HEALTH CENTER AFFILIATIONS WITH RESIDENCY PROGRAMS

Presented By:

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Relevant FQHC Requirements

Eligibility: Corporate Structure

- Public or private non-profit, charitable, tax-exempt organization that receives funding (directly or as a subrecipient) under Section 330 of the Public Health Service Act; OR Is determined by DHHS to meet requirements to receive funding without actually receiving a grant (*i.e.,* an FQHC "lookalike")

Eligibility: Location

- FQHCs must serve a medically underserved area (MUA) or medically underserved population (MUP) designated by DHHS

Program Requirements: Services

- Must provide either directly or through contract or established arrangement:
  - All required primary and preventive services
  - Supplementary services including referrals to other providers
  - Case management services including eligibility assistance
  - Enabling services including outreach, transportation and translation
  - Education regarding the availability and proper use of health services
  - Additional health services as appropriate

Program Requirements: Payment for Services

- Must provide services to all residents of the service area **regardless of ability to pay**
- Must have a schedule of charges designed to cover the reasonable costs of operation and consistent with locally prevailing rates
- Must have a corresponding schedule of discounts adjusted based on ability to pay for persons below 200% of poverty (full discounts for persons below 100% of poverty)

Program Requirements: Governance

- Must be governed by a community-based Board of Directors
  - Must have between 9 and 25 members
  - Majority (at least 51%) must be active consumers of health center services
  - Consumer Board members must reasonably represent the patient population served in terms of demographic factors such as race, ethnicity and gender

Program Requirements: Governance

- Non-consumer Board members must be representative of the community served and be selected for expertise in areas such as finance and banking, legal community affairs, *etc.*
- No more than one half of the non-consumer members can derive more than 10 percent of their income from the health care industry
- If funded under more than one section 330 program, must demonstrate appropriate representation from each of the populations served by the health center

Program Requirements: Governance

- Governing Board must autonomously exercise authorities regarding (among other things)
  - Establishment of operating and service policies (hours, services, personnel, financial management)
  - Approval of annual budget and project plan
  - Strategic and operational planning
  - Selection, evaluation and dismissal of Executive Director/Chief Executive Officer

Program Requirements: Management

- CEO must be directly employed by the health center
  - Preferred that management team and core staff are directly employed, subject to good cause exceptions
- Must have a direct line authority from the Board to the CEO who is responsible for hiring, supervision and termination of staff
- Must have effective administrative and clinical leadership, systems and procedures

Program Requirements: Clinical Operations

- Must employ a core staff of clinical staff that is multi-disciplinary, and culturally and linguistically competent
- Expected to establish appropriate linkages and collaborative arrangements with other community providers: referrals, admitting privileges, after-hours coverage, integrated delivery systems
- Must have ongoing quality improvement programs

Program Requirements: Financial and Information Systems

- Must have a financial system that accurately reflects the financial performance of the organization and assures viability and competitiveness
- Must maximize non-Federal revenue (Medicaid, Medicare, third party, patients, *etc*.)
- Must arrange for an annual independent audit to assess financial performance
- Must have an MIS system that is able to collect, organize and analyze data for reporting and to support management decision-making

Program Requirements: Compliance with 45 CFR Part 74

- Section 330 grantees (but not FQHC lookalike entities) must comply with the requirements and standards set forth in 45 CFR Part 74 (or Part 92, for public entities) regarding
  - Procurement of goods and services utilizing Federal funds (in whole or in part)
  - Acquisition, management and disposition of property and equipment, acquired or improved with Federal funds (in whole or in part)

BENEFITS AVAILABLE TO SECTION 330 GRANTEES

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Benefits Available to Section 330 Grantees

- Access to Federal grants to support the costs of otherwise uncompensated comprehensive primary and preventive health care and "enabling services" delivered to medically underserved populations at sites within the Section 330 approved scope of project
- Access to Federal grants to support the costs of planning/developing practice management or managed care networks/plans, as well as operating costs for networks/plans owned and/or controlled by Section 330–funded health centers

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Benefits Available to Section 330 Grantees

- Access to Federal loan guarantees of the principal and interest on loans made by non-Federal lenders for the costs of developing and operating managed care and practice management networks or plans, which are majority owned and/or controlled by Section 330-supported health centers
- Access to grant support/loan guarantees for capital improvements

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Benefits Available to Section 330 Grantees

- Access to Federal Tort Claims Act ("FTCA") coverage, in lieu of purchasing malpractice insurance
- Safe Harbor under the Federal anti-kickback statute for certain arrangements with other providers or suppliers of goods, services, donations, loans, *etc.*, which benefit the medically underserved population served by the FQHC

