

NOTICE OF DECISION TO TAKE ACTION ON PROPOSED REGULATION

In accordance with section 4-168(d) of the Connecticut General Statutes, the Department of Social Services ("DSS") hereby provides notice that it will proceed with adopting DSS regulation #12-24.

DSS is proceeding with the adoption of this regulation because the existing regulations are outdated and inconsistent with the federal requirements for payments to federally qualified health centers under 42 USC § 1396a (bb). The proposed regulations: add new definitions as necessary; specify services that are covered and not covered; specify services that are billable as an encounter as well as services that are not billable but included in the encounter rate; describe the process by which an FQHC may request an adjustment of its encounter rate based upon a change in scope of services; clarify prior authorization requirements; describe billing requirements and the methodology for calculating the encounter rate; and outline documentation and audit requirements.

DSS received comments on the proposed regulation and has provided responses to those comments. Copies of the revised regulation and the response to comments are attached to this notice. As required by section 4-168(d) of the Connecticut General Statutes, the responses to comments contain the principal considerations that DSS received for opposing certain aspects of the proposed regulation and DSS's reason for either agreeing with or rejecting the considerations, indicating its intended action.

Copies of the revised regulation and the response to comments are also available for copying and inspection pursuant to the Freedom of Information Act (Conn. Gen. Stat. §§ 1-200, et seq.) upon request to:

Department of Social Services
Office of Legal Counsel, Regulations and Administrative Hearings
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Hartford, CT 06105
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IMPORTANT: Read instructions on back of last page (Certification Page) before completing this form. Failure to comply with instructions may cause disapproval of proposed Regulations

State of Connecticut
REGULATION
of

NAME OF AGENCY

Department of Social Services

Concerning

SUBJECT MATTER OF REGULATION

Requirements for Payment to Federally Qualified Health Centers

Section 1. The Regulations of Connecticut State Agencies are amended by adding new sections 17b-262-994 to 17b-262-1005, inclusive, as follows:

(NEW) Sec. 17b-262-994. Scope

Sections 17b-262-994 to 17b-262-1005, inclusive, of the Regulations of Connecticut State Agencies set forth the Department of Social Services' requirements for payment to federally qualified health centers for services provided to clients who are eligible to receive such services under Medicaid pursuant to section 17b-261 of the Connecticut General Statutes. Federally qualified health centers shall be reimbursed in accordance with the Medicaid prospective payment system under 42 USC 1396a (bb).

(NEW) Sec. 17b-262-995. Definitions

As used in section 17b-262-994 to section 17b-262-1005, inclusive, of the Regulations of Connecticut State Agencies:

- (1) "Advanced practice registered nurse" or "APRN" means a person licensed under section 20-94a of the Connecticut General Statutes;
- (2) "Allied health professional" or "AHP" means:
 - (A) A licensed or certified practitioner performing within his or her scope of practice in any of the professional and occupational license or certification categories in Chapters 376b, 378, 379a, 383a, and 383c of the Connecticut General Statutes and shall include alcohol and drug counselors, dental hygienists, marital and family therapists, professional counselors; and registered nurses;
 - (B) A licensed master social worker working under the professional supervision of a physician, APRN, psychologist, licensed marital and family therapist, LCSW or a licensed professional counselor in accordance with section 20-195m of the Connecticut General Statutes; and
 - (C) A license-eligible individual as defined in subsection (26) of this section;
- (3) "Baseline encounter rate" means the encounter rate calculated for the initial or first year under the prospective payment system;

- (4) "Behavioral health encounter" means an encounter between a client and a licensed clinical psychologist, a licensed clinical social worker, a psychiatrist or an allied health professional for the provision of covered behavioral health services;
- (5) "Behavioral health service" means a preventive, diagnostic, therapeutic, rehabilitative or palliative item or service provided by:
 - (A) A physician, psychiatric APRN, psychologist or LCSW acting within the practitioner's scope of practice as defined in chapters 370, 378, 383 and 383b of the Connecticut General Statutes;
 - (B) An AHP acting within the practitioner's scope of practice, as defined in title 20 of the Connecticut General Statutes; or
 - (C) An unlicensed or non-certified individual, who is otherwise qualified to perform services under the applicable licensure category sections of the Regulations of Connecticut State Agencies, working under the direct supervision of a licensed AHP. Supervision of unlicensed or non-certified individuals shall be provided in accordance with sections 20-74s, 20-195c, 20-195m, 20-195n and 20-195dd of the Connecticut General Statutes;
- (6) "Change in the scope of service" means a change in the type, intensity, duration or amount of services provided by an FQHC. A change in the cost of the service alone is not considered a change in the scope of service;
- (7) "Chiropractor" means a person licensed pursuant to section 20-27 of the Connecticut General Statutes;
- (8) "Chiropractic services" means the services described in 42 CFR 440.60 and subsection (1) of section 20-24 of the Connecticut General Statutes;
- (9) "Client" means a person eligible for goods or services under Medicaid;
- (10) "Clinical psychologist" means a person licensed pursuant to section 20-188 of the Connecticut General Statutes;
- (11) "Commissioner" means the commissioner of Social Services or the commissioner's designee;
- (12) "Dental encounter" means an encounter between a client and a dentist or dental hygienist for the provision of covered dental services;
- (13) "Dental hygienist" means a person licensed pursuant to section 20-126j of the Connecticut General Statutes;
- (14) "Dental service" means any diagnostic, preventive, or corrective procedures administered by or under the direct supervision of a dentist;
- (15) "Dentist" means a person licensed pursuant to section 20-106 of the Connecticut General Statutes;
- (16) "Department" or "DSS" means the Department of Social Services or its agent;

- (17) "Early and Periodic Screening, Diagnostic and Treatment Services" or "EPSDT services" means the services provided in accordance with the requirements of 42 USC 1396a (a) (43), 42 USC 1396d (r) and 42 USC 1396d (a) (4) (B) and implementing federal regulations found in 42 CFR 441, Subpart B and section 17b-261 (i) of the Connecticut General Statutes;
- (18) "Early and Periodic Screening, Diagnostic and Treatment Special Services" or "EPSDT Special Services" means services provided in accordance with 42 USC 1396d (r) (5), as amended from time to time;
- (19) "Encounter" means a face-to-face visit between a client and health professional or an allied health professional for medically necessary services and includes the client's visit to the FQHC and all services and supplies incidental to the health professional's services. Visits with more than one health professional or allied health professional or multiple visits with the same health professional or allied health professional that take place on the same day shall be considered one encounter, except under either of the following circumstances:
- (A) A client, subsequent to the first encounter, suffers an illness or injury requiring additional diagnosis or treatment; or
 - (B) A client has different types of encounters (medical, behavioral health and dental) for different diagnoses on the same day. Medicaid pays for one encounter per day for each of these services;
- (20) "Encounter rate" means the all-inclusive PPS rate that the Department reimburses an FQHC for an encounter pursuant to 42 USC 1396a (bb);
- (21) "Federally qualified health center" or "FQHC" has the same meaning as provided in 42 USC 1396d (l) (2) (B);
- (22) "Health professional" means a physician, physician assistant, advanced practice registered nurse, nurse midwife, chiropractor, ophthalmologist, optometrist, podiatrist, dentist, clinical psychologist, licensed clinical social worker or psychiatrist;
- (23) "Health Resources and Services Administration" or "HRSA" means the division of the U.S. Department of Health and Human Services that approves grant awards to and scope of projects for FQHCs;
- (24) "Licensed clinical social worker" or "LCSW" means a person licensed pursuant to section 20-195n of the Connecticut General Statutes;
- (25) "Licensed master social worker" or "LMSW" means a person licensed pursuant to 20-195n of the Connecticut General Statutes;
- (26) "License-eligible" means a person whose education, training, skills and experience satisfy the criteria, including accumulation of all supervised service hours, for any of the professional and occupational license or certification categories in Chapters 370, 376b, 379a, 383a, 383b and 383c of the Connecticut General Statutes, and has applied for but not yet passed the licensure exam;

- (27) "Medicaid" means the program operated by the Department of Social Services pursuant to section 17b-260 of the Connecticut General Statutes and authorized by Title XIX of the Social Security Act;
- (28) "Medical encounter" means an encounter between a client and a health professional or an allied health professional for the provision of covered medical services;
- (29) "Medical service" means a preventive or diagnostic service provided by a physician, physician assistant, advance practice registered nurse or nurse midwife for the treatment of an illness or injury;
- (30) "Medically necessary" and "medical necessity" have the same meaning as provided in section 17b-259b of the Connecticut General Statutes;
- (31) "Nurse midwife" means a person licensed under section 20-86c of the Connecticut General Statutes;
- (32) "Off-site services" means services that are provided at a location other than the FQHC or a satellite of the FQHC;
- (33) "Ophthalmologist" means a physician licensed pursuant to chapter 370 of the Connecticut General Statutes, who within his or her scope of practice as defined by state law, specializes in the branch of medicine dealing with the structure, functions, pathology, and treatment of the eyes;
- (34) "Optometrist" means a person licensed pursuant to Chapter 380 of the Connecticut General Statutes to practice optometry as delineated in subsections (a) (1) and (2) of section 20-127 of the Connecticut General Statutes;
- (35) "Physician" means a person licensed pursuant to section 20-13 of the Connecticut General Statutes;
- (36) "Physician assistant" means a person licensed pursuant to section 20-12b of the Connecticut General Statutes;
- (37) "Podiatric services" means services provided by a podiatrist within the scope of practice under Chapter 375 of the Connecticut General Statutes;
- (38) "Podiatrist" means a person licensed to practice podiatric medicine pursuant to section 20-54 of the Connecticut General Statutes;
- (39) "Point-of-care testing" means medical testing at or near the site of patient care and includes, but is not limited to, blood glucose testing, blood gas and electrolyte analysis, rapid coagulation testing, rapid cardiac markers diagnostics, drugs-of-abuse screening, urine strips testing, pregnancy testing, fecal occult blood analysis, food pathogens screening, hemoglobin diagnostics, infectious disease testing and cholesterol screening;
- (40) "Prior authorization" means approval for the provision of a service or the delivery of goods from the department before the provider actually provides the service or delivers the goods;

- (41) "Provider enrollment agreement" means the agreement between the department and the FQHC for the provision of covered services to Medicaid clients;
- (42) "PPS" means the prospective payment system under 42 U.S.C. 1396a (bb);
- (43) "Registered Nurse" means a person licensed pursuant to 20-93 of the Connecticut General Statutes;
- (44) "Registration" means the process of notifying the department of the initiation of a service, which includes providing information regarding the evaluation findings and plan of care. Registration may serve in lieu of prior authorization if a service is designated by the department as requiring registration only;
- (45) "Routine foot care" means clipping or trimming of normal or mycotic toenails; debridement of the toenails that do not have onychogryposis or onychiauxis; shaving, paring, cutting or removal of keratoma, tyloma or heloma; and nondefinitive shaving or paring of plantar warts except for the cauterization of plantar warts;
- (46) "Scope of project" means the document that delineates the FQHC's approved service sites, services, providers, service area and target population for which grant funds have been approved by HRSA under section 330 of the Public Health Service Act;
- (47) "Simple foot hygiene" means self-care including, but not limited to: observation and cleansing of the feet; use of skin creams to maintain skin tone of both ambulatory and bedridden patients; nail care not involving professional attention; and prevention and reduction of corns, calluses and warts by means other than cutting, surgery or instrumentation;
- (48) "Systemic condition" means the presence of a metabolic, neurologic, or peripheral vascular disease, including, but not limited to, diabetes mellitus, arteriosclerosis obliterans, Buerger's disease, chronic thrombophlebitis and peripheral neuropathies involving the feet, which would justify coverage of routine foot care;
- (49) "Under the direct supervision" means that a health professional or a licensed AHP, as established in (3)(A) of this section:
- (A) Provides weekly supervision of the work performed by unlicensed clinical staff or non-certified staff or individuals in training;
 - (B) Provides a minimum of monthly supervision for the work performed by certified staff; and
 - (C) Accepts primary responsibility for the health services performed by the unlicensed, certified or non-certified staff or individuals in training.
- (50) "Under the professional supervision" has the same meaning as provided in section 20-195m of the Connecticut General Statutes.

