GOV

National Association of
Community Health Centers, Inc.®

GOVERNANCE SERIES

The Board's Role in Evaluating Affiliation Opportunities

"A friendship founded on business is better than a business founded on friendship."

- John D. Rockefeller (1874-1960)

Health center Boards of Directors play a unique role in evaluating whether and how the health center should affiliate with another organization (or multiple organizations). As used by the Health Resources Services Administration (HRSA) in the context of health center activities, the term "affiliation" means an "agreement that establishes a relationship between a [health center] and one or more entities."[1] While forming an affiliation can involve complex legal and policy-related issues and may require extensive negotiation, experience has demonstrated that the benefits of affiliating may be well worth the effort. As the "eyes," "ears," and "voice" of the community, it is important for health center Board members to review a proposed affiliation from the perspective of whether it is consistent with the health center's mission and strategic goals, and most importantly, whether it will benefit the community and/or the special population(s) served by the health center.

1. Board members should verify that the health center's management team and the affiliation partner(s) have clear understandings of the resources that each party can contribute to, and the benefits that they can expect to derive from, the affiliation.

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1 See HRSA Policy Information Notice (PIN) # 97-27: *Affiliation Agreements of Community and Migrant Health Centers* (July 22, 1997). *See also* PIN # 98-24: *Amendment to PIN 97-27 Regarding Affiliation Agreements of Community and Migrant Health Centers* (August 17, 1998). Both are available at: http://www.bphc.hrsa.gov/pinspals/pins.htm.

2. Once a health center Board approves a proposal to assess the feasibility of a particular affiliation arrangement, the Board should expect to be updated regularly throughout the planning process and consulted specifically with respect to key terms of the anticipated arrangement(s).

3. Finally, the Board must verify that the health center management team has taken appropriate steps to ensure that any affiliation agreement(s) complies with all applicable Section 330 statutory and regulatory requirements, policies and expectations.

This Information Bulletin examines each of the actions described above. In particular, this Information Bulletin:

- Provides a brief overview of the reasons health centers affiliate with other providers, as well as common affiliation goals and potential types of affiliations;

- Examines the Board's role in evaluating affiliations by:
  - Assuring that the health center maintains its mission,
  - Assuring that the Board fulfills its fiduciary duties,
  - Assessing the feasibility of proposed affiliation opportunities;

- Reviews the Board's responsibility to approve affiliations.

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THE "WHY'S" AND "WHEREFORES" OF AFFILIATIONS

Why Health Centers Affiliate with Other Providers

There is a vast array of opportunities for collaborative agreements between health centers and other providers. The reasons health centers form affiliations vary based on the particular circumstances, needs and expectations of the individual health center.

- Some health centers affiliate out of necessity, simply 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 their patients' access to, and the availability and efficient coordination of, cost-effective, high quality health care.

- The health center implementing regulations require health centers to "the extent possible, coordinate and integrate project activities with the activities of other federally-funded, as well as state and local, health services delivery projects and programs serving the same population,"[2] and "[u]tilize, to the maximum

2 42 C.F.R. §51c.303(n).

extent feasible, other Federal, state, and local, and private resources available for support of the project, prior to use of project funds under this part."[3]

- HRSA policy consistently encourages coordination, collaboration and integration with other providers in a health center's service area, including:
  - Federal, state and local health and social services delivery projects and programs;
  - Other Federally Qualified Health Centers (FQHCs);
  - Providers of ancillary, secondary and tertiary care.

However, in an effort to assure that health centers maintain governance integrity and autonomy as well as staff accountability, in 1997 and 1998, HRSA issued two Policy Information Notices (PINs) setting forth its expectations regarding health center affiliations and detailing the "do's" and "don'ts" in structuring these arrangements: PIN # 97-27: *Affiliation Agreements of Community and Migrant Health Centers* (July 22, 1997) and PIN # 98-24: *Amendment to PIN 97-27 Regarding Affiliation Agreements of Community and Migrant Health Centers* (August 17, 1998).[4] Affiliation certifications and checklists based on these policies are part of the application for Section 330 funds,[5] and health centers are required to demonstrate through these submissions that collaborations potentially impacting the governance, operation and/or management of a health center comply with Section 330, the implementing rules and HRSA affiliation policies.

Common Affiliation Goals

The goals of affiliations can be as broad as the mission and creativity of the health center and its partner(s) permit. Typical examples of such goals and objectives include:

- Expanding the amount and type of services available (*e.g.,* specialty services and programs), as well enhancing as the continuum of care, and reducing service gaps;
- Expanding access locations by co-locating services and staff with other providers at existing sites or at new sites;
- Maintaining and improving the ability to deliver the appropriate level of care in appropriate settings and at appropriate times;
- 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, thereby 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 managed care organizations, and/or developing other approaches to managed care participation;
- Increasing sources of, and access to, capital and financial support and other resources.

3 **2 C.F.R. §51c.303(r).**

4 **The specific requirements of these policies are discussed in the section of this Information Bulletin entitled "Maintaining compliance with applicable laws, regulations and policies."**

5 ***See* Affiliation Certification (Form 8-A) and Affiliation Checklist (Form 8-B).**

Potential Types of Affiliations

The subject and nature of health center affiliation agreements are as varied as the mission and scope of each organization. They can include:

- Agreements to purchase/lease clinical staff capacity;
- Agreements to purchase/lease management support staff and/or administrative support services;
- Agreements to jointly develop and/or operate sites;
- Joint residency training agreements;
- Contracts for the provision of specific health care services;
- Leases of space, equipment, non-clinical personnel;
- Contracts to co-locate services (*e.g.,* provision of primary care on a hospital site as an alternative to inappropriate non-emergent Emergency Room [ER] utilization; provision of specialty/ancillary services on the health center site);
- Contracts to purchase/lease administrative and/or financial services, other than key staff (*e.g.,* contracts with vendors to provide of some (or all) of the health center's operational infrastructure, such as Management Information Systems [MIS] and billing and claims management);
- Joint purchasing arrangements;
- Establishing a network to perform support services, *e.g.,* practice management, managed care contract negotiations, etc;
- Establishing a prepaid health plan or health maintenance organization.

THE BOARD'S ROLE IN EVALUATING AFFILIATIONS

Assuring that the Health Center Maintains Its Mission

Affiliation proposals, whether first generated by health center leaders, by another provider or by other stakeholders in the community (*e.g.,* employers, community coalitions, elected officials) present important considerations for the Board. First and foremost, consistent with each Board member's "duty of obedience," the Board must determine how any proposed affiliation will further the health center's mission.

1. Will the arrangement preserve (or enhance) patient access, service continuity, and/or freedom of choice?
2. Is the arrangement culturally and linguistically appropriate for patients or must the health center seek additional arrangements to ensure cultural/linguistic competence?
3. Are the affiliating providers willing to take all health center patients upon referral from the health center, regardless of ability to pay or insurance status?
4. Is payment (to or by the health center) "fair"?
5. Will the collaboration contribute to the health center's survival and growth?

The importance of being able to answer "yes" to some versus all of these questions will vary based on the nature and "reach" of the agreement(s). A purchase of laboratory services, for example, would not have a major impact on health center governance and operations, and questions of cultural competence and/or freedom of choice may be irrelevant. In contrast, a collaboration with a major academic medical facility, under which a health center becomes a licensed operator of a hospital outpatient clinic that involves residency rotations, or an agreement pursuant to which an independent behavioral health care practice integrates services with health center primary care operations, could have profound consequences, with the potential to significantly affect clinical capacity and quality, and, as such, all of the questions above should be given serious thought.

Examples of specific issues to consider, depending on the nature of the affiliation, include:

- The scope and schedule of services provided;
- Maintaining health center governance authority and management team oversight of clinical policies, protocols and performance;
- The impact on current clinical and non-provider health center staff, possibly including union issues and different clinical cultures issues;
- Removal, relocation and replacement of providers working at the health center under a contract for clinical capacity, to ensure accountability and productivity;
- The interface of any clinical teaching activities with the provision of direct patient care;
- The impact on current clinical space and the need for new lease or other arrangements;
- The impact of the terms and limitations of any relevant managed care or other significant payor contracts, *e.g.,* the sufficiency of provider panels to serve all health center patients and the ability of the health center to maintain its current patient base;
- Obligations to provide required programmatic reports and maintain records, and connectivity implications;
- Communicating the nature of the affiliation to patients, staff, governing boards, other providers, payors and government agencies.

Assuring that the Board Continues to Fulfill its Fiduciary Duties

Board members of non-profit organizations hold a position of special trust and responsibility in the community. This is especially true of health center Board members charged with the governance of organizations that provide essential services to the most vulnerable populations. The Board plays a vital role as the governing body that sets priorities and policy direction for the health center. It is imperative that the Board ensures that affiliation agreements do not compromise the health center's (and the Board's) responsibility as a responsible steward of federal and other grant funds, accountability to the communities and patient populations served by the health center, and compliance with all applicable laws, regulations and policies.

Examples of fiduciary issues related to the evaluation of affiliation proposals include:

- Ensuring that the proposed terms do not adversely impact the health center's obligations to current populations served or scope of services provided;
- Ensuring that the financial analysis of the affiliation supports, at worst, a break even budget;
- Avoiding conflicts of interest or violations of laws related to the integrity of the health care system, or improper financial interests or benefits.

Assessing the Feasibility of Proposed Affiliation Opportunities

To help accomplish its oversight function in evaluating potential affiliation opportunities, the Board could appoint an ad-hoc committee to meet with the health center management team to:

1. Monitor the development and negotiation of proposed affiliation terms; and
2. Track the approval process to ensure consistency with the health center's mission and strategic plan.

The Board, with or without recommendations from such a committee, should review several aspects of the proposed affiliation to determine whether it is feasible. In particular, the Board should evaluate the proposed affiliation based on information obtained from the health center's management team regarding:

- Each party's due diligence review;
- The financial analysis of the proposed affiliation;
- Whether the terms and conditions of the agreed upon affiliation arrangement and the proposed definitive agreements permit the health center to:
  - Retain sufficient flexibility to execute arrangements with other health care providers/ agencies, and

  - Maintain compliance with applicable law, regulation and policy;

- Whether the health center needs to secure regulatory approvals prior to executing the arrangement.

The Due Diligence Review

"Due diligence" is a term used to denote the investigation by one party to a transaction of the other party regarding the value of assets and potential liabilities, and/or other third party interests (*e.g.,* Federal interests). A due diligence review may involve an investigation of legal, financial, organizational, management, clinical and/or operational aspects of the potential affiliation partner. 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(s). This investigation could consist of, among other activities:

- Reviewing various documents,
- Interviewing key personnel,
- Physically inspecting real and personal properties.

The specific nature of a due diligence review will depend 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 Chief Financial Officer 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 years.

The scope of review should give reasonable assurances that any problems of the potential partner or of the 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. 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 may have negative consequences for the health center, the health center may decide to:

- Restructure the transaction,
- Terminate plans to affiliate,
- 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).

For example, if a health center is negotiating with a hospital to establish an ER diversion program and in the course of conducting its due diligence review, the health center learns that the hospital is facing potential debarment from participation in federal health care programs, it would terminate negotiations immediately. On the other hand, if the health center discovers that a portion of the space initially allocated to the ER diversion program is slated for another purpose, the health center may decide to restructure, rather than terminate, the arrangement.

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 years.

The Financial Analysis of the Proposed Affiliation

In addition to reviewing the other party's financial information (as part of the due diligence review), the Board must seek (and secure) an assurance that the proposed affiliation will not jeopardize the health center's financial viability as well as its ability to continue to operate and provide services. While a due diligence review will verify your potential partner's ability to meet the terms of the proposed affiliation, the results of the financial analysis should confirm that the terms of the proposed affiliation are sound from a business perspective and that the health center will, at worst, break even.

Depending on the nature and type of affiliation, specific issues to consider may include:

- Whether the terms of compensation in leases (or contracts) for provider capacity, space and/or equipment are within fair market value range, from the health center's vantage point;
- The amount of one-time start up/transition costs (*e.g.,* IT-related costs or other capital investments);
- The need for a Community Benefit Grant or other source of financial support to cover the otherwise uncompensated care costs for serving expanded uninsured and underinsured populations;
- If applicable, financial responsibility for all direct and indirect costs incurred of any teaching program borne by the teaching institution;
- The impact of (and on) the terms and limitations of any relevant managed care or other significant payor contracts and reimbursement streams.

Retaining Sufficient Flexibility to Execute Arrangements with Other Health Care Providers

The Board should confirm that affiliation proposals do not impede the health center's flexibility to maintain relationships with other providers/agencies ((both during negotiations and post-collaboration). The terms of any agreements should be non-exclusive (as HRSA interprets the statutory requirement of Section 330(k)(3) requiring health centers to collaborate with other providers). Additionally, exclusive relationships between or among health centers and other entities may also implicate prohibitions in the federal anti-trust and anti-kickback laws. Any restrictive terms of an affiliation agreement, such as an agreement not to compete, should therefore be reviewed by qualified counsel and evaluated for compliance with any applicable "safe harbor" provisions permitting such terms.

Maintaining flexibility may be important in order to ensure the same services are available to the health center's total patient population. For example, a particular referral arrangement may only cover a portion of the health center's service area. Insofar as all services within a health center's scope of project must be available and accessible to all of the health center's patients, the health center may need to supplement one arrangement with additional arrangements. The following considerations should be evaluated by the board:

- Maintaining patient freedom of choice,
- Preserving independent clinical judgment in referring patients to the provider who can appropriately meet the patients' needs,
- Ensuring comprehensive patient access to all health center services.

Maintaining Compliance with Applicable Laws, Regulations and Policies

It is of singular importance that health center Boards ensure that the health center management team and qualified counsel carefully scrutinize each affiliation proposal (whether initially 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. Certain proposals or certain provisions of such proposals may have to be modified in order to maintain compliance with Section 330-related requirements. 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.

As discussed above, HRSA has issued two policies setting forth its expectations regarding health center affiliations and detailing the "do's" and "don'ts" in structuring these arrangements.[6] However, because Section 330-related rules and guidance regarding affiliations are not well understood by most affiliation partners, we recommend sharing the relevant policies at the earliest stages of joint planning. In summary, HRSA guidance addresses four areas of critical concern:

1. Corporate structure — HRSA, 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. In this regard, HRSA pays particular attention to corporate integration, which 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. In general, these types of arrangements 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 Board's exercise of required authorities, and the structure is specifically approved by HRSA.

2. Governance — 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 and policy expectations, and the Board should maintain authority to independently exercise all proscribed authorities. In particular, the health center's governing Board must continue to meet the composition standards and exercise the authorities described in 42 C.F.R. § 51c.304(b) as well as the HRSA Program Expectations set forth in PIN #98-23.

3. Management and finance — Taking into consideration the statutory and regulatory requirements related to the health center's management and financial operations, HRSA will review proposed affiliation arrangements to ensure that:

a. No other entity has the power to select or dismiss the health center's Executive Director/CEO, <u>without exception.</u>

b. No other entity has the power to employ the health center's CFO or Chief Medical Officer (or potentially other key management), subject to certain "good cause" the exceptions.

c. The health center Board retains authority and control over overall strategic and operational plans, budget, personnel policies and financial management policies.

4. Health services and clinical operations — HRSA will also review proposed affiliation arrangements for compliance with the statutory and regulatory requirements related to the health center's provision of health services and clinical operations, to ensure that:

a. The health center maintains it mission of providing care to a medically underserved community/population.

b. No other entity has the power to employ the majority of the health center's primary care clinicians, subject to certain "good cause" exceptions.

c. 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).

6 **See PIN # 97-27 & PIN # 98-24, as described above.**

Securing regulatory approvals prior to executing the arrangement

In conjunction with, or as a result of, analyzing the proposed affiliation's legal compliance, the health center may be required to secure certain regulatory approvals prior to proceeding with the affiliation. For its part, the Board should ensure that the health center management team and qualified counsel seek (and obtain) such approvals before implementing any affiliation activities.

Regulatory approvals common to health center affiliations include:

- Complying with applicable state licensure, certificate of need and credentialing requirements;
- Obtaining HRSA's prior approval of a change in the health center's approved scope of project, in accordance with PIN #2002-07: *Scope of Project Policy"* (December 31, 2001);
- 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).

Board Approval of Affiliations

Ultimately, the Board should retain the authority to approve any significant affiliation proposal and confirm that HRSA's specific requirements for affiliations are met. Health centers contemplating affiliations are required to request and obtain approval of the affiliation arrangement from HRSA, typically through submitting an "Affiliation Checklist" that is verified and signed by the Chairperson of the health center's Board. This checklist also serves as a good indicator to the Board regarding whether the affiliation meets applicable HRSA standards and requirements.

In conjunction with the Affiliation Checklist, all relevant reference documents must be submitted to HRSA, *e.g.,* organizational documents, affiliation agreements, contractual agreements and leases. 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. Nevertheless, a contract, lease, grant or other written affiliation agreement may contain terms that independently transfer to the other party powers that could jeopardize the Board's continuing compliance. In this situation, HRSA expects the health center to provide both the Bylaws and the written affiliation agreement and to submit an Affiliation Checklist with references to both.

Health centers contemplating affiliations are required to request and obtain approval of the affiliation arrangement from HRSA, typically through submitting an "Affiliation Checklist" that is verified and signed by the Chairperson of the health center's Board.

NACHC strongly cautions health centers to seek the assistance of qualified legal counsel and other appropriate professional advisors when developing and/or evaluating complex affiliation proposals and conducting due diligence reviews to ensure that the affiliation agreement complies with all applicable requirements and meets clinical and financial expectations.

CONCLUSION

The Board's role in evaluating potential health center affiliations with other providers, social service agencies, and other organizations is to: (1) assess mission compatibility; (2) determine whether the collaboration is likely to be strategically advantageous; and (3) provide oversight to the planning process, the due diligence review and the implementation of the terms of definitive agreements developed between or among the parties. NACHC strongly cautions health centers to seek the assistance of qualified legal counsel and other appropriate professional advisors when developing and/or evaluating complex affiliation proposals and conducting due diligence reviews to ensure that the affiliation agreement complies with all applicable requirements and meets clinical and financial expectations. Affiliations can yield great results for a health center, but they require time, effort and leadership from the Board in order to be successful.

Affiliation Considerations for Board Members

There are several overarching questions that Board members should ask about proposed affiliations involving their health center:

1. Does the health center maintain its mission?

- How will the affiliation preserve (or enhance) patient access, service continuity, fair payment, and health center survival?
- Is the arrangement culturally and linguistically appropriate for patients?
- Are the affiliating providers willing to take all health center patients upon referral from the health center, regardless of ability to pay or insurance status?
- Is payment (to or by the health center) "fair"?
- Will the collaboration contribute to the health center's survival and growth?

2. Can the Board continue to fulfill its fiduciary duties?

3. Is the proposed collaboration feasible, as documented by

- The due diligence review?
- A financial analysis?
- Whether the terms and conditions of the agreed upon affiliation arrangement and the proposed definitive agreements permit the health center to
  - Retain sufficient flexibility to execute arrangements with other health care providers/agencies; and
  - Maintain compliance with applicable law, regulation and policy?

4. Will the health center need to secure regulatory approvals prior to implementing the arrangement?

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