Benefits Available to Section 330 Grantees

- Access to favorable drug pricing under Section 340B of the Public Health Service Act
- Access to reimbursement under the Prospective Payment System ("PPS") or other state-approved alternative payment methodology (which is predicated on a cost-based reimbursement methodology) for Medicaid services and cost-based reimbursement for services provided under Medicare; "wraparounds" for difference between Medicaid managed care capitation and PPS (wraparound on Medicare managed care payments effective FY 2006)

Benefits Available to Section 330 Grantees

- Absent an alternative approved by the Centers for Medicare and Medicaid Services ("CMS"), right to have State Medicaid agencies outstation Medicaid eligibility workers on FQHC site (or right to contract with Medicaid for FQHC staff to carry out eligibility activities)
- Reimbursement by Medicare for "first dollar" of services rendered to Medicare beneficiaries, *i.e.*, deductible is waived

Benefits Available to Section 330 Grantees

- Safe harbor under the Federal anti-kickback statute for waiver of co-payments to the extent a patient's income is below 200% of Federal poverty guidelines
- Access to providers through the National Health Service Corps if the health center's service area is designated a Health Professional Shortage Area ("HPSA")
- Access to the Federal Vaccine For Children program and eligibility to participate in the Pfizer Sharing the Care Program

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COLLABORATION OPP0RTUNITIES

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Formal Contracts and Agreements

In an arrangement in which a health center partners with a hospital (whether or not in connection with an ER diversion strategy), assuming financial and operational responsibility for operating a new or existing primary care clinic, definitive agreements may include:

- Lease of space and/or equipment
- Lease of clinical personnel and/or support staff (unless workforce transfers)
- "Community Benefit Grant" from the hospital to the health center
- Affiliation Agreement
- Residency Training Agreement
- Medical Records Agreement
- Confidentiality Agreement

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Lease of Clinical Personnel

- Contracted clinicians provide services in accordance with the health center's health care and other applicable policies and procedures (*e.g.*, clinical guidelines, productivity and QA standards, standards of conduct, record-keeping)
- Contracted clinicians meet the health center's professional standards and qualifications, including credentialing and privileging
- Health center CEO (with the CMO) maintains ultimate authority for monitoring/evaluating the performance of contracted clinicians and whether they are compliant with the health center's policies, procedures, standards and qualifications

Lease of Clinical Personnel

- Health center retains the right to terminate the contract or to request/require removal, suspension and/or replacement of any contracted clinician who fails to meet qualifications, is non-compliant with policies and procedures, performs unsatisfactorily or provides sub-standard care
- Health center is responsible for billing and collecting from third parties/patients and retains all revenue secured for services provided by contracted personnel

FTCA Considerations for Lease

- Services must be clearly within scope of project
- Services must be clearly within scope of contract
- Contract must be between individual clinician and health center
- All services must be billed, revenue retained by health center – cannot split/share revenues

FTCA Considerations

- If services include cross/call coverage which requires services to non-health center patients, must "exactly" match an approved regulatory exception or a particularized determination must be obtained

Community Benefit Grant

- To assist in defraying a portion of the costs of providing otherwise uncompensated preventive and primary care to health center patients. Key factors:
  - Represents a "bona fide" charitable donation to assist the underserved population served by the health center as well as the community, as a whole
  - Furthers the charitable missions of the health center and the hospital
  - Presents a minimal risk of abuse of Federal health care programs
  - Terms are narrowly tailored so that the benefit does not exceed what is necessary to accomplish stated purpose
  - Does not limit or restrict patient's freedom of choice and/or the provider's professional judgment

Community Benefit Grant

- The arrangement contains certain safeguards (either contractual or in practice) to protect against prohibited referrals or generation of other business. In particular, the arrangement must be structured to address the following considerations:
  - Based on an annual fixed amount
  - Funds do not include discounts, rebates or reductions in charges
  - No restrictions other than to expend funds for uncompensated costs of care
  - Ancillary agreements consistent with applicable safe harbors (e.g., fair market value leases)

Health Center Safe Harbor

- Signed into law December 8, 2003 – **Final rule** issued October 4, 2007
- Protects from prosecution under the Federal Anti-kickback law certain arrangements between health center grantees and other providers or suppliers of goods, services, donations, loans, etc.
  - Must contribute to the health center's ability to maintain or increase the availability, or enhance the quality, of services provided to its medically underserved patients
- Requirements
  - Written agreement signed by both parties that covers and specifies the amount of all goods, items, services, donations, loans, etc. provided to the health center
    - Amount may be fixed sum, fixed percentage, or established by a fixed methodology
    - Can have multiple agreements between the parties if they reference each other or cross reference a master list

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Safe Harbor for Section 330 Grantees

- OIG was directed to establish standards, taking into consideration whether the arrangement –
  - Results in savings of Federal grant funds or increased revenue to the health center
  - Restricts or limits an individual's freedom of choice
  - Protects a health care professional's medical judgment regarding medically appropriate treatment
- OIG was permitted to consider other factors consistent with Congressional intent of legislation

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Residency Training Agreements (Teaching Programs)

- Hospital maintains control over, and responsibility, for the costs of, teaching activities performed at the health center, which are provided in accordance with the hospital's policies and procedures
  - Classroom teaching, undergraduate programs, and orientation programs
  - Curriculum development and faculty meetings
  - Resident recruitment, selection, placement and evaluation, and setting of schedules (but health center should have input and right to receive prior notice regarding changes)
  - Program administration and evaluation

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Residency Training Agreements (Teaching Programs)

- Hospital retains general responsibility for salaries and benefits (including malpractice insurance) of hospital faculty and residents and other GME costs but health center pays for clinical time of faculty for which it bills (need to avoid "double billing" of Medicare/Medicaid and Federal grants)
  - If hospital incurs substantially all costs of teaching activities, hospital receives direct and indirect GME payments (health center receives payment for direct patient care)
- Hospital provides FMV payment to the health center for the time spent by its clinicians and support staff in providing (as well as equipment and space used for) teaching activities

EMERGENCY ROOM DIVERSION

ER Diversion Grant Program

- The Deficit Reduction Act of 2006 and related CMS guidance (August, 2007) authorize grants to States to support the establishment of "alternate non-emergency services providers" who can furnish alternatives to providing non-emergency care in the emergency room (ER)

ER Diversion Grant Program

- PREFERENCE - In providing for grants to States, DHHS must provide preference to States that establish, or provide for, "alternate non-emergency services providers," or networks of such providers, that --
  - Serve rural or underserved areas where Medicaid beneficiaries may not have regular access to providers of primary care services; or
  - Are in partnership with local community hospitals

ER Diversion Grant Program

- "Alternate non-emergency services providers" include:
  - Physician's offices
  - Health care clinics
  - Community health centers
  - Hospital outpatient departments
  - Similar health care providers
- Alternate non-emergency services provider must be able to provide clinically appropriate services for the diagnosis or treatment of a condition at a time that is contemporaneous with the time that the services would have been provided in the ER of the hospital

ER Diversion and DRA

- The DRA also
  - Authorizes hospital ER to charge patients co-payments as a condition to receiving care for a non-emergency condition if
    - Through a screening exam, it is determined the patient does not have an emergency medical condition BUT he/she still chooses to use the ER for care AND
    - Hospital:
      - Notifies patient of co-pay
      - Identifies an available and accessible alternate non-emergency services provider that can provide the services contemporaneously

CMS Issues Guidance on DRA Emergency Room Diversion

- Overall impact on health centers
  - Provides opportunity for initiating or increasing health center- local hospital collaborative activities that recognize health centers as appropriate alternate non-emergency services providers
  - Establishes legal principle that, after an appropriate EMTALA screening and non-emergency determination, the patient can choose whether to receive care from the hospital or from an alternative provider

CMS Issues Guidance on DRA Emergency Room Diversion

- Outstanding issues:
  - "Contemporaneously" replaced by "concurrently" in CMS guidance but still no definition
    - HOWEVER, indicates services must be provided by the alternate provider at the same time as they would have been provided at the ER
  - Amount of allowable cost-sharing for low-income patients
    - Alternate providers cannot impose cost-sharing higher than the amounts allowed for the ER
    - BUT, ER cost-sharing for individuals 100 – 150% FPL is limited to twice the Medicaid nominal amount
    - What if this amount is less than the health center's charge for the service after applying its schedule of discounts? Is this inconsistent with health center obligations?

Common Issues

- Separating EMTALA screening personnel from ER treating clinicians
- Documenting patient choice
- Meeting "contemporaneous" standard
- "Control" issues
- Collaboration between providers and other staff transition issues
- Determination of ongoing financial support
- Infrastructure

Potential Models for Collaboration

- FQHC acquires existing hospital primary care clinic sites on or near hospital campus
- FHQC and hospital partner around the development of new sites located on or near hospital campus
- Hospital refers patients who present with non-urgent conditions to FQHC's existing site(s), possibly with transportation linkage
- In all scenarios, a key question is whether patients are referred to the FQHC in lieu of treatment of non-emergency condition OR only for follow-up appointment

Change in Scope of Project

- Change in Scope of Project
  - Whether acquiring a "site" (may simply be through a lease of space in the hospital) previously operated by the hospital or starting a new "site", a change in scope request will have to be submitted and approved by HRSA per PIN 2008-01
  - The site may have limited service scope and limited hours (i.e., when ER is busiest), however, the health center must assure that its full scope of services is readily accessible to these patients

