Section 330 Implications of Health Care Affiliations: Introductory Guidance

Background

Section 330 of the Public Health Service Act ("Section 330") defines a health center as an entity serving a medically underserved or special population by providing certain required and, as appropriate, additional services "either through the staff and supporting resources of the center or through contracts or cooperative arrangements."[1] The Section 330 implementing regulations require that an application for grant funds must include "a … description of any contractual or other arrangements (including copies of documents, where available) entered into, or planned for the provision of services."[2]

Neither Section 330 nor its implementing regulations address the specific types of "contracts or cooperative arrangements" by which health centers provide services or the types of services which can be provided in that manner. However, included within the definition of required services are "referrals to providers of medical services (including specialty referral when medically indicated) and other health-related services (including substance abuse and mental health services)."[3]

In the context of health center planning, development and operations, Congress clearly intended that health centers coordinate care with other local providers. To receive grants under Section 330 to support health center planning, development and operations, health centers are required to coordinate care with other local providers. To receive a planning grant, a specific project must include "proposed linkages between the center and other appropriate provider entities, such as health departments, local hospitals, and rural health clinics, to provide better coordinated, higher quality, and more cost effective health care services."[4]

With respect to operational grants, a health center must demonstrate that it 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 … and …has developed an ongoing referral relationship with one or more hospitals."[5]

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1 See Section 330(a)(1) of the Public Health Service Act, 42 U.S.C. § 254b(a)(1); see also 42 C.F.R. § 51c.102(c)(1).

2 See 42 C.F.R. § 51c.104(b)(8).

3 See Section 330(b)(1)(A)(ii); see also 42 C.F.R. § 51c.102(c)(1)(iii) ("referral to providers of supplemental services and payment, as determined by the Secretary to be appropriate and feasible, for their provision of services").

4 Section 330(c)(1)(A)(v).

5 Sections 330(k)(3)(B) and 330(k)(3)(L); see also 42 C.F.R. § 51c.303(n) ("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").

As a general policy matter, the Health Resources and Services Administration ("HRSA") expects that, to strengthen their ability to fulfill their mission, health centers will collaborate with other health care and social service providers in the health center's respective service area.[6] Collaborations are critical to ensuring the effective use of limited health center resources, providing a comprehensive array of services to clients, and gaining access to critical assistance and support (e.g., housing, food, employment). Health centers can ensure that quality specialty, medical, diagnostic and therapeutic services are available to patients through a system of organized referral arrangements.

Affiliation Agreements

Collaborations with other health care providers often take the form of an "affiliation," which is defined by HRSA as an "agreement that establishes a relationship between a [health center] and one or more entities."[7]

Affiliations may be structured through a variety of arrangements, for a variety of purposes and with a variety of partners.[8] In particular, structural options range from contractual relationships (i.e., single contracts; multiple contracts; a combination of the two, comprised of a single broad "umbrella" agreement governing the basic relationship of the affiliation partners with specific follow-on agreements to implement particular activities) to joint ventures (i.e., establishment of new entities; formation of integrated delivery systems), to certain forms of corporate participation and/or integration. Through past practice, HRSA has indicated that affiliations are desirable when they lead to integrated systems of care which strengthen the safety net for underserved clients.

Affiliation agreements may include, but are not limited to:

- Transfer Agreements: Where teaching hospitals transfer ambulatory clinics to the health center's license;
- Purchase of Clinical Capacity Agreements: Where health center leases provider services;
- Co-Location Agreements: Where a health center leases space from another provider;

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6 See Health Resources and Services Administration, *Health Center Site Visit Guide* (Nov. 2014/Fiscal Year 2015), p. 20. Hereafter referred to as the "HRSA Site Visit Guide."

7 See PIN 97-27 *Affiliation Agreements of Community and Migrant Health Centers* (Jul 22, 1997), p.5; and PIN 98-24 *Amendment to PIN 97-27 Amendment to PIN 97-27 Regarding Affiliation Agreements of Community and Migrant Health Centers* (Aug 17, 1998).

8 While recognizing the variability inherent in affiliation arrangements, HRSA has encouraged health centers to affiliate with clinical training programs that will contribute to the mission of the health center, meet the educational objectives of health care professional "in training," and, in general, increase the understanding of the health care needs of the underserved.

- Residency Training Agreements: Where a teaching hospital compensates a health center for precepting services and awards a community benefit grant to cover the health center's otherwise uncompensated care costs related to the residency program;
- Emergency Room Care Coordination Affiliations: Where a health center and hospital partner around the development of new sites located on or near the hospital campus to provide patients with an alternative to the emergency room for non-emergent health care needs.

Regardless of the structure, purposes and/or partners, HRSA expects health centers to ensure that all laws, regulations, and policies regarding health center governance requirements will be maintained by the health center (assuming that the health center desires to retain eligibility for federal funding). Further, HRSA has indicated that affiliations are desirable when they contribute to the availability, accessibility, quality, comprehensiveness, and coordination of care.

Of particular concern to HRSA are affiliation arrangements that affect the health center's compliance with federal grant requirements pertaining to health center integrity and autonomy.[9] Specifically, arrangements that give one or more entities powers which, in turn, diminish the health center's compliance with governance, management and/or clinical operations requirements or that result in the health center "merely serv[ing] as a conduit to another party for a grant award and/or other benefits … and/or vest in another party the ultimate authority to oversee and approve key aspects of health center activities" pose risk to health center integrity or autonomy.[10]

To ensure that affiliation agreements do not adversely impact health center autonomy and integrity, HRSA has identified the following areas for critical consideration: corporate structure; governance; management and finance; and health services.[11]

Corporate Structure

HRSA is particularly concerned with the "sole corporate member" model of integration, whereby another entity becomes the only "member" of the health center corporation. In particular, a sole corporate member, either through agreement between the parties or under state law expressed in the health center's Bylaws, may have powers and authorities that supersede those typically granted to, or reserved by, the Board of Directors of the health center corporation. Specific authorities required by Section 330 to be vested in the health center Board may instead be reserved to the sole corporate member, resulting in the health center's non-compliance with certain Section 330 grant-related requirements (thereby jeopardizing continued receipt of the grant and related benefits).[12]

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9 See PIN 97-27 *Affiliation Agreements of Community and Migrant Health Centers* (Jul 22, 1997), pp. 5-6.
10 Id.
11 Id. at p. 9.
12 Id. at pp. 9-10.

Accordingly, HRSA has indicated that it will not lightly approve a sole corporate member structural model, stating that "no 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."[13]

HRSA will scrutinize proposed sole corporate member affiliations to determine whether the particulars of the sole member relationship impact the health center's compliance with Section 330 and its implementing regulations 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. Further, HRSA will not allow sole corporate members to obtain actual or effective control over those powers and responsibilities that must be exercised by the health center Board under Section 330.

Governance

Under all affiliations, the health center's Board of Directors must continue to meet the composition standards described in 42 C.F.R. §51c.304(b). To the extent that an outside entity (or entities) might be authorized to nominate representatives to the health center's Board of Directors, the outside entity (or entities) representatives may not comprise the majority of the total number of health center Board members, a majority of the non-consumer Board members, the chairperson/president of the Board of Directors, or the majority of Executive Committee members.[14] Further, a third party may not limit the selection of Board member candidates or, conversely, require the dismissal of any current health center Board members not nominated by that third party.[15]

HRSA policy explicitly requires the Board of Directors to maintain all Board authorities and responsibilities required by law or regulation, and prohibits a third party (e.g., an affiliation partner) from securing overriding approval authority, veto authority (through "super-majority" requirement or other means), or "dual majority" authority with respect to such authorities and responsibilities, including the amendment of the health center's corporate documents (i.e., the articles of incorporation and bylaws).[16]

All health centers with existing affiliation agreements or considering new affiliation agreements should examine their arrangements to assure their governing board remains in compliance with all governance requirements.[17] HRSA further specifies that the following agreements may

[13] Id. at p. 10 (emphasis added).
[14] Id. at p. 12.
[15] Id.
[16] Id.
[17] PIN 2014-01 *Health Center Governance* (Jan 27, 2014) p. 15.

require HRSA review from a programmatic and/or grants management perspective to ensure the governing body's authorities are not compromised or limited:

- Mergers;
- Acquisitions;
- Parent-subsidiary arrangements;
- Establishment of a new entity;
- Subrecipient agreements; and
- Contracts for a substantial portion of the project (e.g., contracts for key management staff or core service delivery plan providers and/or services).[18]

Management and Finance

In evaluating the impact of an affiliation on management and finance, HRSA requires the health center to retain the authority to select and dismiss the CEO, the Finance Director and the Medical Director. Further, the long-term strategic plan, the budget, and general policies and procedures must be prepared and approved under the direction of the Board, with the involvement of the health center's administrative and medical staffs.[19]

Health Services

With respect to health services, the health center must remain focused on its mission of providing care to the medically underserved populations residing or working in its service area. No outside entity should have the ability to dictate, preclude or otherwise control health center relationships with other providers, except when the control is so limited that it does not preclude or have the potential to preclude the health center from complying with its obligations to establish local provider relationships that will assure accessible, high quality, continuous care for the target population(s).[20]

Purchase of Services Agreements

Under a purchase of services agreement, the health center contracts with another provider (organizational or individual) to furnish services to the health center or to the health center's patients on behalf of health center. These types of contracts may be used to procure clinical, administrative, and/or managerial expertise and experience that the health center cannot obtain directly but wants to include in-scope. The health center is financially, clinically, and legally responsible for the services purchased and in the case of a contract for clinical services, the patients receiving the services from the contractor are considered health center patients.

[18] Id.
[19] Id. at pp. 8-9.
[20] See PIN 97-27 at p. 16.

In general, HRSA prefers health centers to directly employ key personnel and the majority of their primary care providers. However, upon request, HRSA may grant an exception to its preference, permitting a health center to contract for such services (i.e., management or clinical services contract) under limited circumstances and for a limited amount of time. Approval of such exception is based on:

(i) An assurance of sufficient health center accountability (based on the criteria set forth below) with respect to operations of the grant- approved project and the expenditure of grant funds in accordance with applicable rules; and
(ii) The expected programmatic benefit which includes the following areas:

- Continued or improved access (i.e., increased capacity evidenced by additional services provided and/or more people served).
- Improved expertise (i.e., management, financial, and/or clinical).
- Increased capital (i.e., increased working capital, improved infrastructure, more efficient use of available resources).
- Maintained or improved quality of care (i.e., improved services, as measured through patient satisfaction, and/or improved care, as measured through improved health outcomes).[21]

Further, HRSA will review such agreements to ensure that the health center is in compliance with Section 330 grant-related requirements and that it is maintaining sufficient accountability with respect to its arrangements with other parties. Criteria of accountability include:

- 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 a third party, showing that work cannot be more efficiently and effectively performed directly by grantee.
- 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 Department of Health and Human Services ("DHHS") administrative requirements with respect to establishing policies related to the activities to be performed; implementing financial, program and property management systems and records and providing the health center and the Federal Government with access to such records; submitting financial and programmatic reports to the health center; complying with federal procurement standards; and terminating the agreement for contractor breach.[22]

[21] See PIN 98-24, pp. 2, 4.
[22] See id. at pp. 2, 3.

To establish a purchase of services arrangement, the health center typically executes a legally binding contract, the contents of which will vary with the type of contract. Generally, contracts for the purchase of good or services are "procurement contracts."[23]

With respect to payment rates, the regulations specify that the health center must "establish rates and methods of payment … made pursuant to agreements, with a schedule of rates and payment procedures maintained by the project. The project must be prepared to substantiate that such rates are reasonable and necessary."[24]

Referral Arrangements

Referral arrangements are relationships between the health center and another community provider under which the referral provider agrees to furnish services to the health center's patients who are referred to the referral provider by the health center.

Unlike a purchase of services agreement, the referral provider (not health center) is financially, clinically, and legally responsible for the services provided, and bills and collects payment for such services from applicable third party payors and patients. Under this type of arrangement, the health center does not retain control over the services; however, it does have a degree of assurance that its patients have access to services the health center does not (and/or cannot) provide.

As noted above, Section 330 and the implementing regulations discuss the importance of referral arrangements as components of the health center's overall health care delivery system. Further, HRSA scope policy recognizes the necessity of using such arrangements to assist in fulfilling the health center's obligation to provide required services. While the terms of referral arrangements may vary significantly based on the particular arrangement, if the health center wants to provide an in-scope service through a referral arrangement, HRSA requires a written referral agreement that includes provisions addressing:

- The manner by which the referral will be made and managed;
- The process for tracking and referring patients back to the health center for appropriate follow-up care;
- The process by which: (1) the health center and the referral provider will share medical notes / records regarding diagnosis and treatment for continuum of care purposes; and (2) the referral provider will furnish feedback and results to assist the health center in providing follow-up care.

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[23] When grant funds are used to finance a procurement contract, in whole or in part, certain additional provisions must be incorporated within the contract. For more information regarding procurement procedures, see Federal procurement requirements: Introductory guidance.

[24] See 42 C.F.R. §51c.303(t).

- An assurance that the health center will maintain responsibility for the patient's overall treatment plan and will furnish and pay/bill for any appropriate follow-up care furnished by the health center based on the outcome of the referral;
- An assurance that the referral provider is appropriately licensed or otherwise certified to furnish the services and is eligible to participate in federal programs: will furnish services consistent with the prevailing standards of care; and will offer services on a sliding fee scale to health center patients eligible for discounted services (i.e., uninsured and underinsured patients with incomes less than or equal to 200% of Federal Poverty Level); and,
- An assurance that the services furnished by the referral provider will be available equally to all health center patients regardless of ability to pay or An assurance that the health center maintains the right to enter into similar arrangements with other providers so that the service(s) furnished by the referral provider is available equally to all health center patients regardless of ability to pay..[25]

Advice and Recommendations[26]

Affiliation Agreements

As discussed above, HRSA is concerned about affiliation arrangements that impact the health center's ability to comply with federal grant requirements, in particular those regarding autonomy and integrity. It is of utmost importance that health centers carefully scrutinize each affiliation proposal (whether generated by the health center or by a potential partner) for compliance with such requirements and policies, as certain proposals or certain provisions of such proposals may have to be modified in order to maintain required compliance.

In particular, health centers must ensure that the affiliation proposals do not adversely affect daily management or governance. For example, the health center's management team, led by its CEO under the direction of the health center's Board of Directors, must remain ultimately responsible for health center operations (including personnel, clinical, and financial operations). Further, the affiliation proposal must not diminish the Board's role in carrying out its Section 330-related responsibilities, by delegating certain decisions to the affiliation partner(s) directly or permitting the partner(s) to effectively exercise control through various voting mechanisms.

Many times an affiliation partner will request the right to nominate representatives to the health center's Board. This is a right which the Authors believe should be reciprocal. Regardless of

[25] See PIN 2008-01 *Defining Scope of Project and Policy for Requesting Changes* (Dec 31, 2007), pp. 10 – 11; the *Health Center Visit Guide*, p. 4; PIN 2014-02 *Sliding Fee Discount and Related Billing and Collections Program Requirements* (Sept 22, 2014), p 12.

