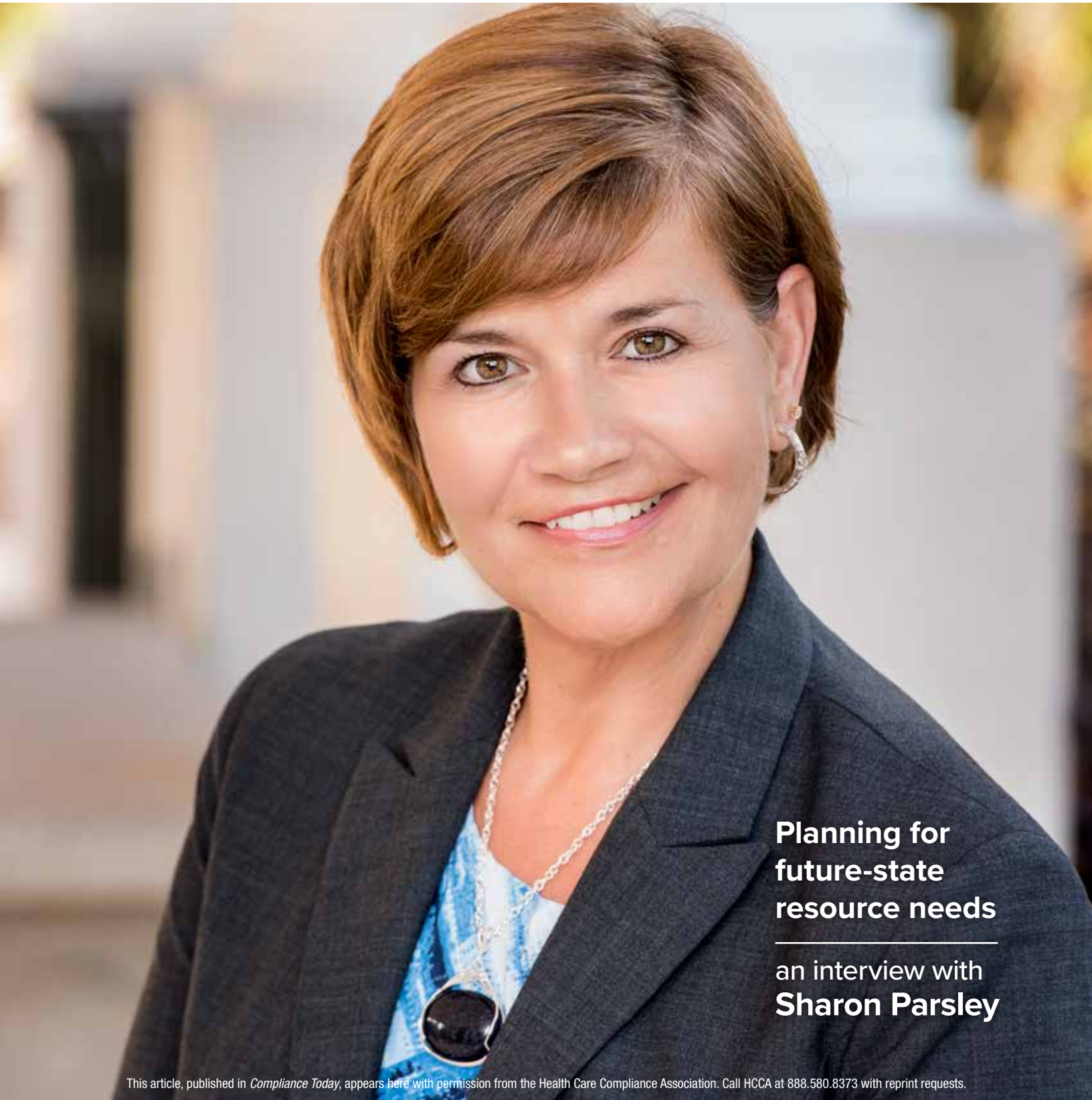
HCCA
hcca-info.org

Compliance TODAY

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

OCTOBER 2018



Planning for future-state resource needs

an interview with **Sharon Parsley**

by Jared Brooner, Esq.