(NEW) Sec. 17b-262-996. Provider Participation

In order to participate in the Connecticut Medicaid program and provide FQHC services eligible for reimbursement from the department, each FQHC shall:

- (1) Comply with all applicable state licensing requirements;

- (2) Comply with all departmental enrollment requirements, including sections 17b-262-522 to 17b-262-532, inclusive, of the Regulations of Connecticut State Agencies;
- (3) Ensure that all health professionals employed by or under contract arrangements with the FQHC to provide services meet all applicable federal and state licensing and certification requirements;
- (4) Submit a copy of the FQHC's scope of project and any amendments to the scope of project in accordance with subsection (c) of section 17b-245d of the Connecticut General Statutes; and
- (5) Submit a copy of the HRSA Notification of Grant Award Authorization of Public Health Service Funds.

(NEW) Sec. 17b-262-997. Services Covered

- (a) Covered core services for FQHCs include the following:
 - (1) Medical services furnished by a physician, physician assistant, advanced practice registered nurse or nurse midwife. The services shall be within the scope of practice of his or her profession under state law. There shall be a written agreement between the FQHC and the health professional stating that he or she will be paid by the FQHC for such services; and
 - (2) Services and supplies furnished as incident to professional services furnished by a physician, physician assistant, or advanced practice registered nurse.
- (b) Covered noncore services for FQHCs are those services, other than core services, that include the following:
 - (1) Behavioral health services;
 - (2) Chiropractic services;
 - (3) Dental services provided by a dentist or dental hygienist;
 - (4) Podiatric services provided by a podiatrist, except for routine foot care, which is only covered if the client has a systemic condition and is limited to one treatment every 60 days services;
 - (5) Tobacco cessation counseling services; and
 - (6) Vision care services provided by an ophthalmologist or optometrist.

(NEW) Sec. 17b-262-998. Services Not Covered

The following services are not covered:

- (1) Services that are not covered in the Medicaid state plan;
- (2) Services that are not medically necessary;
- (3) Canceled services or appointments that are not kept;
- (4) Inpatient services;
- (5) Simple foot hygiene;

- (6) Any service requiring authorization or registration for which the provider did not obtain such authorization or registration;
- (7) Any procedures or services that are solely educational, social, research, recreational, experimental or generally not accepted by medical practice; or
- (8) Visits for the sole purpose of obtaining or refilling a prescription, the need for which was previously determined.

(NEW) Sec. 17b-262-999. Billable Services

- (a) Billable services for FQHCs shall include core and noncore services identified in section 17b-262-997 of the Regulations of Connecticut State Agencies;
- (b) Covered core and noncore services shall be billed on an encounter basis in accordance with section 17b-262-1002 and are subject to the following limitations:
 - (1) Billable encounters shall include encounters that:
 - (A) Take place at a service site approved by HRSA as part of an FQHC; or
 - (B) Take place in a patient's home for the purpose of providing services to FQHC patients; and
 - (C) Are documented in the patient health records.
 - (2) The services of a registered nurse shall be billed as a medical encounter unless provided incident to a medical encounter as described in subsection (b)(3) of this section;
 - (3) Encounters with more than one health professional for the same type of service (e.g., a nurse and a physician provide a medical encounter) and multiple interactions with the same health professional that take place on the same day constitute a single encounter except when the patient, after the first interaction, suffers illness or injury requiring additional diagnosis and treatment.
 - (4) Tobacco cessation counseling shall be prescribed by a physician, physician's assistant, dentist or APRN and may be billed as a medical encounter, behavioral health encounter or dental encounter depending upon the type of health professional or allied health professional providing the service. The following health professionals may provide tobacco cessation counseling:
 - (A) Physicians;
 - (B) Physician assistants;
 - (C) APRNs;
 - (D) Dentists;
 - (E) Clinical Psychologists;
 - (F) LCSWs; and
 - (G) Allied health professionals.

(5) Group sessions prescribed by a health professional shall be billed as an encounter subject to the following limitations:

(A) All group sessions shall be limited to a maximum of twelve participants, be facilitated by a health professional or allied health professional practicing within his or her scope of practice and shall last at least 45 minutes; and

(B) The services provided in the session shall be documented in each client's health record if the FQHC bills the session as an individual encounter for each participant.

(6) Consultations with anyone other than the patient are not considered encounters, and are therefore not billable.

(c) The following services shall be included in the encounter rate and the FQHC shall not bill separately for these services:

(1) Services and supplies incidental to the services of a health professional or allied health professional when the services and supplies are:

(A) Of the type commonly furnished in a physician's office;

(B) Of a type commonly rendered either without charge or included in the FQHC's bill;

(C) Furnished as an incidental, although integral, part of the professional service; and

(D) Provided by FQHC employees under the direct supervision of a physician, clinical psychologist or licensed clinical social worker.

(2) Laboratory, point-of-care testing or radiology services provided in conjunction with an FQHC encounter and furnished by FQHC staff;

(3) Diabetes self-management training (DSMT) and medical nutrition therapy (MNT), when a physician, physician assistant or APRN has prescribed DSMT or MNT for a client diagnosed with diabetes. DSMT and MNT shall be provided in a DSMT program that meets the following requirements:

(A) Accredited or certified by a national organization assessing standards for quality in diabetes self-management education; and

(B) Complies with national standards for diabetes self-management education and have an instructional team that consists of a certified diabetes educator (CDE) certified by the National Certification Board for Diabetes Educators;

(4) Vaccines that are available through the Vaccines for Children ("VFC") program for children under 19 years of age;

(5) Weight check or blood pressure check;

(6) A clinic visit for immunizations or injections only; and

- (7) Transportation provided by the FQHC.
- (d) The following services are not billable under a provider's FQHC provider number. These services should be billed by an FQHC under a different Medicaid provider number as a fee-for-service ambulatory care provider:
- (1) Inpatient hospital services;
 - (3) Delivery of a baby; and
 - (4) Outpatient surgery.
- (e) The following services may be billed for by the provider of the services in accordance with the Medicaid fee schedule:
- (1) Laboratory services beyond point of care testing that are referred to and performed by an independent laboratory; and
 - (2) The technical component of radiology tests that are referred to and performed by an independent radiologist.
- (f) An FQHC shall not seek reimbursement for services provided under subsections (c) (d) and (e) of this section as an FQHC encounter. The non-FQHC services shall not be included in the overall costs of providing services at the FQHC.

(NEW) Sec. 17b-262-1000. Prior Authorization Requirements

- (a) In order to receive payment from the department, each FQHC shall comply with all prior authorization requirements. The department in its sole discretion determines what information is necessary to approve a prior authorization request. Prior authorization does not guarantee payment unless all other requirements for payment are met.
- (b) The department shall designate services that require prior authorization or registration on the department's fee schedule, on the department's website or by other means accessible to providers with advance written notice to providers before establishing or amending such requirements. Registration may serve in lieu of prior authorization only if the department designates a service as requiring registration but not prior authorization. Prior authorization is also required for the following:
- (1) Dental procedures or services that require prior authorization as set forth on the dental fee schedule;
 - (2) Chiropractic services in excess of 5 encounters per month;
 - (3) EPSDT Special Services; and
 - (4) Any procedure or service that is not listed on the department's medical clinic, behavioral health clinic or dental fee schedule as applicable.
- (c) The provider shall attach a prescription from a physician, APRN or PA to all prior authorization requests for EPSDT Special Services. The provider may attach a physical or electronic copy of the prescription from the licensed practitioner to the prior authorization request in lieu of the

actual signature of the licensed practitioner on the prior authorization request form. The provider shall keep the original prescription on file and subject to the department's review.

- (d) The length of the initial prior authorization or registration period shall be for no longer than three months except as follows:
 - (1) For longer periods as determined by the department on a case-by-case basis; and
 - (2) For up to one year for routine psychotherapy.
- (e) If the client needs a service beyond the initial authorization period, the provider may request authorization to continue services for up to six additional months of continued treatment per request.
- (f) If the department denies a request for prior authorization for continuation of services, the recipient may request an administrative hearing in accordance with section 17b-60 of the Connecticut General Statutes.

(NEW) Sec. 17b-262-1001. Change in Scope of Services

- (a) Each FQHC shall notify the department of any increase or decrease in the scope of services provided by the FQHC in accordance with section 17b-245d of the Connecticut General Statutes. If the FQHC seeks an adjustment to its encounter rate based on the change in scope of services, the FQHC shall submit a written request with the department in accordance with subsection (c) of this section.
- (b) Examples of changes in scope of services by an FQHC for which the department may adjust the encounter rate include, but are not limited to, the following:
 - (1) A change in the volume or amount of services as a result of a significant expansion or reduction of an existing clinic, or the addition or discontinuance of a satellite or new site;
 - (2) A change in operational costs that is attributable to capital expenditures, including new service facilities or regulatory compliance, provided that the additional costs result in a change to the volume, amount, or intensity of services. The cost of a new or expanded building alone would not necessarily qualify;
 - (3) The addition or deletion of any Medicaid covered service eligible under the FQHC reimbursement program;
 - (4) A change in the operational costs attributable to changes in technology or medical practices at the FQHC;
 - (5) A change of costs due to recurring taxes, malpractice insurance premiums, or workers' compensation premiums that were not recognized and included in the PPS baseline calculation;
 - (6) A change in federal or state regulatory requirements that would impact FQHC costs; or