Collaborative Decision-Making

- Cross Board participation
  - Cross membership on each other's Boards of Directors
  - Participation in key committees
- Joint Steering Committee

LEGAL CONSIDERATIONS

BPHC Affiliation Policies

- Policy Information Notice ("PIN") #97-27: Affiliation Agreements of Community and Migrant Health Centers
  - Only applies to health centers receiving funds under the community health center (Section 330(e) and migrant health center (Section 330 (g) programs
  - An "affiliation" is any arrangement with another entity or entities (contract, joint venture, corporate integration) that affects a health center's compliance with Federal grant requirements pertaining to health center integrity and autonomy

BPHC Affiliation Policies

- Requirements of PIN #97-27
  - Areas of critical concern:
    - Corporate structure
    - Governance
    - Management and finance
    - Health services/clinical operations
- Corporate Structure
  - No parent/subsidiary or similar structures (*e.g.*, Sole Member) unless the health center retains all Board selection and composition requirements and authorities, and structure is specifically approved by BPHC

BPHC Affiliation Policies

- Governance
  - Under all affiliation arrangements, Board must remain compliant with all Section 330-related selection and composition requirements
    - Size
    - Consumer majority
    - Limit on health care industry representation
    - Demographic composition
    - Appropriate expertise of non-consumer members
    - Conflict of interest standards

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BPHC Affiliation Policies

- Governance (cont.)
  - No other party may:
    - Select (1) the majority of the health center Board members; (2) the majority of the non-consumer members; (3) the Board Chairperson; or (4) the majority of members of Executive Committee
    - Preclude the selection, or require the dismissal, of Board members not appointed by that party

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BPHC Affiliation Policies

- Governance (cont.)
  - Under all affiliation arrangements, Board must retain all authorities required by law or regulation
    - Preparing and approving the health center's overall plan, including its strategic and operational plans
    - Preparing and approving the health center's annual budget
    - Establishing and adopting personnel, financial management, and health care policies and procedures

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BPHC Affiliation Policies

- Governance (cont.)
  - Authorities (cont.)
    - Evaluating the health center's activities
    - Establishing and maintaining collaborative relationships with other health care providers and social agencies in the relevant service area
    - Maintaining a commitment to provide services to the medically underserved population(s) served by the health center

BPHC Affiliation Policies

- Governance (cont.)
  - No other party may, with respect to such authorities:
    - Have overriding approval authority
    - Have veto authority (through "super-majority" requirement or other means)
    - Have "dual majority" authority

BPHC Affiliation Policies

- Management and Finance: No other party can
  - Select or dismiss the health center's Executive Director/CEO (no exceptions)
  - Select or dismiss the health center's CFO or CMO (subject to good cause exception)
- Health Services/Clinical Operations: No other party can
  - Hire or dismiss the majority of the health center's full-time primary care providers (subject to good cause exception)
  - Control the health center's relationships with other entities unless there is no impact on compliance with statutory and/or regulatory requirements

BPHC Affiliation Policies

- PIN #98-24: Amendment to #97-27
  - BPHC states a *preference* that health centers directly employ CFO, CMO, and majority of full-time primary care providers
  - BPHC may grant a "good cause" exception based on:
    - Demonstration of programmatic benefit
    - Maintenance of sufficient accountability for operation and direction of grant-approved project and expenditure of grant funds

BPHC Affiliation Policies

- Programmatic Benefit
  - Continued or improved access
  - Improved expertise
  - Increased capital
  - Maintained or improved quality of care

BPHC Affiliation Policies

- Accountability criteria
  - Reservation of sufficient rights and control to maintain overall responsibility
  - Justification for the performance of the work by a third party
  - Establishment of appropriate systems/processes to assure satisfactory performance in accordance with Section 330
  - Execution of a written agreement that complies with DHHS administrative requirements

BPHC Affiliation Policies

- Review Process
  - As part of the Review Process, either in conjunction with a grant application or under an independent submission (for a new affiliation established in the interim between applications), the health center may need to submit an "Affiliation Checklist" and related documents that demonstrate compliance with accountability requirements

Other Legal Considerations

- Other Section 330-related laws, regulations, expectations and policies
  - PIN # 98-23: Program Expectations
  - PIN # 2002-07: Scope of Project Policy
  - Other PINs and Program Assistance Letters (PALs)
  - 45 CFR Part 74 (or Part 92): Procurement and property standards (incorporating OMB Circulars A-110 and A-122)
  - Public Health Service ("PHS") policies
  - Notice of Grant Award ("NGA") and special terms and conditions
  - FTCA coverage
  - Section 340B discount drug pricing

Other Legal Considerations

- Medicaid and Medicare
- Tax considerations
- Fraud and abuse (anti-kickback, false claims)
- Physician self-referral (Stark I & II)
- Antitrust
- State laws and regulations