Compliance considerations in the organization and operation of Federally Qualified Health Centers

» Federally Qualified Health Center (FQHC) is a designation administered by CMS.
» FQHCs must comply with Section 330 governance and operations requirements.
» The Health Center Compliance Manual is a valuable resource.
» FQHCs must also comply with the Stark Law, Anti-Kickback Statute, and civil monetary penalty (CMP) regulations.
» FQHC safe harbors provide some protection and flexibility for FQHCs.

Jared Brooner *(jbrooner@polsinelli.com) is Shareholder at Polsinelli in Kansas City, MO.*

The designation "FQHC" is assigned by the federal Health Resources and Services Administration (HRSA) Bureau of Primary Health Care (BPHC) and the Centers for Medicare & Medicaid Services (CMS) to private nonprofit or public healthcare organizations that serve predominantly uninsured or medically underserved populations, in accordance with the Health Center Program authorized by Section 330 of the Public Health Service (PHS) Act.[1] Once designated as an FQHC, certain Medicare and Medicaid payment methodologies are applied to the center's reimbursement, and other benefits (e.g., 340B Drug Program eligibility) can be pursued.


Brooner

FQHCs must comply with Section 330 program requirements and all applicable state and federal regulations. FQHCs are required to be located in or serve a federally designated Medically Underserved Area or Population (MUA or MUP). All FQHCs must be governed by a consumer board of directors and provide comprehensive primary health services to persons in all stages of life. FQHCs must offer their services to all persons regardless of ability to pay and charge for services on a board-approved, sliding fee scale based on patients' family income and size.

Section 330 program requirements

Section 330 refers to a section of the Public Health Service Act that defines federal grant funding opportunities for organizations to provide care to underserved populations. FQHCs must meet all applicable Section 330 requirements, including the following.

Governance requirements

In order to obtain/maintain FQHC status, an organization seeking FQHC status must maintain a governance structure that complies with

each of the Section 330 governance requirements.[2] Section 330 requires all FQHC boards to have a majority of consumer members who are served by the FQHC and who reasonably represent the individuals served by the FQHC in terms of demographic factions (e.g., ethnicity, race, sex). To be considered "served" by the FQHC, the board member must be a current registered patient of the FQHC and have accessed the FQHC in the past 24 months to receive at least one in-scope service that generated the visit.[3] Non-consumer members are selected from professional fields present in the community, such as legal, financial, healthcare, and social services. No more than half of the non-consumer members can earn more than 10% of their income from the healthcare field.[4]

The FQHC governing board must have between nine and 25 members. Employees and their relatives (e.g., spouses, children, parents, siblings) are ineligible to serve on the board. FQHC bylaws must prescribe specific methods for selecting new board members. FQHC boards have legal and fiduciary responsibilities for clinic operations and grants, must perform periodic strategic planning, and evaluate progress toward organizational goals. Specifically, the board must meet at least once a month, select services to be provided by the FQHC, schedule the hours during which services will be provided, and approve the selection of a director for the FQHC.[5]

Mission and strategy requirements

The mission of all FQHCs must include the improvement of the health status of underserved populations in their targeted service area. FQHCs must assess the needs of the community and populations that they serve and document such an assessment. After setting up the services, FQHCs must measure the effectiveness and quality of services provided. They must collaborate with other healthcare providers, such as specialty providers, hospitals, and other social service agencies.[6]

The mission of all FQHCs must include the improvement of the health status of underserved populations in their targeted service area.

Health services requirements

FQHCs must provide the following services, either directly or through a written contractual arrangement: primary care; dental; mental health; substance abuse; diagnostic lab and X-ray; prenatal and perinatal; cancer and other disease screening; blood level screenings (e.g., lead levels, communicable diseases, and cholesterol); well child services; child and adult immunizations; child eye and ear screening; family planning; emergency medical; pharmaceutical; case management; outreach and education; eligibility and enrollment services; transportation and interpretation; and referrals to specialty providers and hospital services.

FQHCs must provide all patients with a "continuum of care." This means that patients have access to all required services, access to specialty and hospital services, and after-hours coverage. Hours of operation must encourage access to care by having some early morning, evening, or weekend hours. FQHC healthcare providers must ensure the appropriate mix of services for the target population. Also, FQHCs must consider the mix of services already available to patients through other providers to minimize the duplication of services and maximize the efficient use of their financial resources. If FQHCs do not directly provide required services, they must have

written agreements with other providers for those services.

