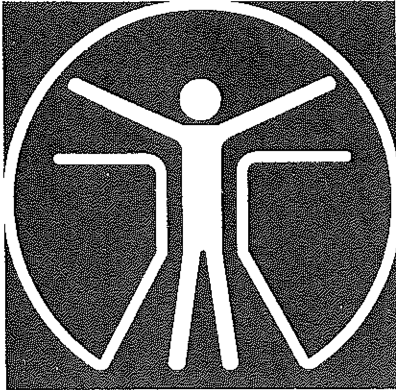

THE ABA HEALTH LAW SECTION

THE HEALTH LAWYER

IN THIS ISSUE

Federally Qualified Health Centers: A Healthcare Delivery Model for a Newly Reformed Health System 1

MS.01.01.01 (formerly known as MS 1.20): The Joint Commission's Standard for Medical Staff Bylaws.............. 10

An Obituary for Physician-Owned Specialty Hospitals....... 24

Immigrants and Healthcare: A Voice for Coverage............. 35

"Work-Arounds" for Physician-Owned Hospitals: Are They Workable?.............. 44

Updates to EMI 2010 Presentations 51

Volume 23, Number 2
December 2010

FEDERALLY QUALIFIED HEALTH CENTERS: A HEALTHCARE DELIVERY MODEL FOR A NEWLY REFORMED HEALTH SYSTEM

Kathy Poppitt, Esq.
Cox Smith Matthews Incorporated
Austin, TX

Sheryl Tatar Dacso, Dr.P.H., Esq.
Seyfarth Shaw
Houston, TX

The Patient Protection and Affordable Care Act of 2010 is a landmark healthcare bill designed to substantially reform how healthcare is financed and delivered in the United States.[1] One of the central funding initiatives in the legislation is the expansion of federally qualified health centers ("FQHCs" or "health centers") as a means of improving access to primary healthcare services for millions of Americans.

FQHCs also benefited from the enactment of the American Recovery and Reinvestment Act ("ARRA"), which has infused slightly more than two billion dollars to community health centers for capital improvements, expansion (or retention) of personnel and services, and adoption of health information technology.[2] This amount was intended to offset the double burden of reduced local funding streams and increases in the number of medically underserved individuals.

FQHCs are not new. The FQHC benefit under Medicare was added effective October 1, 1991, when Section 1861(aa) of the Social Security Act (the "Act") was amended by Section 4161 of the Omnibus Budget Reconciliation Act of 1990.[3] FQHCs are "safety net" providers such as community health centers, public housing centers, outpatient health programs funded by the Indian Health Service, and programs serving migrants and the homeless. The main purpose of the FQHC Program is to enhance the provision of primary care services in underserved urban and rural communities.

In terms of health outcomes, studies have shown that the presence of, or patients' receipt of care from, FQHCs can reduce rates of avoidable hospitalizations and improve birth outcomes. Other studies have examined the impact of health centers on access to care, measured as having a usual source of care or more physician visits, and found a strong positive relationship.[4]

The purpose of this article is to familiarize the reader with FQHCs as an important player in the healthcare delivery system of the future.

continued on page 3

continued from page 1

What is an FQHC?

FQHCs are community-based health centers that primarily serve medically underserved communities and vulnerable populations, and have a clear mission to serve the poor.[5] To be designated as federally qualified, a center must meet several criteria: (1) serve a health professional shortage area, medically underserved area, or medically underserved population; (2) provide services without regard to patients' insurance status; (3) use a sliding-fee discount payment system tied to uninsured patients' income; and (4) operate as a not-for-profit entity. What distinguishes FQHCs from free clinics and other community health centers is the receipt of federal funding under Section 330 of the Public Health Services Act, ("PHS Act") to provide comprehensive primary care services to uninsured and underinsured populations.[6]

FQHCs are regulated by the U.S. Department of Health and Human Services Health Resources and Services Administration ("HRSA"). There is no typical "model" health center, but all share common attributes, such as their mission to provide primary and preventive health services to underserved populations; their imperative to maintain strong leadership, finances and infrastructure; and the desire to deliver high quality clinical services.[7]

An entity may qualify as an FQHC if it is receiving a grant under Section 330 of the PHS Act; is receiving funding from such grant under a contract with the recipient of a grant and meets the requirements to receive a grant under Section 330 of the PHS Act; or was treated by the Secretary of the Department of Health and Human Services ("HHS") as an FQHC for Medicare Part B purposes as of January 1, 1990.[8] Additionally, a center may qualify as an FQHC if it is operating as an outpatient health program or facility of a tribe or tribal organization under the Indian Self-Determination Act or as an urban Indian organization receiving funds under Title V of the Indian Health Care Improvement Act as of October 1, 1991.[9]

A center may quality as an FQHC "Look-Alike" even if it is not receiving a grant under Section 330 of the PHS Act if it has been determined by the Secretary of HHS to meet the requirements for receiving such a grant based on the recommendation of the HRSA. As discussed in more detail below, Look-Alikes receive many, but not all, of the benefits of full FQHCs.[10]

Who is Eligible to Obtain FQHC Funding?

Public and private non-profit healthcare organizations may apply to receive Section 330 funding. Applications and funding opportunities through HRSA include: [11]

- **New Access Points Grants** – provide funding to support new service delivery sites that will provide comprehensive primary healthcare and access to oral and mental health services. Applicants can be existing grantees or new organizations that do not currently receive Section 330 grant funds.
- **Expanded Medical Capacity Grants** – provide funding to expand access to primary health services in the health center's current service area (e.g. by adding new medical providers or medical services or expanding hours of operation) Only existing grantees are eligible to apply.
- **Service Expansion Grants** – provide funding to add new or expand existing mental health/substance abuse, oral health, pharmacy, and enabling services[12] for special populations at existing health centers. Only existing grantees are eligible to apply.
- **Service Area Competition Grants** – provide ongoing competing continuation funding for service areas currently served by health center grantees. Both currently funded section 330 grantees whose project periods have expired and new organizations proposing to serve the same areas or populations being served by existing Section 330 grantees may apply.

Applicants must document a need for primary care services in their area, their plan for addressing these needs, the history and clinical capacity of their organizations, and the environment of the communities they serve. They must also provide detailed budget and staffing information. HRSA sends all applicants written notification of the outcome of the review of their applications, including a summary of the review committee's assessment of the application's merits and weaknesses, and whether the application was selected for funding.

FQHC Scope of Services

FQHCs are expected to provide primary care and preventive healthcare services. These services must include, but are not limited to, physician services; services and supplies incident to the services of physicians; nurse practitioner ("NP"), physician assistant ("PA"), certified nurse midwife ("CNM"), clinical psychologist ("CP"), and clinical social worker ("CSW") services; services and supplies incident to the services of NPs, PAs, CNMs, CPs, and CSWs; visiting nurse services to the homebound in an area where the Centers for Medicare & Medicaid Services ("CMS") has determined that there is a shortage of home health agencies; otherwise covered drugs that are furnished by, and incident to, services of a FQHC

continued on page 4

continued from page 3

provider; and outpatient diabetes self-management training and medical nutrition therapy for beneficiaries with diabetes or renal disease (effective for services furnished on or after January 1, 2006).[13] FQHCs are also expected to provide the supportive services (education, translation, transportation, etc.) that promote access to healthcare.[14] These services can be provided directly or through contracts or cooperative arrangements. The services must be responsive to the needs and culture of the target community and/or populations.[15]

Program Fundamentals

In order to qualify for FQHC or "look alike" status, a health center must be organized, governed and operated consistent with certain federal requirements and culture of the target community and/or populations[16] as well as maintain, expand and improve the availability and accessibility of essential primary and preventive healthcare services and related "enabling" services provided to low income, medically underserved and vulnerable populations that traditionally have limited access to affordable services and face the greatest barriers to care. To meet these requirements and goals, health centers are required to be located in or serve a high need community (designated Medically Underserved Area or Population) and to provide services available to all, with fees adjusted based on ability to pay.[17] Centers are also required to be governed by a community board composed of a majority of health center patients who represent the population served and to meet strenuous performance and accountability requirements regarding administrative, clinical, and financial operations.[18]

These health centers serve people of all ages, races and ethnicities. According to the latest information collected by the HRSA (available on its website at http://bphc.hrsa.gov/about/), in 2008 FQHCs provided services to over 17 million individuals; approximately 36 percent of patients were children, seven percent were 65 or older, 28 percent were African-American and 33 percent were Hispanic/Latino. Also according to the HRSA information for 2008, in that year FQHCs served approximately 834,000 migrant and seasonal workers and their families; nearly 934,000 homeless individuals; and nearly 157,000 residents of public housing.

Programs receiving funding to serve homeless individuals and families also must provide substance abuse services.[19] Substance abuse services include treatment for alcohol and/or drug abuse and may use a variety of treatment modalities.

Required services may be provided by health center staff or through defined arrangements with other individuals or organizations. When a required service is not provided directly by health center staff, written agreements should be developed specifying how the service is provided. Additionally, all health centers should have ongoing referral arrangements with one or more hospitals. Health center clinicians should obtain admitting privileges and hospital staff membership at their referral hospitals so health center patients can be followed by health center clinicians.[20] In cases where hospital arrangements (including admitting privileges and membership) are not possible, the health center must firmly establish arrangements for hospitalization, discharge planning and patient tracking.[21] All health centers are also required to establish arrangements for after-hours coverage which, at a minimum, should ensure telephone access to the covering clinician and assure timely follow-up by health center clinicians for patients seen after-hours.[22]

All health centers are required to maintain a core staff of primary care clinicians with training and experience appropriate to the culture and identified needs of the community served. All staff must be appropriately credentialed and licensed.[23] It is preferred that the health center directly employ its core clinical staff or at least give the Chief Executive Officer the authority to select and dismiss individual providers.[24] Health centers are also required to maintain a fully staffed health center management team as appropriate for the size and needs of the center.[25] There must be a Project Director/Executive Director/Chief Executive Officer who is accountable to the governing board. The governing board of an FQHC must meet specific requirements, including the fact that at least 51 percent must be consumers (representative of the clients of the Center). The size of the board may range from nine to 25 members.[26] The duties of the board include overseeing the Center's mission, vision and values; determining the nature and scope of services; and assuring compliance with federal, state and local laws and regulations. The board grants professional staff privileges and evaluates the quality and utilization of services. Financial management is key to the success of an FQHC. Once the board selects an Executive Director/CEO, it is expected that the policies of the board will be discharged through that individual.

What are the Attributes and Benefits of FQHC Designation and Look-Alikes?

There are several benefits to an FQHC designation, including:

a. Receipt of Section 330 funding;

b. Enhanced reimbursement for services provided to Medicare and Medicaid patients;

c. Anti-kickback Statute Safe Harbor protection;[27]

d. Medical malpractice coverage under the Federal Torts Claims Act ("FTCA"), as explained below;[28]

e. The right to have out-stationed eligibility workers and National Health Services Corps placement;[29] and

f. Access to Vaccines for Children Program,[30] PHS Drug Pricing Discounts (Section 340B Drug Pricing),[31] and grant support and loan guarantees for capital improvements.[32]

"Look-Alikes" receive most of the benefits listed above, with certain important exceptions. One key difference is that designated Look-Alikes do not receive Section 330 grant funds. FQHC Look-Alikes also cannot apply for malpractice coverage under the FTCA, so those centers must maintain separate malpractice insurance.[33] A third key difference is that Look-Alikes are not covered by the anti-kickback Safe Harbor which protects arrangements between health centers and other providers/suppliers of services that maintain or expand accessibility or reduce the cost of services provided to health center patients. The Look-Alike designation does place a center in good position to convert to full FQHC status at a later time.