- (7) A HRSA-approved change in the scope of project, provided that the change is consistent with federal and state Medicaid regulations.
- (c) In the event of a change in scope of service for which an FQHC seeks a rate adjustment, an FQHC shall submit a written request to the Commissioner that includes the following:
- (1) a description of the change in scope of services and the reason for the change;
 - (2) the impact on capital and operating costs;
 - (3) the requested change in rate; and
 - (4) All documentation submitted to HRSA regarding a change in scope of project, if applicable.
- (d) An FQHC shall file a preliminary cost report to support its request for a rate adjustment not later than 90 days after the date on which the FQHC submitted its request for a rate adjustment.
- (e) If an FQHC has received approval for a change in scope of project from HRSA for which it seeks a rate adjustment for a change in scope of services, the FQHC shall submit a written request for a change in scope of service in accordance with subsection (c) of this section not later than sixty days after the FQHC has received approval from HRSA for the change in scope of project. The FQHC shall submit all documentation submitted to HRSA regarding the change in scope of project.
- (f) If an FQHC is not required to file a change in scope of project with HRSA but plans an increase or decrease in services or sites to be offered by the FQHC that result in a change to the FQHC's scope of services, the FQHC shall submit a written request for a change in scope of service in accordance with subsection (c) of this section not later than sixty days after the end of the FQHC's fiscal year. An FQHC shall submit all documentation required or requested by the department with respect to the change in scope of service.
- (g) The department may initiate a change in scope of service and resulting encounter rates following a review of the FQHC's scope of project, subsequent amendments to the scope of project, cost reports and audited financial statements by notifying the FQHC in writing and requesting documentation with respect to the proposed change in scope of service. An FQHC shall submit all requested documentation not later than ninety days after receipt of the notice of the proposed change in scope of services;
- (h) In making its determination with respect to whether an FQHC's encounter rate may be adjusted based upon a change in scope of services, the department shall review the following:
- (1) The FQHC's Medicaid cost report;
 - (2) The FQHC's audited financial statements; and
 - (3) Any other documentation relevant to the change in scope of services;
- (i) The department shall issue a decision on a request for an adjustment to the FQHC's encounter rate not later than 120 days after the date on which the FQHC submits the request to the department;

- (j) If the department approves the request, the new encounter rate shall take effect on the date the department renders its decision. The FQHC shall submit a final cost report by January 1 of the year following the request for an adjustment to its encounter rate.

(NEW) Sec. 17b-262-1002. Billing Requirements

- (a) Each FQHC shall bill for FQHC services per encounter. Claims are limited to one all-inclusive encounter per day to include all services received by a client on the same day unless the client suffers an illness or injury subsequent to the first encounter that requires additional diagnosis or treatment or if the client has different types of visits on the same day such as medical and dental or medical and behavioral health.
- (b) Each FQHC shall submit medical and behavioral health claims on the CMS-1500 claims form utilizing both the encounter code and all applicable HCPCS code(s) on the FQHC fee schedule that identify the services provided.
- (c) Each FQHC shall submit dental health claims on the original designated ADA Dental Claim form.
- (d) Each FQHC shall submit claims electronically or on the department's designated form and shall include all information required by the department to process the claim for payment.

(NEW) Sec. 17b-262-1003. Reimbursement

- (a) The department shall reimburse an FQHC an all-inclusive encounter rate per client encounter in accordance with a PPS as required by 42 USC 1396a (bb).
- (b) The department shall establish the baseline encounter rate for each FQHC in existence during fiscal years 1999 and 2000 as follows:
- (1) Total encounters and costs shall be obtained from the annual reports submitted by the FQHC for fiscal years 1999 and 2000;
 - (2) Each year's total costs shall be divided by the total encounters. The FQHC shall include the costs of all Medicaid covered services provided by the FQHC;
 - (3) A two-year average of the calculated cost per encounter rates for fiscal years 1999 and 2000 will be used for each facility. The department shall determine the two-year average for each FQHC by calculating the average cost per encounter rate separately for each year, then adding the averages together and dividing by two.
- (c) For an FQHC that did not file a 1999 annual report, the baseline encounter rate shall be based upon the annual report submitted for fiscal year 2000.
- (d) For a center that first qualified as an FQHC after fiscal year 2000, the department shall determine the baseline encounter rate based upon the encounter rate established under this section for FQHCs located in the same area with similar services.

- (e) The department shall adjust annual encounter rates by applying the percentage increase in the Medicare economic index (MEI) as defined in 42 USC 1395u (i)(3) to the previous fiscal year's encounter rate in accordance with 42 USC 1396a (bb) (3) (A).
- (f) The department may adjust the encounter rate for a change in the scope of services provided by an FQHC in accordance with section 17b-262-1002 of the Regulations of Connecticut State Agencies.

(NEW) Sec. 17b-262-1004. Documentation and Audit Requirements.

- (a) Each FQHC shall maintain a specific record for all services provided to each client including, but not limited to: name, address, birth date, Medicaid Identification Number, pertinent diagnostic information; treatment notes signed by the provider, documentation of services provided and the dates on which the services were provided.
- (b) For services performed by an LMSW, an unlicensed individual, a non-certified individual or an individual in training, progress notes shall be co-signed by the supervisor at least weekly for each client in care and shall contain the name, credentials and the date of such signature. For services provided by a certified individual, evidence of clinical supervision for each client in care shall be documented in the client's chart and shall contain the name, credentials and the date of such signature. The supervisor's signature means that the supervisor attests to having reviewed the documentation.
- (c) Each FQHC shall maintain all required documentation in its original form for at least five years or longer in accordance with statute or regulation, subject to review by authorized departmental personnel. In the event of a dispute concerning a service provided, the provider shall maintain the documentation until the dispute is resolved.
- (d) The department may disallow and recover any amounts paid to the provider for which the required documentation is not maintained and not provided to the department upon request.
- (e) The department may audit all relevant records and documentation and may take any other appropriate quality assurance measures it deems necessary to assure compliance with all regulatory and statutory requirements.
- (f) Notwithstanding the provisions of subsections (a) through (d) of this section, FQHCs may maintain an electronic medical record system such that medical records for all patients treated within the FQHC shall be available to, and shared by, all health professionals.

Section 2. Sections 17-134d-70 to 17-134d-78, inclusive, of the Regulations of Connecticut State Agencies are repealed.

Statement of Purpose

(A) The purpose of the proposed regulation is to establish, in regulation form, the requirements for payment for federally qualified health center services provided to Medicaid clients. The problems, issues or circumstances that the regulation proposed to address the existing regulations are outdated and inconsistent with the federal requirements for payment to federally qualified health centers under 42 USC 1396a (bb). (B) The main provisions of the regulation propose to: (1) add new definitions as necessary; (2) specify core and non-core services that are covered; (3) specify services that are not covered; (4) specify services that are billable as a encounters or not billable but included in the encounter rate; (5) describe the process by which an FQHC may request an adjustment of its encounter rate based upon a change in scope of services; (6) clarify prior authorization requirements; (7) describe billing requirements and the methodology for calculating the encounter rate; and (8) outline documentation and audit requirements. (C) The legal effect of the regulation is to adopt the department's current policies and procedures regarding the payment for federally qualified health center services provided to Medicaid clients as a regulation and to repeal sections 17-134d-70 to 17-134d-78, inclusive, of the Regulations of Connecticut State Agencies.

CERTIFICATION

This certification statement must be completed in full, including items 3 and 4, if they are applicable.

- 1) I hereby certify that the above (check one) Regulations Emergency Regulations
- 2) are (check all that apply) adopted amended repealed by this agency pursuant to the following authority(ies): (complete all that apply)
- a. Connecticut General Statutes section(s) 17b-262 and 17b-245b.
- b. Public Act Number(s) _____.
(Provide public act number(s) if the act has not yet been codified in the Connecticut General Statutes.)
- 3) And I further certify that notice of intent to adopt, amend or repeal said regulations was published in the **Connecticut Law Journal** on _____;
(Insert date of notice publication if publication was required by CGS Section 4-168.)
- 4) And that a public hearing regarding the proposed regulations was held on _____;
(Insert date(s) of public hearing(s) held pursuant to CGS Section 4-168(a)(7), if any, or pursuant to other applicable statute.)
- 5) And that said regulations are **EFFECTIVE** (check one, and complete as applicable)
- When filed with the Secretary of the State
- OR on (insert date) _____

DATE	SIGNED (Head of Board, Agency or Commission)	OFFICIAL TITLE, DULY AUTHORIZED

APPROVED by the **Attorney General** as to legal sufficiency in accordance with CGS Section 4-169, as amended

DATE	SIGNED (Attorney General or AG's designated representative)	OFFICIAL TITLE, DULY AUTHORIZED

*Proposed regulations are **DEEMED APPROVED** by the Attorney General in accordance with CGS Section 4-169, as amended, if the attorney General fails to give notice to the agency of any legal insufficiency within thirty (30) days of the receipt of the proposed regulation.*

(For Regulation Review Committee Use ONLY)

- Approved Rejected without prejudice
- Approved with technical corrections Disapproved in part, (Indicate Section Numbers disapproved only)
- Deemed approved pursuant to CGS Section 4-170(c)

By the Legislative Regulation Review Committee in accordance with CGS Section 4-170, as amended	DATE	SIGNED (Administrator, Legislative Regulation Review Committee)

Two certified copies received and filed and one such copy forwarded to the Commission on Official Legal Publications in accordance with CGS Section 4-172, as amended.

DATE	SIGNED (Secretary of the State)	BY

(For Secretary of the State Use ONLY)

GENERAL INSTRUCTIONS

1. All regulations proposed for adoption, amendment or repeal, *except* emergency regulations, must be presented to the Attorney General for his/her determination of legal sufficiency. (See CGS Section 4-169.)
2. After approval by the Attorney General, the original and one electronic copy (in Word format) of all regulations proposed for adoption, amendment or repeal must be presented to the Legislative Regulation Review Committee for its action. (See CGS Sections 4-168 and 4-170 as amended by Public Act 11-150, Sections 18 and 19.)
3. Each proposed regulation section must include the appropriate regulation section number and a section heading. (See CGS Section 4-172.)
4. New language added to an existing regulation must be in underlining or CAPITAL LETTERS, as determined by the Regulation Review Committee. (See CGS 4-170(b).)
5. Existing language to be deleted must be enclosed in brackets []. (See CGS 4-170(b).)
6. A completely new regulation or a new section of an existing regulation must be preceded by the word "(NEW)" in capital letters. (See CGS Section 4-170(b).)
7. The proposed regulation must have a statement of its purpose following the final section of the regulation. (See CGS Section 4-170(b).)
8. The Certification Statement portion of the form must be completed, including all applicable information regarding *Connecticut Law Journal* notice publication date(s) and public hearing(s). (See more specific instructions below.)
9. Additional information regarding rules and procedures of the Legislative Regulation Review Committee can be found on the Committee's web site: <http://www.cga.ct.gov/rr/>.
10. A copy of the Legislative Commissioners' Regulations Drafting Manual is located on the LCO website at http://www.cga.ct.gov/lco/pdfs/Regulations_Drafting_Manual.pdf.