All FQHCs must have a medical director who supervises all clinical activities, and medical doctors who are licensed and residency-trained. Other clinicians must have appropriate licensure. Also, all FQHCs must establish policies and procedures for hours of operation, patient referral and tracking, use of clinical protocols, risk management, procedures, patient satisfaction assessment, a consumer bill of rights, and a patient grievances process.[7]

Other regulatory considerations

In addition to the requirements for federal grant funding, FQHCs also face other considerations.

Compliance Manual

The Health Center Program Compliance Manual (*Compliance Manual*) applies to all FQHCs with respect to their Health Center Program activities. (The *Compliance Manual* does not apply to activities conducted outside of an FQHC's scope of project approved by HRSA.) The *Compliance Manual* is a valuable resource to assist FQHCs in understanding and demonstrating compliance with the Section 330 and other requirements, and identifies requirements found in the Health Center Program's authorizing legislation and implementing regulations. The *Compliance Manual* is not intended to address best practices or strategies related to performance improvement for FQHCs, but it is a vital resource that all FQHCs should become familiar with.[8]

Ownership

There has been some scrutiny and pushback by HRSA and the BPHC concerning the ownership, control, and operation of an FQHC by another entity. There is no express prohibition on an FQHC being owned, controlled, or operated by another entity, but this could be grounds for denial of Section 330 funding and, subsequently, denial of FQHC status. The BPHC has publicly stated that it does *not* look favorably upon corporate structures involving ownership or control of FQHCs by other entities, particularly parent-subsidiary relationships, because a sole member or a parent organization of an FQHC may have certain powers and authorities which could supersede those required to be vested solely in the FQHC's board.

Specifically, in Policy Information Notices (PINs) 97-27 and 98-24, the BPHC stated 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.[9,10]

However, PINs 97-27 and 98-24 were recently expressly superseded by the new *Compliance Manual*.[11] Given the uncertainty surrounding this issue, we recommend seeking initial approval or, at the very least, starting a dialogue with the BPHC prior to seeking a grant under Section 330 if you are considering a parent-subsidiary model for an FQHC.

Requirement for Section 330 grant funding enrollment

To obtain FQHC status, the entity must apply for and receive Section 330 grant funding pursuant to the grant's specific form and guidelines. The Section 330 grants are awarded through a competitive process, and there are announced application deadlines that must be met. Once the paperwork is submitted, the application is deemed

to be in its final form and will either be approved or declined by HRSA — there is no opportunity to amend the application. Applicants must clearly document and submit:

- the need for primary care services in the area (which can be hard to show if there is another FQHC in the same service area),
- the plan for addressing these needs,
- the history and clinical capacity of the organization,
- the environment of the communities served, and
- a detailed budget and staffing information.

Applicants also must demonstrate compliance with all relevant program requirements and related federal and state requirements, including those regarding governance and board composition.

Compliance with healthcare fraud and abuse laws

Generally speaking, FQHCs are subject to the same healthcare fraud and abuse laws as other healthcare provider entities, including the Anti-Kickback Statute (AKS), the physician self-referral law (Stark), and the civil monetary penalty statute (CMP) restrictions on gainsharing or beneficiary inducement. As such, all arrangements between an FQHC, its physicians, and any other healthcare providers should be reviewed under a standard fraud and abuse analysis to ensure compliance. Notwithstanding the foregoing, the AKS does contain two safe harbors that are uniquely designed to encourage support for FQHCs.

The first safe harbor is the Health Centers safe harbor, which provides that the transfer of any goods, items, services, donations, or loans (whether the donation or loan is in cash or in-kind) shall not be considered prohibited remuneration as long as the following standards are met:

- The transfer is made pursuant to a contract, lease, grant, loan, or other agreement that (a) is set out in writing; (b) is signed by the parties; and (c) covers and specifies the amount of all goods, items, services, donations, or loans to be provided by the individual or entity to the FQHC;
- The goods, items, services, donations, or loans are medical or clinical in nature or relate directly to services provided by the FQHC as part of the scope of the FQHC's section 330 grant;
- The FQHC reasonably expects the arrangement to contribute meaningfully to the FQHC's ability to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the FQHC, *and* the FQHC documents the basis for the reasonable expectation prior to entering the arrangement;
- At reasonable intervals, but at least annually, the FQHC must reevaluate the arrangement to ensure that the arrangement is expected to continue to satisfy the standard set forth in paragraph (w)(3) of this section (contribute meaningfully to the FQHC's ability to maintain/increase the availability, or enhance the quality, of services provided to a medically underserved population), and must document the re-evaluation contemporaneously;
- The individual or entity does not require the FQHC (or its affiliated healthcare professionals) to refer patients to a particular individual or entity or restrict the FQHC (or its affiliated healthcare professionals) from referring patients to any individual or entity;
- Individuals and entities that offer to furnish goods, items, or services without charge or at a reduced charge to the FQHC must furnish such goods, items, or

services to all patients from the FQHC who clinically qualify for the goods, items, or services, regardless of the patient's payer status or ability to pay;

- The agreement must not restrict the FQHC's ability to enter into agreements with other providers or suppliers of comparable goods, items, or services, or with other lenders or donors, if it chooses to do so;
- The FQHC must provide effective notification to patients of their freedom to choose any willing provider or supplier. In addition, the FQHC must disclose the existence and nature of an agreement under this section to any patient who inquires. The FQHC must provide such notification or disclosure in a timely fashion and in a manner reasonably calculated to be effective; and
- The FQHC *may*, at its option, elect to require that an individual or entity charge a referred FQHC patient the same rate it charges other similarly situated patients not referred by the FQHC, or that the individual or entity charge a referred FQHC patient a reduced rate.[12]

The Health Centers safe harbor provides considerable flexibility for arrangements related to the financial and/or operational support of an FQHC, as long as the arrangement is reasonably designed to increase the availability, or enhance the quality, of services provided to a medically underserved population served by the FQHC.

More recently, U.S. Department of Health & Human Services Office of Inspector General (OIG) added the FQHC and Medicare Advantage Organizations (MAO) safe harbor, which protects certain remuneration between MAOs and FQHCs.[13] To receive protection under this safe harbor, the MAO and FQHC must enter into a written agreement that provides for a payment to the FQHC for services it provides. The agreement must stipulate that payment is not less than the amount the MAO would make for such services if the services had been furnished by an entity other than a FQHC. This safe harbor only extends to those payments made to a FQHC for the treatment of MAO plan enrollees and does not protect any remuneration between FQHCs and MAOs that is unrelated to Medicare Advantage plan enrollees being treated at the FQHC. For example, the provision of free space or financial support for outreach activities would not qualify for protection.

Conclusion

FQHCs play an essential role in promoting access to preventive and primary care among medically underserved populations, and are entitled to certain benefits such as federal grant funding and 340B Drug Program eligibility. However, in order to obtain and maintain FQHC status, the applicable provider entity must comply with a fairly stringent set of requirements. Prior to pursuing FQHC status, or entering into an arrangement with an existing FQHC, providers should carefully review the FQHC regulations and consult legal counsel to ensure compliance with applicable requirements.

1. 42 U.S.C. 254b (Health centers)
2. 42 CFR 51c.304 (Governing board)
3. HRSA Policy Information Notice 2014-01: "Health Center Program Governance" January 27, 2014. Available at http://bit.ly/2PAnpHe
4. Ibid, Ref #2
5. Idem
6. See 42 U.S.C. 254b(k)(3).
7. Idem
8. HRSA: *The Health Center Program Compliance Manual*. Available at http://bit.ly/2wnMFYu
9. HRSA: Policy Information Notice 97-27: "Affiliation Agreements of Community and Migrant Health Centers" July 22, 1997. Available at https://bit.ly/2ONLcTS
10. HRSA: PIN 98-24 "Amendment to PIN 1997-27 Regarding Affiliation Agreements of Community and Migrant Health Centers" August 17, 1998. Available at https://bit.ly/2OdnOxV
11. Ibid, Ref #8, page 6
12. 42 CFR 1001.952(w) (Exceptions, Health centers)
13. 42 CFR 1001.952(z) (Exceptions, Federally Qualified Health Centers and Medicare Advantage Organizations)