Both grant and "Look- Alike" FQHCs receive Medicare reimbursement at 80 percent of the All Inclusive Reimbursement Rate ("AIRR").[34] The AIRR is determined based on the average cost per visit determined by the health center's cost report. The term "visit" is defined by CMS as a face-to-face encounter between the patient and a physician, PA, NP, CNM, visiting nurse, CP, or CSW during which an FQHC service is rendered.[35] Encounters with (1) more than one health professional; and (2) multiple encounters with the same health professional which take place on the same day and at a single location, constitute a single visit unless the patient subsequently suffers an illness or injury requiring additional diagnosis or treatment.[36] Patients are responsible for 20 percent of the health center's usual and customary cost. Patients do not pay Part B deductibles, so health centers receive Medicare "first dollars."[37]

Only those activities that are part of the health center's approved scope of project under either the grant or FQHC Look-Alike designation are entitled to enhanced FQHC Medicaid and Medicare reimbursements and section 340B Drug Pricing benefits. For purposes of reimbursement, CMS does not distinguish between FQHC look-Alikes and Section 330 grantees.[38] Both types of centers are considered FQHCs and are reimbursed in the same manner.

Community Collaboration Opportunities

FQHCs are frequently provided with, or seek out, opportunities to enter into arrangements with hospitals or other providers or suppliers to further the health centers' mission. For example, providers or suppliers may agree to provide health centers with capital through community development grants, low cost loans, reduced price services, or in-kind donations of supplies, equipment, or space and other forms of arrangements. Congress has enabled such collaboration and support by relaxing laws that generally restrict such activities. FQHCs enjoy special treatment under federal anti-kickback and Stark laws. Section 431 of the MMA amended the antikickback statute to create a new Safe Harbor to allow some health centers to accept needed goods, items, services, donations, or loans for free or at reduced rates from willing providers and suppliers.[39] In 2007, the Office of Inspector General of the Department of Health and Human Services ("OIG") published the final Safe Harbor that protects certain remuneration provided by an individual or entity to certain health centers when all of the following conditions are satisfied:[40]

a. There must be a signed, written agreement detailing the items or services provided to the health center;

b. The amount of goods and services provided must be set out in a fixed sum, percentage or other fixed methodology which is not based on value or value of referrals;

c. Goods or services must be clinical or medical in nature or relate to the services provided by the health center as part of the scope of its grant;

d. The health center must reasonably expect the arrangement to contribute meaningfully to its ability to maintain or increase the amount or quality of its services;

e. At least annually, the health center must re-evaluate the arrangement to ensure it continues to meet the above standard and this re-evaluation must be documented;

f. The health center cannot be required to or restricted from making referrals to a particular individual or facility;

g. Services furnished free of charge or at a reduced rate must be offered to all patients regardless of their payor status or ability to pay;

h. The arrangement must not restrict the health center's ability to enter into other agreements with other entities or donors for comparable goods or services;

i. The health center must provide effective notification to patients of their ability to choose any willing provider or supplier and must disclose the existence and nature of

continued on page 6

continued from page 5

the agreement arranged under this safe harbor; and

j. The health center can elect to require that an entity charge a referred patient the same rates charged other non-referred patients or a reduced rate, where such reduction applies to the entire charge.

On February 1, 2008, the OIG issued Advisory Opinion No. 08-01, which approved an arrangement involving the participation of FQHCs and free clinics in "bulk replacement" patient assistance programs ("PAP"s). A bulk replacement PAP is an arrangement that allows pharmaceutical companies to donate drugs from the company's bulk replacement[41] to FQHCs and free clinics. Bulk replacement PAPs provide a bulk volume of free drugs (typically on a monthly or quarterly basis) to hospitals, pharmacies, health centers, clinics, and other institutions to replace drugs dispensed to patients who meet established PAP criteria. Participating FQHCs and free clinics must agree to distribute the free drugs only to patients whose incomes are less than 200 percent of the federal poverty level and who do not have any form of outpatient prescription drug coverage. Accordingly, donated PAP drugs may not be dispensed to Medicare Part D enrollees or Medicaid patients. As the OIG recognized, PAPs provide important safety net assistance to these uninsured patients with limited means.[42]

In addition to the special treatment of FQHCs under the federal anti-kickback law, an important feature of 330 grant FQHCs is the availability of FTCA protection. The FTCA was enacted in 1946 and permits individuals injured by the wrongful or negligent acts or omissions of federal employees, including medical malpractice, to seek and receive compensation from the federal government through an administrative process and, ultimately, through the federal courts.[43] The FTCA, with few exceptions, provides the exclusive means by which individuals can seek compensation when injured by federal employees acting within the scope of their work for the federal government. FTCA settlements and judgments in medical malpractice cases are paid by the federal government, which becomes the primary source of providers' insurance for those claims and which, in effect, largely immunizes federal employees from tort liability, including medical malpractice. In 1993, medical malpractice coverage under the FTCA was extended to FQHCs in order to allow the centers to redirect the funds that would otherwise be spent on private insurance to the provision of health services. Coverage under the FTCA is provided at no cost to the health centers.[44]

Health centers must apply to HRSA to be covered, or "deemed," as organizations that together with their employees are recognized as federal employees under the FTCA for the purposes of claims for medical malpractice.[45] As part of this application process, health centers must demonstrate that they have policies and procedures in place to minimize the risk of malpractice.[46] FTCA coverage for health center providers covers only personal injury caused by negligent or wrongful acts or omissions within their scope of employment and within the health center's scope of project. As of December 2008, the latest year for which this information is available, 85 percent of all health centers (915 of 1,082) were deemed by HRSA for FTCA medical malpractice protection.[47]

FTCA coverage is not the same as having commercial malpractice coverage. There are very specific requirements that must be met, and many common activities engaged in by FQHCs are not covered by FTCA. Events that could cause potential coverage gaps include furnishing services off-site (for example, on-call arrangements with hospitals), furnishing services to non-health center patients (for example, providing after-hours cross coverage), or employing part-time contractors.

Only appropriately credentialed, licensed and/or certified full-time individual contractors of the health center are eligible for FTCA malpractice protection. The coverage is restricted to acts or omissions which: 1) occur on or after the effective date that the Secretary of the HHS has deemed the center covered; 2) are within the approved scope of the health center's project; and 3) are within the scope of employment, contract for services, or duties as an officer or director of the corporation.[48] The contractors are protected if they are contracted for more than 32.5 hours per week and the health center is the entity that receives payor compensation for the services the contractor provides.[49] If contracted for less than 32.5 hours per week, protection eligibility will depend on the services provided. If a practitioner provides family practice, obstetrics/gynecology, pediatrics, or general internal medicine services, then he or she can receive FTCA protection even if he or she is a part time contracted provider.[50] Again, the health center must be the entity that receives payer compensation for the services provided by the contractor. This usually means that the health center receives the compensation directly, but in certain circumstances the compensation may be passed through the contractor to the health center.

A health center must contract with individual physicians in order for them to receive malpractice protection.[51] If a health center contracts with a group practice or any other professional, personal or private corporation, or any other entity, then that corporation or entity is not

eligible for FTCA protections and it assumes its own liability. Additionally, all payments for service must be made from the health center directly to the individual contractor and not to that practitioner's professional corporation or any other entity for the physician to be covered.[52]

Trends and Opportunities

Affiliation Agreements

In 1997, the Bureau of Primary Health Care ("BPHC") stated it encouraged health centers to affiliate with other entities to strengthen their ability to achieve their mission.[53] However, BPHC has also stated that it is concerned that some affiliation agreements may compromise health centers' compliance with grant requirements, particularly those of Section 330. Non-compliance with grant requirements will result in loss of the health center's Section 330[54] and/or FQHC status and associated benefits. Therefore, it is important that health centers consider and comply with their grant requirements when entering into any collaborations.

An affiliation agreement is an agreement that establishes a relationship between a health center and one or more entities such as other health centers, primary care providers, specialists, hospitals, HHS agencies, managed care organizations, and management services organizations. Types of formal affiliations may include contractual arrangements, joint ventures and corporate integration. The risk is that through these affiliations, the health center may diminish its substantive Section 330 role in carrying out health center activities and merely serve as a conduit to another party for a grant award and/or other benefits (e.g., those of FQHC, FTCA, and the Drug Pricing Program), and or give another party the ultimate authority to oversee and approve key aspects of health center activities.

Health centers considering affiliation agreements should examine the proposed affiliation to assure that the following remain in compliance with all Section 330 requirements:

1. **Corporate structure.** The BPHC is particularly concerned about the "parent-subsidiary model" of corporate integration in which the health center becomes a subsidiary of another corporation.[55]
2. **Governance.** The governing board must meet the composition requirements, especially the Executive Committee. The Chairman of the Board may not be selected by any other entity and no other entity may select a majority of the members of the Executive Committee. Additionally, no other entity may have veto power, including "super-majority" provisions which give another entity an effective veto power.[56]
3. **Management and Finance.** The governing board in particular and the health center in general must remain in control of management and finance. The budget must be prepared under the direction of the health center governing board. No other entity can have the authority to select or dismiss the Executive Director, the Finance Director or the Medical Director. The establishment of personnel policies and procedures must remain under the control of the health center board.[57]
4. **Health Services.** No other entity should dictate, preclude or otherwise control health center relationships with other entities. The health center board should not be precluded from exercising its authority and fulfilling its responsibilities relative to 1) evaluating service utilization patterns, productivity of the center, patient satisfaction, achievement of center objectives, development of a patient grievance process; and 2) adopting healthcare policies which include scope and availability of services, location and hours of services, and quality of care audit procedures.[58]

The BPHC will review proposed affiliation agreements for compliance on request. The focus of these reviews is on federal statutory and regulatory requirements and program expectations. In many instances health centers do not risk loss of integrity or autonomy with affiliation agreements such as contracts for ancillary services and allied health services or agreements with other entities subject to Section 330 requirements, and the BPHC will likely not have much concern over these proposals. However, the BPHC has expressed greater concern for agreements between health centers and entities whose missions are not in line with that of the health center. In response to a review, the BPHC will provide the health center with definitive guidance, to the extent that policy interpretations have been made.

Community-Based Collaborative Care Networks

The Patient Protection and Affordable Care Act[59] includes a provision to enable the development of Community-Based Collaborative Care Networks. These are defined as "...a consortium of healthcare providers with a joint governance structure that provides comprehensive coordinated and integrated health care services for low-income populations."[60] Each network must include a safety net hospital that provides services to a high volume of low income patients.[61] All FQHCs located within the geographic area served by the coordinated care network have the option to participate or not. Funding will be authorized for years 2011 – 2015.[62]

Nothing in this arrangement, however, shall change the FQHC's obligations to continuously comply with its mandated requirements and scope of services based on its HRSA grant.

continued on page 8

continued from page 7

Conclusion

FQHCs are an important player in the continuum of healthcare for all Americans, whether eligible for public or private insurance. The status and role of FQHCs will be significantly impacted by the recently approved healthcare reform legislation, especially in regard to the Community-Based Collaborative Care Networks. Americans can anticipate an increase in collaborations and alignments between private and public systems with FQHCs in the near future.

Kathy Poppitt is a partner with the law firm of Cox Smith Matthews, Incorporated in Austin, Texas. She has spent more than 20 years building a career focused on healthcare regulatory law, healthcare litigation and administrative law. Ms. Poppitt advises providers on operational issues such as hospital/physician integration, compliance and governance, HIPAA, peer review, credentialing, Recovery Audit Contractors ("RAC") audits, licensing and certification and all types of joint ventures and contracting. She also represents providers of Medicare and Medicaid and private payor reimbursed services in reimbursement matters, as well as in resolution of issues involving regulatory agencies. She is called upon frequently to speak and write about healthcare industry issues. She may be reached at *kpoppitt@coxsmith.com*.

Sheryl Tatar Dacso, Dr.P.H., Esq. is of counsel with the law firm of Seyforth Shaw in Houston, Texas. Dr. Dacso has represented healthcare organizations, individual physicians and physician groups for over 30 years. She is Board Certified in Health Care Law by the Texas Board of Legal Specialization and certified in healthcare compliance by the Health Care Compliance Association. Dr. Dacso concentrates her practice on healthcare compliance, regulations and transactions, including physician practice mergers, acquisitions and business ventures. Dr. Dacso is an AHLA-trained negotiator/mediator for resolution of healthcare disputes and has handled many complex transactions involving healthcare organizations. In November 2002, she was named by Texas Lawyer as the number one "Top Notch Lawyer" in healthcare law in Texas. This year, she was listed in Texas *Best Lawyers*. She has written several text books and articles on a broad range of healthcare topics ranging from managed care contracting to virtual practice arrangements among physician practices. Dr. Dacso holds a faculty appointment at the University of Houston where she teaches at the Law School in the Health Law Institute and in the College of Technology. She may be reached at *sdacso@seyforth.com*.

Endnotes

1 Patient Protection and Affordable Care Act of 2010 ("PPACA"), Publ. L. No. 111-148 (2009).

2 Peter Shin, PhD, MPH, et. al. The Economic Stimulus: Gauging the Early Effects of ARRA Funding on Health Centers and Medically Underserved Populations and Communities, Policy Research Brief No. 17, February 16, 2010.

3 Omnibus Budget Reconciliation Act of 1990 ("OBRA-90"), Pub. L. 101-508, 104 Stat. 1388, Nov. 5, 1990.

4 Anthony T. Lo Sasso and Gayle R. Byck, Funding Growth Drives Community Health Center Services; Health Affairs; 29, no. 2 (2010): 289-296.

5 Hawkins DR, and Rosenbaum S. The challenges facing health centers in a changing healthcare system. In: SH Altman, UE Reinhardt, and AE Shields, editors. The future U.S. healthcare system: who will care for the poor and uninsured? Chicago (IL): Health Administration Press; 1998 and Rosenbaum S, Hawkins DR, Rosenbaum E, and Blake S. State funding of comprehensive primary medical care service programs for medically underserved populations. Am J Public Health. 1998;88(3).

6 Public Health Services Act, ("PHS" Act) 42 U.S.C. § 254b, Section 330.

7 There are approximately 1,200 FQHCs in the United States as of 2009. These FQHCs operate in 7,500 delivery sites and serve about 20 million patients annually. *Fact Sheet on America's Health Centers*, The National Association of Community Health Centers, October 2009.

8 *Id.*

9 Indian Self-Determination Act, 25 USCS §§ 450 et seq.

10 To ensure that there are appropriate numbers of health centers to serve the millions of uninsured and underinsured populations throughout the country, FQHC Look-Alike status was made available to those health centers that do not receive funding under section 330, but operate and provide services similar to grant-funded programs. As such, FQHC Look-Alike entities are expected to demonstrate the same commitment as grantees to serve all populations residing in their respective medically underserved communities, and to satisfy the administrative, management, governance and service-related requirements unique to section 330 funded health centers.

11 PHS Act 42 U.S.C. §254b, Section 330.

12 Enabling services are non-clinical services that aim to increase access to healthcare and improve health outcomes, and include services such as health education, interpretation, child care, transportation, and case management.

13 *Id.*

14 *Id.*

15 *Id.*

16 *Id.*

17 *Id.*

18 *Id.*

19 *Id.*

20 *Id.* at Section 330(k)(3)(L).

21 *Id.*

22 *Id.* at Section 330(k)(3)(A).

23 *Id.* at Section 330(a)(1) and (b)(1), (2).

24 Bureau of Primary Health Care ("BPHC") Policy Information Notice 98-23. The BPHC is one of the bureaus of HRSA and is tasked with the funding and oversight of funding of health centers.

25 *Id.* at Section 330(k)(3)(H)(ii).

26 *Id.* at Section 330(k)(3)(H) and 42 CFR 51c.304(d)(iii) and (iv)

27 FQHCs are covered by the anti-kickback safe harbor, which protects arrangements between health centers and other providers/suppliers of services that maintain or expand accessibility or reduce the cost of services provided to health center patients. *See* Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Federally Qualified Health Centers Arrangements Under the Anti-Kickback Statute, 42 C.F.R § 1001 (2007).

28 Federal Tort Claims Act, 28 U.S.C. §§ 1346(b), 2671-2680.

29 Out-stationed eligibility workers distribute and process Medicaid applications for children and pregnant women in places other than Medicaid offices. The National Health Service Corps is a program in which health professionals provide primary health care services in underserved communities. In exchange, the providers are given either loan repayments or scholarships throughout their medical education (not to exceed four years).

30 The Vaccines for Children Program is a federally funded program that supplies vaccine free of charge to participating providers. The vaccine may then be made available to children up to 19 years of age who are: Medicaid Enrolled; uninsured; underinsured; or American Indian or Alaska Native.

31 The federal 340B Drug Pricing Program provides access to reduced price prescription drugs to over 14,250 health care facilities (as of December 2009) certified by the HHS as "covered entities."

32 The American Recovery and Reinvestment Act of 2009 supplemented the grants available to FQHCs in the form of capital improvement program grants and facility improvement grants.

33 PHS Act 42 U.S.C. §254b, Section 330.

34 Medicare Benefit Policy Manual, Chapter 13-Rural Health Clinic and Federally Qualified Health Center Services, Section 30.

35 Medicare Benefit Policy Manual, Chapter 13-Rural Health Clinic and Federally Qualified Health Center Services, Section 30.

36 *Id.*

37 If the patient was paying out of pocket, such as in the case of a deductible, the FQHC would only collect the amount dictated by the sliding payment scale. Because the patient does not pay the deductible and the FQHC bills Medicare directly, it receives a higher payment.

38 *Id.*

39 Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), §431.

40 *See* Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Federally Qualified Health Centers Arrangements Under the Anti-Kickback Statute, 42 C.F.R § 1001 (2007).

41 Once individuals are deemed to be qualified for PAP, the pharmacy dispenses their PAP medications and notes that the medications were dispensed for a PAP patient. At the end of each month (or quarter, depending in the manufacturer's policy), the pharmacy determines the quantity of each manufacturer's drugs dispensed to PAP patients and sends a report with this information to the manufacturer. The manufacturer then ships the pharmacy a sufficient quantity of each product to replace what was dispensed to PAP patients.

42 http://oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-01C.pdf.

43 28 U.S.C. §§ 1346(b),2671-2680.

44 Federally Supported Health Centers Assistance Act ("FSHCAA:) of 1992 and 1995, 42 U.S.C. §233(a)-(n).

45 *Id.*

46 *Id.*

47 GAO-09-693R Federal Tort Claims Act to Congressional Committees, June 24, 2009.

48 FSHCAA at §233.

49 Bureau of Primary Health Care Program Information Notice (PIN) 99-08.

50 *Id.*

51 *Id.*

52 *Id.*

53 Bureau of Primary Health Care PIN 97-27, updated with PIN 98-24.

54 *Id.*

55 *Id.* at 10.

56 *Id.* at 12-13.

57 *Id.* at 15-16.

58 *Id.* at 18.

59 PL 111-148.

60 *Id.* at § 10333.

61 *Id.*

62 *Id.*

ABA HEALTH LAW SECTION INTEREST GROUPS

Free Member Benefit: Get the latest info on your specialty(ies)!

Please enroll me in the following Interest Groups (Section Members may join up to three Interest Groups):

- ❑ Business & Transactions
- ❑ eHealth, Privacy & Security
- ❑ Employee Benefits & Executive Compensation
- ❑ Healthcare Facilities Operations
- ❑ Healthcare Fraud & Compliance
- ❑ Healthcare Litigation & Risk Management
- ❑ Managed Care & Insurance
- ❑ Medical Research, Technology & Clinical Ethical Issues
- ❑ Payment & Reimbursement
- ❑ Physician Issues
- ❑ Public Health & Policy
- ❑ Tax & Accounting

Name: ____________________

ABA No. ____________________

Affiliation: ____________________

Address: ____________________

City/State/Zip: ____________________

Phone: ____________ Fax: ____________

E-Mail: ____________________

QUESTIONS? Call:

Wanda Workman, Section Director at 312/988-5548

Return to:

Wanda Workman
Health Law Section
American Bar Association
321 N. Clark Street
Chicago, IL 60654-7598