CERTIFICATION STATEMENT INSTRUCTIONS

(Numbers below correspond to the numbered sections of the statement)

1. Indicate whether the regulation is a regular or an emergency regulation adopted under the provisions of CGS Section 4-168(f).
2.
 - a) Indicate whether the regulations contains newly adopted sections, amendments to existing sections, and/or repeals existing sections. Check all cases that apply.
 - b) Indicate the specific legal authority that authorizes or requires adoption, amendment or repeal of the regulation. If the relevant public act has been codified in the most current biennial edition of the *Connecticut General Statutes*, indicate the relevant statute number(s) instead of the public act number. If the public act has not yet been codified, indicate the relevant public act number.
3. Except for emergency regulations adopted under CGS 4-168(f), and technical amendments to an existing regulation adopted under CGS 4-168(g), an agency must publish notice of its intent to adopt a regulation in the *Connecticut Law Journal*. Enter the date of notice publication.
4. CGS Section 4-168(a)(7) prescribes requirements for the holding of an agency public hearing regarding proposed regulations. Enter the date(s) of the hearing(s) held under that section, if any; also enter the date(s) of any hearing(s) the agency was required to hold under the provisions of any other law.
5. As applicable, enter the effective date of the regulation here, or indicate that it is effective upon filing with the Secretary of the State. Please note the information below.

Regulations are effective upon filing with the Secretary of the State or at a later specified date. See CGS Section 4-172(b) which provides that each regulation is effective upon filing, or, if a later date is required by statute or specified in the regulation, the later date is the effective date. An effective date may not precede the effective date of the public act requiring or permitting the regulation. Emergency regulations are effective immediately upon filing with the Secretary of the State, or at a stated date less than twenty days thereafter.



STATE OF CONNECTICUT

DEPARTMENT OF SOCIAL SERVICES
OFFICE OF THE COMMISSIONER

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MEMORANDUM

To: Individuals Who Commented on Regulation 12-24/MD
Requirements for Payments to Federally Qualified Health Centers

From: Roderick L. Bremby, Commissioner *RLB*
Department of Social Services
55 Farmington Avenue
Hartford, CT 06105

Date: June 30, 2014

Re: Responses to Comments on the Proposed Regulation 12-24/MD

The Department of Social Services (“Department”) provides the following responses to public comments received concerning the proposed regulation referenced above. The Notice of Intent for this regulation was published on the Secretary of State’s website and the Department’s website on November 29, 2013. A public hearing was held on December 19, 2013. A copy of the regulation with revisions based on public comments is attached.

The Department received comments from the following individuals and organizations: (1) American Academy of Physician Assistants (AAPA); (2) Community Health Center Association of Connecticut (CHCACT); (3) Community Health Center, Inc. (CHC); (4) Connecticut Association for Marriage & Family Therapy (CAMFT); (5) Connecticut Association of Optometrists (CAO); (6) Connecticut Chiropractic Association (CCA); (7) Connecticut Podiatric Medical Association (CPMA); (8) Diane Michaelsen, LCSW, LADC, Director of Field Education, Southern Connecticut State University, Director of MSW Admissions; (9) Generations Family Health Center; (10) Greater Danbury Community Health Center; (11) Legislative Delegation of Southeastern Connecticut; (12) National Association of Social Workers, Connecticut Chapter; and (13) United Community and Family Services (UCFS).

1. General Comment Regarding State Plan FQHC Provisions

Comment: Federal law requires that a State's methodology for Medicaid payments to FQHCs be set forth in the State Plan. The State Plan states that CT's FQHC payment methodology is set forth in an addendum. The addendum is labeled as a state regulation, but the regulatory sections in the title of the addendum are listed as "reserved" in the Regulations of the Connecticut State Agencies. Connecticut has never had state regulations on the books that reflect the federal statutory requirements for FQHC services effective January 1, 2001, as set forth in Medicare, Medicaid and SCHIP Benefits Improvement Act of 2000 ("BIPA"). The only codified state regulations currently in force are obsolete, reflecting the federal requirement for cost-based payment in effect between 1989 and 2000.

We support the goal of clarifying the FQHC payment rules through regulation, but in order to comply fully with federal law, it is even more important that DSS amend the State Plan to describe the PPS methodology. (The State Plan should also be amended to remove the "shadow regulations" that currently appear as an addendum to the State Plan.)

Response: The Department is in the process of amending the rate payment methodology in the State Plan Amendment to describe the PPS methodology as well as any proposed alternative payment methodologies.

2. Provider Participation - § 17b-262-996

Comment: This provision appears reasonable. The only objection relates to the requirement that FQHCs submit grant proposals and notices of grant award from the Health Resources and Services Administration (HRSA) (§ 17b-262-996 (4) and (5)). We respectfully suggest that provision of these documents would be onerous and, moreover, that these documents are irrelevant to DSS's administration of the Medicaid program. In addition, FQHC grant proposals are preliminary in nature and frequently include proprietary information that would, if submitted to DSS, be exposed to public release under the State FOI process. In general, several sections of the Proposed Regulations appear to assume that the HRSA grant process is closely connected with Medicaid reimbursement rules, which is incorrect.

Response: The Department is requesting the documentation to verify that a clinic has been designated an FQHC by HRSA. The Department revised the regulation to remove the requirement that FQHCs submit the entire grant proposal. DSS will continue to require a copy of the grant award, however, to verify a clinic's designation as an FQHC.

3. Scope of Services Covered - §§ 17b-262-995, 17b-262-997

- a. Comment: The proposed regulation defines the scope of the FQHC benefit more narrowly than allowed under federal law. The benefit is defined in the Proposed Regulation primarily by two groups of services (“required primary health services” and “additional health services”) that do not correspond to the full scope of services included in the FQHC benefit as defined at Social Security Act § 1905(a)(2)(C). For example, it is unclear whether the term “required primary health services” includes services incident to the provision of services by a core provider; however, under federal law, “incident to” services are included in “FQHC services.” Similarly, under federal law, the Medicaid FQHC benefit must encompass any ambulatory service listed under the state plan and provided by the FQHC. The State may not limit the scope of “other ambulatory services” through the list of “additional health services” in the Proposed Regulations.

Along these lines, proposed § 17b-262-997(b) states that Medicaid reimbursement for FQHCs “shall be limited to medically necessary services that are covered by the Medicaid state plan or are required EPSDT services or EPSDT special services.” This provision is not clearly worded. The Medicaid FQHC benefit must include any “FQHC service” furnished by a core provider, even if that service would not be covered under the state plan if provided by a different type of provider. We recommend that this section be replaced by a provision stating that DSS covers the full Medicaid FQHC benefit as set forth at Social Security Act § 1905(a)(2)(C).

The Proposed Regulations also contain some specific limitations on covered services that are inconsistent with federal law. For example, we recommend deleting proposed § 17b-262-997(a). The health center’s HRSA scope of project does not govern the scope of services paid for under the Medicaid FQHC benefit.

Response: The commenter is incorrect in the statement that the HRSA scope of project does not govern the scope of services paid for under the Medicaid FQHC benefit. To the contrary, HRSA issued a Policy Information Notice that specifically states that the “scope of project defines...the basis for Medicare and *Medicaid* Federally Qualified Health Center reimbursements...” See attached HRSA PIN 2008-01. It further explains that a health center’s scope of project is important because it:

Defines the approved service sites and services necessary for State Medicaid Agencies to calculate payment rates under the Prospective Payment System (PPS) or other State-approved alternative payment methodology.

See attached HRSA PIN 2008-01, p. 3.

DSS has revised the regulation to ensure consistency with federal law and clearly delineate covered services and billable encounters.

- b. Comment: As a policy matter, we object to the provisions of the Proposed Regulations that appears to narrow the current FQHC Medicaid benefit in Connecticut. For example, presently (under the addendum to the State plan) “nutrition counseling” is a covered “primary health service.” See State plan Att. 4.19-B, addendum to page 1(b), § 17b-262-661(13). Under the new regulations, on the other hand, the benefit would be more narrowly defined to resemble the Medicare diabetes self-management training and medical nutrition therapy benefits. See § 17b-262-997(e)(3). Only patients diagnosed with diabetes would be eligible.

The State should restore the scope of the existing nutrition counseling/therapeutic nutrition benefit, under which registered dietitians, who are licensed/certified in Connecticut by DPH as certified dietitians/nutritionists, currently treat patients with diabetes, obesity, lipidemia, hypertension, and other ailments. The service is an important preventive and treatment primary care service (when determined by a core provider to be clinically necessary) for all those patients. The nutrition counseling benefit has been offered in its present form since the base years used in establishing the PPS rate (1999 and 2000).

If DSS persists in reducing the scope of this service, and in refusing to consider these services as a billable encounter (please see comments below), then DSS, per the scope change regulation, should offer health centers an opportunity to apply for a rate adjustment to reflect the change.

Response: DSS does not reimburse the services of dietitians and nutritionists under the State Plan; therefore, it is not required to reimburse an FQHC for this service. An FQHC may apply for a change in scope and provide documentation demonstrating that visits with registered dietitians and nutritionists were previously included in the establishment of the PPS rate for the FQHC.

- c. Comment: Proposed § 17b-262-997 conflates the scope of “covered services” (*i.e.*, allowable service costs on the FQHC cost report) with “billable encounters” (*i.e.*, specific visits eligible for the per-visit payment). For example, subsections (c) - (e) of § 17b-262-997 relate to the mechanism for billing covered service (full PPS rate, group session rate, embedded in PPS rate); they do not relate to the scope of the covered benefit. It would make more sense for those provisions to be included in a separate section on billable encounters. This is not just a formal distinction: the Proposed Regulations are unclear as to which services are allowable service costs but are not counted as encounters, and thus will make it difficult (or impossible) for health centers when preparing cost reports.

Response: DSS has revised the regulation to clearly delineate the services that are billable as an encounter and the services that should be included in the cost reports but not billed as an encounter.

4. Services Not Covered - § 17b-262-998

- a. Comment: With respect to item (1) (services “not listed in the FQHC scope of project”), it is Social Security Act § 1905(a)(2)(C), not the HRSA scope of project, that defines the Medicaid FQHC benefit. The HRSA scope of project is a mechanism developed by HRSA in informal guidance and does not control the scope of the Medicaid benefit. We recommend that DSS delete this item.

Response: DSS agrees that the scope of project does not define the Medicaid benefit; however, the scope of project does define the HRSA approved services and service sites. The service sites and the services provided by an FQHC is information that is necessary for DSS to calculate the PPS rate. This information will also be necessary if an FQHC notifies the department of a change in scope of services and seeks an adjustment to the encounter rate.

DSS has, however, revised the regulation to ensure consistency with federal law and eliminate any confusion with respect to services covered or not covered and billable encounters.

- b. Comment: In addition, item (4) (“services normally provided free of charge to patients”) is inconsistent with federal law and should be deleted. This is described as the “free care” concept and was included in CMS guidances that were later found to be unenforceable.

Response: DSS has revised the regulation accordingly.

5. Billable Encounters - §§ 17b-262-995, 17b-262-997

- a. Comment: The rules concerning billable encounters are scattered throughout the Proposed Regulations, (e.g., in the definitions and in the regulation on covered services). “Covered services” and “billable encounters” are different concepts: the former defines the scope of the benefit and the latter is a cost allocation mechanism. DSS should promulgate a separate regulation on billable encounters.

Response: DSS has revised the regulation to clearly delineate the rules with respect to covered services and billable encounters.

- b. Comment: The “encounter” definition in the Proposed Regulations is either narrower than allowed by federal law or too narrow as a policy matter in several regards.

Response: The encounter definition is consistent with federal law. DSS, however, has made a minor revision to the definition.

- c. Comment: The definition of “health professionals” in the proposed regulations at § 17b-262-995(22) is acceptable. It corresponds to the definition of the core providers of FQHC services under federal statutory and case law. On the other hand, as to “allied health professionals” (§ 17b-262-995(3)), while it is in the State’s discretion to decide which clinicians other than the core providers may provide billable encounters, the list is too narrow. The State’s existing rules and policies allow for billing for an encounter with any “health professional” -- a broad term that is undefined in the current State rules – and in practice, DSS has up until now allowed health centers to bill for evaluation/management visits with registered nurses (RNs) under the supervision of a core provider, as well as visits with registered dietitians. The Proposed Regulations appear to exclude both of those types of currently-billable encounters.

We urge DSS to reevaluate this decision and to broaden the definition of “allied health professional” to include both RNs and registered dietitians. RNs provide high-quality care that could also be provided by physicians; indeed, RNs may be increasingly relied upon in various health care settings because of the impending primary care physician shortage, combined with a projected increased demand for primary care services. In particular, services provided by RNs under CPT code 99211 (evaluation and management of an established patient) should be billable. In these visits, RNs provide services that have the hallmarks of a billable visit provided by a core provider (they are exercising independent professional judgment), and they are supervised by a core provider.

Response: DSS has revised the regulation to include RNs in the definition of Allied Health Professionals. Since dietitians and nutritionists are not reimbursed under the State Plan, DSS is not required to reimburse FQHCs for the services of a dietitian or a nutritionist.

- d. Comment: Registered dietitians, similarly, should continue to be permitted to provide billable encounters. We urge DSS to retract proposed § 17b-262-997(e), which would render diabetes self-management training and medical nutrition therapy training “incident-to” services that do not qualify as an encounter. Registered dietitians have National Provider Identifier numbers and should be enrolled in Medicaid as providers (even if the services are provided only under a prescribing order from a core provider).

Response: Registered dietitians are not reimbursed under the State Plan; therefore, DSS is not required to reimburse an FQHC for the services of a registered dietitian.

- e. Comment: We appreciate the inclusion of “license-eligible individuals” in the allied health professionals who may furnish encounters, we note that this group does not include social workers who have earned an MSW who have not yet earned their supervision hours and received their license. Given the shortage of

behavioral health clinicians, this is problematic. We understand that DSS's solution to this problem is to implement a "licensed master social worker" (LMSW) provider category. DPH has not yet implemented the license procedures for the LMSW. We urge the two state agencies to work together to move quickly on this solution and in addition, to include LMSWs within the definition of "allied health professionals."

Response: DSS has revised the regulation to include LMSWs in the definition of allied health professionals.

- f. Comment: We urge DSS to not move forward with narrowing the types of professionals who can provide an encounter. If DSS does move forward, then we note that the change in the definition in "encounter" will give rise to a change in the scope of services. DSS should provide affected health centers with the opportunity to seek an adjustment of their PPS rate. By excluding these types of encounters, DSS will have altered the parameters that defined costs per visit in the base years (1999-2000). (If these types of visits had been non-billable in the base years, then the total visit count would have been lower, and the rate per visit higher.)

Response: DSS has revised the regulation to allow RNs, LMSWs, certain unlicensed clinicians, and student interns who are under the supervision of a licensed health professional to provide services. An FQHC may bill for these services provided that the other requirements for a billable encounter are satisfied.

- g. Comment: In the definition of "encounter" at § 17b-262-995(19), the limitation, "Only services provided at the sites approved by HRSA in the FQHC scope of project are billable. . . ." is not required under federal law. Federal law permits FQHC providers to deliver services at other than FQHC sites (e.g., some visits at hospitals and nursing homes). In addition, this limitation on the definition of "encounter" was not applied under the prior rules – including those that applied in the base years of 1999 and 2000. As a result, as one example, FQHC physicians have in the past provided clinic-type services to health center patients who are hospitalized, and received the PPS rate for those services (more on that issue, below). As with the narrowing of qualified health professionals, this change would impact the assumptions used to develop the PPS rates in the base years, and DSS would be required to allow affected health centers to seek a rate adjustment to reflect the new "encounter" definition.

Response: DSS has revised the regulation. The newly revised section 17b-262-999 adequately covers the types of services that may be billed as an encounter.

- h. Comment: As to medical encounters (§ 17b-262-997(c)(1)), the Draft Regulations state that chiropractor encounters are allowable "when prescribed by a physician, physician assistant or APRN." Chiropractors are included in the definition of

“physician” pursuant to federal case law, and so the prescription of a physician, etc., is not required for those services.

Response: DSS has revised the regulation accordingly.

- i. Comment: Section 17b-262-997(c)(2) of the draft regulations states that the number of dental encounters “shall be limited at the discretion of the department.” We recommend that DSS delete this language and instead clearly state the rules for allowable dental encounters.

Response: DSS has revised the regulation accordingly. The dental fee schedule specifies the number of encounters allowed per procedure.

- j. Comment: We object to the bar on hygienist encounters billed on the same day as dentist encounters. A definition permitting same-day dentist and hygienist encounters promotes efficiency, and encourages improved patient care (taking care of all the patient’s dental needs at one time avoids the risk of the patient not returning for follow-up visits).

Response: The department has never allowed more than one dental encounter per day. The regulation will remain as written.

- k. Comment: Section 17b-262-997(c)(4) should be revised to allow FQHCs to bill for smoking cessation encounters when it has been prescribed by any core provider (including APRNs, PAs, psychologists, LCSWs), not just physicians.

Response: DSS has revised the regulation accordingly.

- l. Comment: As noted above, medical nutrition therapy services should continue to be treated as billable encounters.

Response: As noted above, DSS does not reimburse nutritionists or dieticians for medical nutrition therapy services under the State Plan; therefore, DSS is not required to reimburse FQHCs for these services.

- m. Comment: The proposed regulations do not include specific requirements regarding what dental services are covered and billable as “encounters,” rather it depends on the discretion of the department for the number of dental encounters for certain types of procedures.

Response: The regulation specifies that dental services provided by a dentist or dental hygienist are billable as encounters. Additionally, only one dental encounter per day is allowed. The dental fee schedule specifies the number of encounter allowed per procedure.

6. Separately Reimbursable Non-FQHC Services (§ 17b-262-999)

- a. Comment: The proposed revision relates to the provision of visits to FQHC patients who are hospitalized. Under DSS's prior practice, these visits were considered part of the FQHC benefit and qualified for the PPS encounter rate. The Proposed Rules appear to eliminate these services from the FQHC benefit. Subsection (a) states, "Physicians employed by an FQHC may provide services to clients at a hospital, nursing facility or other off-site location and shall be reimbursed according to the Medicaid physician fee schedule." Subsection (c) characterizes these services "non-FQHC" services and as unallowable FQHC costs.

Response: DSS met with the FQHC providers to discuss this and it was agreed that the Department would seek guidance from CMS. CMS confirmed that services provided to hospitalized patients are not FQHC services and should be reimbursed in accordance with the Medicaid physician fee schedule. Specifically, the letter from CMS stated as follows:

We wish to confirm that rounding services provided by FQHC-employed physicians should be reimbursed the Medicaid fee schedule amount and believe this position is consistent with the criteria in the September 10, 1995 letter to California cited by the Association. CMS agrees with the state that rounding services are not "of the type commonly furnished in the clinic setting" precisely because they occur only when a patient is hospitalized. For this reason, services provided in the inpatient setting do not qualify for PPS regardless of whether the service is an evaluation or management service or something else.

See attached CMS Letter to Deputy Commissioner Brennan, November 19, 2012.

Therefore, the regulation will remain as written.

- b. Comment: DSS should issue final regulations that continue to authorize the PPS rate for FQHC visits provided to hospital inpatients. The decision by DSS to exclude from the definition of "FQHC services" evaluation and management services and well-baby services provided to FQHC patients who are hospitalized is inconsistent with federal law. Further, it is a poor policy decision that will undermine comprehensive and cost-effective care.

This policy decision has a two-fold impact: it deprives the FQHC of the means necessary to provide or arrange for such services and it deprives the FQHC patient of access to his or her physician to maintain continuity of care.

Response: Please see response to comment 6 (a), above.

- c. Comment: Reimbursing FQHCs at the level of their encounter rate for rounding is necessary for health centers to comply with their obligations under Section 330

of the Public Health Service (“PHS”) Act. Under the PHS Act, health centers must ensure that their physicians have admitting privileges at one or more referral hospitals, or other such arrangement to ensure continuity of care. (PHS Act § 330(k)(3)(L) of the PHS Act, 42 U.S.C. § 254b(k)(3)(L).) In cases where hospital arrangements (including admitting privileges and membership) are not possible, health centers must firmly establish arrangements for hospitalization, discharge planning, and patient tracking. In other words, such rounding is not optional for FQHCs – and neither should be the related PPS reimbursement from Medicaid.

Response: Please see response to comment 6 (a), above.

- d. Comment: More generally, we object to the assumption implicit in subsection (a) that a service provided by an FQHC clinician to an FQHC patient at an “off-site location” may not be an allowable service cost or billable encounter. DSS’s rules for FQHC encounters in effect up to present (as reflected in the addendum to the State plan) have not limited “encounters” to services provided at a service site included in the health center’s HRSA scope of project, and no such requirement applies under federal law.

Response: The Department reimburses FQHCs for health center sites approved by HRSA, including school based health centers, mobile sites, shelters and other sites listed on the HRSA Health Centers and Look-alike Sites Site Directory for Connecticut FQHCs.

- e. Comment: DSS has obtained informal guidance from CMS to the effect that DSS may treat evaluation and management visits furnished to hospitalized FQHC patients as non-FQHC services and pay for them under the Medicaid fee schedule. We understand that DSS has indicated that effective January 1, 2012, it intends to adopt that policy; however, DSS has since then withheld *all payments* for the services at issue provided since that date.

Response: Effective July 1, 2014, FQHCs will be able to bill for these services. Each FQHC may bill retroactively to January 1, 2012. Additionally, the department issued interim payments upon request from an FQHC.

7. Changes in the Scope of Services (§ 17b-262-1001)

- a. Comment: We are supportive of this new regulation, which seeks to address a gap in policymaking at the Department. The definition of a change in the scope of service as a change in the “type, intensity, duration or amount of services provided by an FQHC” is consistent with federal guidance. We also approve of the non-exclusive list of types of events that may give rise to a scope change.

Some aspects of the Proposed Regulation unduly restrict change-in-scope rate adjustments. The list of scope change events should include changes in state law. Specifically, in the list of circumstances that comprise a change in the scope of

services in § 17b-262-1001(b)), we recommend that item (6) (“change in federal regulatory requirements”) be revised to refer to “federal or state regulatory requirements.” If state law alters either the definition of covered services or the definition of billable encounters in a way that alters the premises that were used to establish average costs per visit on the cost reports covering the base years, then health centers should have an opportunity to seek a PPS rate adjustment. This principle applies where a change in state law adds or removes a service or increases or reduces the scope of the service (for example, the type of reduction of medical nutrition therapy being proposed in this Proposed Rule). The principle also applies where due to a change in state law, a type of visit that was billable in the base years is no longer recognized as a billable encounter.

Response: DSS has revised the regulation accordingly.

- b. Comment: Some aspects of the procedures that DSS has set forth for rate adjustments in § 17b-262-1001(c) are inconsistent with federal law. In particular, we urge DSS to revise item (4), which calls for a community needs assessment, business plan, and evidence that the scope change is cost effective. These requirements mischaracterize the nature of the State’s Medicaid rate adjustment determination. Under federal law, a health center already provides such information to HRSA in seeking a “change in scope.” In addition, the State Medicaid program is *required* to adjust the health center’s PPS rate to reflect “an increase or decrease in the scope of services” when a health center (among other circumstances) begins to provide a new service within the FQHC benefit (as described in Section 1905(a)(2)(C) of the Act) that it had not provided before. *See* SSA § 1902(bb)(3). The health center is entitled to provide and receive payment for any service covered under the Medicaid FQHC benefit per federal law. Unlike a certificate of need process, the application for a rate adjustment is *not* an application by the health center for a determination by DSS whether it is a good business decision to provide the service; it is simply a request for the State to recognize through a rate adjustment that the scope of the health center’s offering has changed.

Response: DSS has revised the regulation accordingly.

- c. Comment: DSS should reconsider the timelines it has established in describing the procedures for a change-in-scope rate adjustment in subsection (e).

The Proposed Regulation would require that FQHCs apply for a rate adjustment within sixty days after a change in scope of service. For some of the types of changes in the scope of services described in subsection (b) (for example, “a change in the operational costs attributable to changes in technology or medical practices at the FQHC”), a health center will likely be able to determine that the event comprised a change in the scope of services only *after* its fiscal year is over. At that point, the health center may determine for the first time that the change (for example, the implementation of electronic health records or electronic

practice management) resulted in increased costs per encounter. The rules should provide for a later deadline for health centers to apply for rate adjustments.

Response: DSS has revised the regulation to allow the health center to apply for a rate adjustment within 60 days of the end of the FQHC's fiscal year.

- d. Comment: In addition, the regulation does not establish any timeframe for a health center to provide cost report documentation relating to the scope change. Such information is typically not available immediately to the health center. The final regulations could require that a preliminary cost report to support the rate adjustment application be filed within 90 days of the change in scope/rate change request. A final cost report supporting the rate adjustment request would be completed by the following January 1, consistent with the current statute.

Response: DSS has revised the regulation accordingly.

- e. Comment: In general, the Draft Regulations provide deadlines for the health center's actions (deadline to apply for a rate adjustment; deadline to submit documentation requested by the State) but not for DSS's actions. The regulation should state that DSS must evaluate the health center's initial application and notify the health center of any needed additional information within a fixed timeframe (perhaps sixty days) of receipt of the application. The regulations should also specify a maximum total timeframe for DSS to adjudicate a rate adjustment request following a health center's submission of its final cost report.

Response: DSS has revised the regulation accordingly.

- f. Comment: Finally, the Draft Regulations do not state on what date the rate adjustment takes effect once DSS has approved a scope change rate adjustment. We recommend that DSS add a provision stating that the adjustment takes effect as of the date of the change in the scope of service.

Response: DSS has revised the regulation accordingly.

- g. Comment: The statutory provisions in the Social Security Act relating to Medicaid rate adjustments for FQHCs (which refer to the "scope of services," *see* SSA § 1902(bb)(3)) are unrelated to the HRSA policies concerning the health center's project under its Section 330 grant. (Those policies refer to the health center "scope of project.") Health centers do routinely apply to HRSA for changes in their scope of project when they add new sites or services. The documentation associated with those requests may be used by a health center in seeking a Medicaid rate adjustment. However, the HRSA scope change procedure and the Medicaid rate adjustment are separate concepts and not directly related.

Response: DSS understands the difference between the change in scope and the scope of project. As noted previously, while the two are not directly related, the scope of project “[d]efines the approved service sites and services necessary for State Medicaid Agencies to calculate payment rates under the Prospective Payment System (PPS) or other State-approved alternative payment methodology.” See attached HRSA PIN 2008-01

- h. Comment: The new regulations are much like the old regulations in as much as the process by which an FQHC may request an adjustment of its encounter rate is based upon a change of scope of services that does not require any time frame for DSS to act.

Response: DSS has revised the regulation to require action by DSS on the change in scope request within 120 days of receipt of all of the requested documentation.

8. Reimbursement - § 17b-262-1003

- a. Comment: With one major exception, described below, we are supportive of this draft regulation. The prior rules on FQHC rates (the addendum to the State Plan) contained references to cost containment mechanisms (a provider productivity screen and offset of grant revenues) that were used in establishing health centers’ original (2001) PPS rates and that the State subsequently suspended (resulting in a recalculation of PPS rates) pursuant to court order or negotiation. We support the promulgation of new regulations that omit those unlawful cost containment mechanisms. (As noted above, the State plan should also be amended to describe the FQHC payment methodology.)

Response: The regulation includes a repealer section that repeals the prior rules. Additionally, DSS is in the process of amending the state plan to reflect the current FQHC payment methodology.

- b. Comment: We object to § 17b-262-1003(g) -- the proposal to reimburse FQHCs for group sessions under a system using elements of the RBRV system. Initially, as a legal matter, we note that adopting this type of methodology for the group visits (which DSS acknowledges are part of the Medicaid FQHC benefit) amounts to carving the associated services out of the PPS methodology. Services included in the FQHC benefit (and hence in the PPS methodology) may be paid for either as billable encounters or as “incident-to” services whose costs are embedded in the PPS encounter rate.

The proposal to shift to the RBRV system is effectively a proposal to remove the costs associated with the behavioral health visits from the pool of FQHC allowable costs that are paid for on a per-visit through PPS payments, and instead to reimburse health centers for the costs associated with these specific visits through the separate RBRV system.

We urge DSS to reevaluate this decision and to continue to recognize each group behavioral health visit as an encounter. As noted above in Section 5.c, a switch to the RBRV system will put financial strain on FQHCs and will imperil access to behavioral health services in Connecticut.

Response: DSS has revised the regulation to recognize each group behavioral health visit as an encounter.

- c. Comment: The proposed regulation is outdated and incomplete with changes required for payment to FQHCs. DSS is proposing that the costs of FY 1999 and 2000 provide the baseline costs. These costs are now 15 years old and were calculated prior to implementation of electronic health records, Patient Centered Medical Homes, the Affordable Care Act and the capital investments that have been made in the community health centers. There are no proposed regulations to include the costs subsequent to FY 2000, so that the costs of these services is accurately reflected in the process of setting these rates.

Response: Federal law requires that DSS set the PPS rate based upon cost reports from FY 1999 and 2000. If the commenter seeks a change, they should contact HHS or CMS. The regulation will remain as written because it is consistent with federal law.

9. PCMH

- a. Comment: A concept that is missing from the regulations is the payment for patient-centered medical home (PCMH) recognition and all related payments (e.g., quality payments for HUSKY, payments in the SIM Initiative). Most of Connecticut's FQHCs have achieved PCMH status, either through NCQA or the Joint Commission, and currently they are the only providers in the state singled out for exclusion from this program. Yet, FQHCs treat a full one-third of Connecticut Medicaid enrollees, and therefore could have significant impact if they were included in quality incentives. These regulations (in combination with amendments to the State plan) are an opportunity to right that wrong and the department should reconsider this decision.

Response: This comment is beyond the scope of the FQHC regulation. There are separate regulations governing PCMH.

- b. Comment: The industry is moving toward payment mechanisms that are holistic and based on population management and the quality of care. DSS has actively involved community health centers in the formal adoption of the Patient Centered Medical Homes (PCMH) and the SIM grant envisions Advanced Medical Care Homes. However, none of these innovations appears in this methodology or contemplate a mechanism to address these costs or be included later. There is no adjustment for case management, acuity and risk of patients, or for workforce shortages.

Response: This comment is beyond the scope of the FQHC regulation. There are separate regulations governing PCMH.

10. Consistency/Clarification of Annual Medicaid Cost Reports

Comment: DSS should promulgate guidance on Medicaid cost reports. FQHCs have generally applied Medicare guidance in the preparation of Medicaid annual reports; however, due to both the differing scopes of the Medicare and Medicaid FQHC benefits and the different rules concerning cost containment mechanisms in the two programs, separate rules and guidelines are critical for Medicaid cost reports. Formal adoption of definitions and allowable cost principles would provide clarity on issues such as overhead and depreciation and help centers avoid unintentional errors. The provision of fully functional Excel reporting and rate computation forms would also be appreciated.

Response: The Department is still in the process of reviewing the cost reports that were submitted this year. Upon completion of the review, the Department will update the cost report as well as the instructions to complete the cost report. At that time, the Department will consider revising the regulation to incorporate additional guidance with respect to the submission of cost reports.

11. Physician Assistants and Smoking Cessation – § 17b-262-997 (c) (4)

Comment: In the proposed regulations, PAs are not authorized to prescribe smoking cessation counseling. To allow PAs to prescribe smoking cessation counseling, we suggest the following remedy:

Sec. 17b-262-997. Services Covered

(4) Smoking cessation counseling when a physician OR PHYSICIAN ASSISTANT has prescribed it for a client. Smoking cessation counseling may be billed as a medical encounter, behavioral health encounter or dental encounter depending upon the type of health professional providing the service. The following health professionals may provide smoking cessation counseling:

- (A) Physicians;
- (B) Physician assistants;
- (C) APRNs;
- (D) Dentists;
- (E) Clinical Psychologists;
- (F) LCSWs; and
- (G) Allied health professionals.

Response: DSS has revised the regulation to allow for a PA, APRN or dentist to prescribe smoking cessation counseling.

12. Pediatric Eye Examinations – § 17b-262-995 (42) (B) (v)

Comment: “Preventive health services” is defined in a way that appears to require a pediatric eye “screening” rather than an eye “examination” for children. We encourage the department to consider amending this section to permit a full eye examination as screenings can easily miss many eyed conditions. The Affordable Care Act deems pediatric vision care to be an essential health benefit. Insurance plans in Connecticut are generally covering an annual eye examination for children and the Connecticut Association of Optometrists would urge the Department to mirror this provision in the FQHC regulations.

Response: DSS has revised the regulation to include vision care services as a covered non-core service. Vision care services include eye examinations.

13. Podiatric Services - § 17b-262-996 (c) (1) (C)

Comment: The Connecticut Podiatric Medical Association supports the inclusion of podiatric services for Medicaid clients utilizing FQHCs and finds the limitation of one treatment for routine foot care to every sixty days to be reasonable.

Response: DSS appreciates the support for this regulation.

14. Services covered – 17b-262-997 (c) (3) – Non-licensed providers

- a. Comment: The proposed changes will exclude service delivery by marriage and family therapy student trainees and post-graduates working to achieve licensure in Connecticut.

Professional not-for-profit agencies with seasoned clinicians who provide required supervision and training to students/interns would be greatly affected by any decision where they could not bill for client hours. During a time when there is a rapidly growing need for mental health providers, this loss of compensation would likely result in the loss of training arrangements for students, a dramatic shift in agency capacity and significant loss of access to behavioral health treatment for consumers.

Requirements for licensure for Marriage and Family Therapy (MFT) trainees includes 500 hours of face-to-face contact with families, couples and individuals providing exclusively clinical services while they obtain their Masters degree. Post-graduates are then required to pass the national licensing exam and complete an additional 1,000 hours of clinical face-to-face contact before they are eligible to become licensed. These graduation and licensing requirements must be completed under the supervision of a licensed practitioner in a professional setting. This may be compared to student teaching in education, which ensures

that trainees demonstrate the required skills that are necessary to provide quality services. These requirements are outlined in our licensing statute.

The referenced proposal is particularly concerning for Marriage and Family Therapists, as the delivery of therapeutic services is this discipline's sole means of fulfilling requirements for licensure. MFT trainees are not allowed to obtain licensing credit for non-client contact hours, as compared to trainees from other disciplines who may also include alternative clinical tasks that are not specifically linked to in-person therapy delivery, such as case management, paperwork completion, or phone consultation. The rigorous standard for required client-contact hours was created to focus on clinical skill development treating families, children and individuals and meant to ensure that graduates provide quality services directly following completion of their degree and upon becoming licensed to work independently.

While these rigorous standards are a benefit to the delivery of quality mental health services, a lack of established internship sites does not allow trainees a means to achieve licensure.

Response: DSS has revised the regulation to allow for MFT trainees to provide services under the supervision of a licensed MFT pursuant to section 20-395c of the Connecticut General Statutes.

- b. Comment: There is extraordinary value in being able to place students in field placements where they are able to learn firsthand the skills necessary to round out their educational experience. At the school of Health and Human Services at Southern Connecticut State University, we are educating future social workers, marriage and family therapists, nursing students, and speech pathologists. Without the opportunity to learn at the elbow of an experienced helper, so much is lost.

Response: DSS has revised the regulation to allow for unlicensed or non-certified social workers, marital and family therapists, professional counselors and alcohol and drug abuse counselors to provide services under the supervision of a licensed health professional.

- c. Comment: FQHCs are a training ground for behavioral health interns – students who are in Masters-level programs in Behavioral Health fields of study, and who must complete significant supervised internship hours at a working clinic to be eligible for a degree. We also hire many Bachelor-level staff and Masters-level staff working their license eligibility. These services are typically billable to Medicaid, as they are provided under the direct supervision of a licensed provider. They are also allowable per the Department's Payment of Behavioral Health Services regulation

If it is the department's intent to allow only those who have completed all requirements to attain a license to be eligible, excluding interns, Bachelor-level staff and Masters-level staff working on requirements to be license, capacity for Behavioral Health services in Eastern CT will be significantly reduced.

Response: DSS has revised the regulation to allow for unlicensed providers to provide services under the direct supervision of a licensed health professional. The FQHC may bill for these services provided all other requirements for an encounter are satisfied.

- d. Comment: The regulations appear to restrict services by clinical social workers to only those listed as a Clinical Social Worker (LCSW) under the CGS section 20-195n. Section 20-195n of the statute now licenses both licensed master social worker (LMSW) and LCSWs. The proposed language only mentions LCSW, not the LMSW that is expected to begin in the spring of 2014. Since both LCSW and LMSW are in § 20-195n it is somewhat contradictory to cite the section for provider eligibility yet not include both license levels. The LMSW will be for new MSW graduates and requires they work under the supervision of a licensed mental health provider. These are qualified licensed clinical social workers who we strongly recommend be included as providers.

Response: DSS has revised the regulation to allow for LMSWs and unlicensed social workers to provide services under the supervision of a licensed health professional. The FQHC may bill for these services provided all other requirements for an encounter are satisfied.

- e. Comment: The proposed regulation will also disallow an FQHC from utilizing graduate level social work interns as providers. Many FQHCs utilize social work interns for therapeutic behavioral health sessions under supervision. If the new regulations indeed disallow interns, it will have a negative impact on service delivery. The number of persons the FQHC will be able to serve will drop dramatically. This is particularly an issue in more rural parts of the state, such as Eastern Connecticut, where there is already a shortage of mental health clinicians.

Response: DSS has revised the regulation to allow the graduate level social work interns to provide services under the supervision of a licensed health professional. The FQHC may bill for these services provided all other requirements for an encounter are satisfied.

15. Group psychotherapy and group counseling sessions - § 17b-262-997 (d)

- a. Comment: The Proposed Regulations impose the requirement of prior authorization for group sessions. DSS should ensure that any prior authorization requirements imposed for psychotherapy are consistent with the Mental Health Parity and Addiction Equity Act of 2008 and implementing regulations. We also note that the rules concerning prior authorization for behavioral health appear to

be in tension with the rules under the behavioral health billing regulations (§ 17b-262-817 et seq.) that would apply to other types of providers. The maximum group size (8) is also inconsistent with the behavioral health regulations.

Response: DSS has revised the regulation accordingly.

- b. Comment: DSS's proposal to adopt a new payment methodology, under which group sessions will no longer be billable under the PPS rate but instead under a system similar to the resource based relative value (RBRV) system used in Medicare, would effectively carve these services, which are part of the FQHC benefit, out of the PPS rate methodology. A switch to the type of system DSS describes (in vague terms) in the Proposed Regulations will put a further financial strain on FQHCs and will create a disincentive to the use of group therapy. This is not consistent with efficiency or best practices. Group therapy is an important behavioral health service. State regulations already prohibit payment for groups that are social, recreational or educational in nature, which ensures that group therapy sessions, as currently constructed and billed, are medically necessary in nature.

Overall, these changes to the behavioral health billing (prior authorization, limiting group size and change in payment methodology) will have the combined effect of limiting access to behavioral health services *at the exact time* that policymakers have made it a goal to improve access to those services. These changes will have a direct, negative impact on people seeking those services.

Response: DSS has revised the regulation to allow for reimbursement for group sessions at the encounter rate.

- c. Comment: DSS has proposed new regulations for FQHC reimbursement that will reduce access to mental health and behavioral health services in Connecticut, particularly for Medicaid clients. We provide over 3,000 group visits for Medicaid clients each year. The proposed regulation will reduce the per client Medicaid reimbursement for group visits by 80% AND limit the number of clients per group to 8 clients. By reducing the group rates and the number of clients that can be seen in a group, access will be reduced and wait lists will be longer, denying people the treatment that they need. A one hour group will be replaced by individual appointments. The equivalent of converting a single group of 12 clients to individual visits is almost 3 full days of a clinician's time.

We strongly oppose the proposed changes as it will result in either reducing group work or eliminating groups as a treatment modality.

Response: DSS has revised the regulation to allow for reimbursement of group sessions at the encounter rate.

16. Chiropractic Services

- a. Comment: The treatment a chiropractor is permitted to make is limited to the manual manipulation of a patient's spine. Our work and scope of practice in Connecticut goes well beyond this, however, and encompasses many aspect of primary and preventive care. We can provide additional treatments beyond spinal manipulation and believe the proposed regulation should be changed to refelect that fact.

Response: Pursuant to General Statutes § 20-24, chiropractic services are limited to the following: "adjustment, manipulation and treatment of the human body in which vertebral subluxations and other malpositioned articulations and structures that may interfere with the normal generation, transmission and expression of nerve impulse between the brain, organs and tissue cells of the body, which may be a cause of disease, are adjusted, manipulated or treated." The regulation has been revised to reference both state and federal law. See also sections 17b-262-539 to 17b-262-540 of the Regulations of Connecticut State Agencies for services covered and limitations and services not covered.

- b. Comment: The proposed regulation requires prior authorization for any treatments beyond five a month. We believe chiropractic physicians are in the best position to know what number of encounters per month best fit the patient's needs. Requiring this level of prior authorization is likely to simply result in delay in needed treatment.

Response: This is consistent with the Department's prior authorization requirements for chiropractic services in a non-FQHC clinic or hospital. See Section 17b-262-542 of the Regulations of Connecticut State Agencies.

17. Conflict with Federal and State law

- a. Comment: The proposed regulation is an unwise and unwarranted "mission-creep" by the department. FQHCs are currently regulated at both the Federal level by HRSA and the state level through DPH. Indeed, HRSA's oversight of FQHCs is further substantially enhanced by FQHC's participation in the Federal Tort Claims Act (FTCA) Program for malpractice coverage, which requires in depth attention to clinical quality and best practices.

The role of DSS is primarily that of a funding authority regarding payment for FQHC services provided to Medicaid patients. The department's proposal to insert itself into FQHC operational matters, through review, for example, even of FQHC grant proposals, is counterproductive. Such an expanded role for DSS would represent to the FQHCs "triplication" of oversight. That approach of the proposed regulations is also not in the best interest of the department.

Response: It is not the Department's intent to "insert itself" into FQHC operational matters. Rather, the requirement for the submission of grant proposals is so the department can verify that an FQHC has been designated by HRSA as an FQHC or an FQHC look-a-like. The Department has revised the regulation to remove the requirement of the submission of the entire grant proposal. The regulation will continue to require a copy of the grant award for verification of a clinic's designation as an FQHC. It is the Department's obligation to promulgate regulations for providers describing covered services, limitations and payment requirements.

- b.** Comment: The proposed regulations are also in several respects inconsistent with federal laws and regulations that establish the framework for FQHC operations. The proposed regulations should be carefully reviewed to eliminate such inconsistencies.

Response: Without citing specific sections in the regulation that are inconsistent, the department is unable to correct or explain a perceived inconsistency with federal laws and regulations. The Department has thoroughly researched the federal laws and regulations and is confident that the proposed regulation is consistent with federal law and regulations. To the extent that there were inconsistencies pointed out by other commenters, the Department has revised the regulation as noted above to correct any such inconsistencies.

Attachment 1



POLICY INFORMATION NOTICE

DOCUMENT NUMBER: 2008-01

DATE ISSUED: December 31, 2007

DATE REVISED: January 13, 2009

DOCUMENT NAME: Defining Scope of Project and Policy for Requesting Changes

TO: Health Center Program Grantees
Primary Care Associations
National Cooperative Agreements

The purpose of this Policy Information Notice (PIN) is to define what constitutes the scope of project for health centers funded under section 330 of the Public Health Service (PHS) Act, to specify which types of changes in scope of project require prior approval and to describe the process for health centers seeking to make changes in the approved scope of project. This PIN supersedes PINs 2000-04 and 2002-07, "Scope of Project Policy."

Scope of project defines the activities that the total approved section 330 grant-related project budget supports, the parameters for using these grant funds, the basis for Medicare and Medicaid Federally Qualified Health Center reimbursements, Federal Tort Claims Act coverage, 340B Drug Pricing eligibility and other essential benefits. Therefore, proper recording of scope of project is critical in the oversight and management of programs funded under section 330 of the PHS Act.

In this PIN, the Health Resources and Services Administration (HRSA) has updated several policies related to scope of project to clarify and improve the recording of critical information for health centers supported under the Health Center Program. Among the clarifications, HRSA has updated the definition of a service site and established site category types to assist health centers in reporting sites supported under the Health Center Program. HRSA also has included additional guidance to clarify the requirements for recording the service delivery method for required and additional services which will assist grantees to better represent the manner in which services under a health center's approved scope of project are available to the target population.

In implementing these policy clarifications, HRSA will provide all grantees with an opportunity to update their scope of project information. HRSA will work with grantees to resolve any potential issues.

This PIN also establishes expectations for the timely implementation of any request for prior approval to add or delete a service or add, delete or relocate a new service site. The effective date of an approved change in scope will be no earlier than the date of receipt of a complete application or, in cases where a grantee is not able to determine the exact date by which the

change in scope will be fully accomplished, grantees will be allowed up to 120 days following the date of the NGA indicating approval for the change in scope to implement the change (e.g., open the site or begin providing a new service). Therefore, a grantee should carefully consider its ability to accomplish the requested change within this anticipated timeframe prior to submitting a request.

HRSA will continue to utilize an electronic process, through the HRSA Electronic Handbooks (EHBs), for processing requests for prior approval of changes in scope of project. This electronic system provides for efficient processing, review and decision-making on the requested changes. However, because of the importance of the scope of project, it is crucial that grantees submit change in scope requests, to the extent practicable, 60 days in advance of the desired implementation date. It is HRSA's goal to communicate decisions on these requests within 60 days of receipt of a complete request.¹

All grantees considering a change in scope are encouraged to carefully review this PIN prior to initiating a request. In considering a change in scope, all grantees should review the proposal with their Board of Directors and consult with their Project Officer.

If you have any questions or require further guidance on the policies detailed in this PIN, please contact the Office of Policy and Program Development on 301-594-4300. If you have any questions or require further guidance on the process for submitting requests for prior approval for changes in scope of project, please contact your Project Officer.

James Macrae
Associate Administrator

Attachment

¹ Please see PIN 2009-03 available at <http://bphc.hrsa.gov/policy/pin0903.htm>.

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I. PURPOSE

The purpose of this Policy Information Notice (PIN) is to describe the Health Resources and Services Administration's (HRSA) policy for an approved scope of project for health centers funded under section 330 of the Public Health Service (PHS) Act,² the five components of an approved scope of project, and the policy and process for health centers seeking prior approval to make changes in the approved scope of project. This PIN supersedes PINs 2000-04 and 2002-07, "Scope of Project Policy."

II. APPLICABILITY

This PIN applies to all HRSA health service delivery grants awarded under section 330 of the PHS Act, including the Community Health Center, Migrant Health Center, Health Care for the Homeless, and Public Housing Primary Care Programs collectively referred to as "grantees" or "grantee health centers." The grantee named on the Notice of Grant Award (NGA) is the entity legally accountable to HRSA for performance of the health center activities as detailed and documented in the application for section 330 funding. Please note that only the grantee of record (the organization named on the NGA) can request a change in the approved scope of project. Changes in scope involving subrecipients or subcontractors must be submitted by the grantee of record.³

III. DEFINING SCOPE OF PROJECT

The scope of project defines the activities that the total approved section 330 grant-related project budget supports.⁴ Specifically, the scope of project defines the approved service sites, services, providers, service area(s) and target population(s) which are supported (wholly or in part) under the total section 330 grant-related project budget. A grantee's scope of project must be consistent with applicable statutory and regulatory requirements, Health Center Program Requirements, and the mission of the health center.⁵

² Organizations that are designated under the FQHC Look-Alike Program that are seeking a change to their approved scope of project should follow the process outlined in PINs for FQHC Look-Alikes on <http://bphc.hrsa.gov/policy/>.

³ A subrecipient is an organization that "(ii)(I) is receiving funding from such a grant under a contract with the recipient of such a grant, and (II) meets the requirements to receive a grant under section 330 of such Act . . ." (§1861(aa)(4) and §1905(l)(2)(B) of the Social Security Act). Subrecipients must be compliant with all of the requirements of section 330 to be eligible to receive FQHC reimbursement from both Medicare and Medicaid. The subrecipient arrangement must be documented through a formal written contract/agreement (Section 330(a)(1) of the PHS Act).

⁴ Note: a "change in scope of project" under section 330 is not the same as "change in the scope of services" in Medicaid as defined in the Benefits Improvement and Protection Act (BIPA) of 2000, Section 702. The Centers for Medicare and Medicaid Services (CMS) and State Medicaid Agencies define the term "change in the scope of services" as a mechanism for adjusting the Medicaid reimbursement rate of a FQHC due to "a change in the type, intensity, duration and /or amount of services." A State approved "change in the scope of service" can result in an increase or decrease in FQHC Medicaid reimbursement. "Change in the scope of services" is defined differently in each State's Medicaid Plan. The State Medicaid Agency must be contacted directly if a change in scope of services is being requested by a health center. Please see Section VI.B. (page 27) of this PIN for additional information.

⁵ For more information regarding the operation of health centers, please refer to the Health Center Program Requirements found at <http://bphc.hrsa.gov/about/requirements/index.html>.

A health center's scope of project is important because it:

- Stipulates the total approved section 330 grant-related project budget, specifically defining the services, sites, providers, target population, and service area for which grant funds have been approved. This total project budget includes program income and other non-section 330 funds.
- Determines the maximum potential scope of coverage (subject to certain exceptions) of the Federal Tort Claims Act (FTCA) program that provides medical malpractice coverage for deemed health centers and most individual employees (see page 26 of this PIN for more information on FTCA coverage).
- Provides the necessary site information which enables covered entities to purchase discounted drugs for their patients under the section 340B Drug Pricing Program (see page 28 of this PIN for more information on the 340B Drug Pricing Program).
- Defines the approved service sites and services necessary for State Medicaid Agencies to calculate payment rates under the Prospective Payment System (PPS) or other State-approved alternative payment methodology (see PAL 2001-09 posted on <http://www.bphc.hrsa.gov/policy/> and section 1902(bb) of the Social Security Act).⁶
- Defines the approved service sites necessary for the Centers for Medicare and Medicaid Services (CMS) to determine a health center's eligibility for Federally Qualified Health Center (FQHC) Medicare all-inclusive rate.

It is important to note that certain benefits, i.e., utilization of section 330 funds and related program income, FQHC Medicaid reimbursement, Medicare FQHC reimbursement, FTCA coverage, and 340B Drug Pricing benefits, require that activities be part of the section 330 approved scope of project and do not apply to activities that are not part of the approved scope of project. A section 330 grantee's approved scope of project may be part of a larger health care delivery system and, as such, must be distinctly defined within that context. Section 330 funded health centers may carry out other activities (i.e., other lines of business) that are not part of their scope of project and, thus, are not subject to section 330 requirements and expectations. For example, a grantee corporation may run a day care center that is not within the scope of the Federal project and does not use section 330 funds or related program income for support; therefore, it would not be eligible for the benefits that extend to activities within the grantee's scope of project such as FTCA coverage or Medicare or Medicaid reimbursement. In addition, the revenue generated from other activities (in the example above, the day care center) should be sufficient to support direct costs of the activity plus a reasonable share of overhead to ensure that section 330 funds and other grant-related income are not used inappropriately to support costs outside the approved scope of project.

⁶ All Program Information Notices (PINs) and Program Assistance Letters (PALs) are available on the HRSA web site at <http://www.bphc.hrsa.gov/policy/>.

NOTE: While identification as a service site within a scope of project is required for participation in the FTCA, 340B Drug Pricing, and FQHC programs, it is not a guarantee that these benefits will be realized. Each of these programs has a specific application process and a comprehensive set of requirements, of which scope of project is only one. In other words, identification as a service site within a scope of project is necessary, but not sufficient, to ensure participation in the other programs. To participate, all of the requirements of the other programs must also be met. For additional information, see Section VI of this PIN.

A. ROLE OF THE BOARD IN SCOPE OF PROJECT

The governing board of a health center provides leadership and guidance in support of the health center's mission and is legally responsible for ensuring that the health center is operating in accordance with applicable Federal, State and local laws and regulations. The health center governing board is responsible for establishing and approving the health center's scope of project. The annual application for section 330 funds details the scope of project supported by the grant and, per section 330(k)(3)(H) of the PHS Act (42 U.S.C. 254b), the health center governing board must approve the health center's application. It is the responsibility of the governing board to approve the overall plan and budget for the health center, the hours of operation for the health center sites, as well as the selection of the services provided by the health center. In fulfilling these responsibilities to accurately and completely delineate the health center's scope of project, the health center governing board is assuring that the health center will effectively utilize its available resources in pursuing its mission. As the board is responsible for the oversight of the health center operations, all requests for change in scope of project must be approved by the health center's governing board with approval documented in the board minutes.

B. FIVE CORE ELEMENTS OF SCOPE OF PROJECT

Five core elements constitute scope of project and address these fundamental questions:

- Where will services be provided (service sites)?
- What services will be provided (services)?
- Who will provide the services (providers)?
- What geographic area will the project serve (service area)?
- Who will the project serve (target population)?

1. Service Sites

A service site is any location where a grantee, either directly or through a sub-recipient or established arrangement,⁷ provides primary health care services to a defined service area or target population (discussed respectively in Sections III.B.4. and III.B.5. of this PIN). Sites may be permanent, seasonal, mobile van, migrant voucher or intermittent as defined further below based on many factors and as

⁷ Here and throughout this document "established arrangements" are intended to mean an arrangement where a service is provided through a formal written contract or cooperative arrangements (Section 330(a)(1) of the PHS Act).

appropriate for providing health care services to the target population. A service site may provide comprehensive primary care services or may provide a single service such as oral or mental health services, based on the identified needs in the community/population. Only those service sites listed on Form 5-Part B: Service Sites from the most recent approved application for Federal support or approved change in scope request are a part of a grantee's approved scope of project.

a) Definition of a Service Site

Service sites are defined as locations where all of the following conditions are met:

- health center encounters are generated by documenting in the patients' records face-to-face contacts between patients and providers;
- providers exercise independent judgment in the provision of services to the patient;
- services are provided directly by or on behalf of the grantee, whose governing board retains control and authority over the provision of the services at the location; and
- services are provided on a regularly scheduled basis (e.g., daily, weekly, first Thursday of every month).⁸ However, there is no minimum number of hours per week that services must be available at an individual site.

b) Permanent Service Sites

Permanent sites meet the definition of a service site above at a fixed address specified on Form 5 – Part B: Service Sites. These sites are open year round and may be operated on a full-time or part-time basis as appropriate to meet the needs of the target population. Services at a permanent site may be offered either directly or through an established arrangement. The name and address of each permanent service site at which the grantee provides care must be listed on Form 5 – Part B: Service Sites.

c) Seasonal Service Sites

Due to the seasonality of employment, shelter, or the mobility of patients served, grantees may operate some service sites on a seasonal basis or for only part of the year. Seasonal sites meet the definition of a service site above but operate at a fixed location for less than 12 months during the year. When open, seasonal sites may be operated on a full-time or part-time basis as appropriate to meet the needs of the target population. Grantees should list the name and address of each seasonal site on Form 5 – