing of the affiliation partner.
2. Descriptions of all health care services, health education programs, case management services, linkages with other providers, call coverage and rounding arrangements, and other clinical initiatives.
3. Results of any patient satisfaction surveys conducted within the last two (2) years.
4. Copies of prototype service provider/clinical services contracts for primary care services, specialist services, hospital services, and ancillary services including descriptions of all types of reimbursement mechanisms and rates.

I. Material Claims, Litigation and Settlement

1. Summary of all pending or threatened litigation including, but not limited to, malpractice, employee, environmental and administrative claims, involving the affiliation partner as a defendant or plaintiff, including information as to insurance reserves with respect to each claim as well as the name and telephone number of both the claimant and counsel, if any, asserting the claim
2. Copies of all attorney opinion letters furnished to auditors in connection with the three (3) most recent annual audits.
3. Summary of all pending or threatened arbitration proceedings including the name and telephone number of the opposing party and counsel, if any.
4. Summary of all pending or threatened administrative proceedings and investigations by any Federal, State or local government agency (including, but not limited to, the Office of Inspector General, the State Medicaid Fraud Unit, the Office of Civil Rights, the Equal Employment Opportunity Commission), and a detailed description of the matters involved.
5. Summary of all adverse orders, judgments, consent or other decrees and/or settlements or releases entered into during the three (3) most recently completed fiscal year and the current fiscal year.