[26] The Authors of these materials include attorneys at the law firm of Feldesman Tucker Leifer Fidell LLP. The advice and recommendations consist of general guidance based on federal law and regulations, and do not necessarily apply to all health centers under all facts and circumstances. Further, these materials do not replace, and are not a substitute for, legal advice from qualified legal counsel.

such nomination authority, the Board must remain fully compliant with Section 330 size, composition, and selection requirements. The Board members nominated by the affiliation partner(s) cannot block the Board from taking any actions necessary to comply with Board authorities, functions, and responsibilities prescribed by law, regulation, and policy and cannot restrict the Board from exercising sufficient control, autonomy and accountability for the direction of the Section 330- related project. HRSA has expressed these conditions in PINs 97-27, 98-24, and 2014-01 (as well as the "Affiliation Checklist" contained in the single grant application) and health centers are well-advised to consider these requirements in conjunction with their review of affiliation proposals.

Purchase of Services Agreements

As a preliminary matter, a health center must appropriately decide whether it should award a sub-grant or a procurement contract. While there is no bright line test for determining whether an award of federal funds under a grant should take the form of a subrecipient agreement or a procurement, guidance is set forth in the Federal Uniform Grant and Cooperative Agreement Act. A grant or cooperative agreement is generally awarded in order to carry out the public purpose which the health center has agreed to carry out (typically in a specific location within the health center's service area) by an entity that itself would be eligible to receive the grant (i.e., a Section 330-compliant health center), while a contract/procurement is typically issued in order to purchase goods or services for the direct benefit of the grantee.

Note that the rules for subrecipients differ somewhat from procurement standards. In particular, all federal statutory and regulatory requirements, including 45 C.F.R. Part 75 and the Nineteen Requirements contained in the HRSA Site Visit Guide, should be imposed via a subrecipient agreement. On the other hand, procurement standards contained in 45 C.F.R. Part 75 specify certain contractual provisions be included in procurement contracts. Generally, contractors are not required to comply with all requirements contained therein.

Once a health center has determined whether to enter into a procurement contract or a sub-grant (also a form of contract, but not a "procurement" contract), the health center should determine the contract terms and conditions. In this regard, the health center should assess various grant-related requirements as to whether they should be passed through to the contractor. For example, if a health center is contracting for services that will be performed within its scope of project, the health center may require the contractor to develop and furnish programmatic reports (or at a minimum, certain data to assist in the development of such reports) that are required by DHHS under the health center's Notice of Grant Award.

- Considerations for purchase of services agreements: Checklist

Referral Arrangements

It is advisable to codify all referral arrangements in writing, regardless of whether the arrangement is included in the health center's scope of project. Further, all referral arrangements (whether in or out of scope) should include, at a minimum, the terms set forth in PIN 2008-01, PIN 2014-02, and the HRSA Site Visit Guide. Health centers also should receive assurances (including documentation) from the referral provider that the referral provider is appropriately licensed or otherwise certified to furnish the services, is eligible to participate in federal programs, and will furnish services consistent with the prevailing standards of care. Finally, the parties should include the provisions specified above and define the process by which: (1) the health center and the referral provider will share medical notes / records regarding diagnosis and treatment for continuum of care purposes; and (2) the referral provider will furnish feedback and results to assist the health center in providing follow-up care.

On a practical note, health centers should institute certain precautions in making referrals to avoid potential liabilities. Consider the following suggestions:

- Provide a minimum number of referral options from which the patient can choose;
- Do not express a preference or influence the selection process (except based on independent medical judgment) and remind patients that the final decision belongs to them;
- State the basis for the referral and indicate a rationale for including a particular provider;
- Include the date on referral lists;
- Set and follow uniform policies and establish a consistent course of conduct;
- Establish a written referral policy and train the staff in this policy; and
- Unless the health center directly supervises the referral providers, maintain a professional distance.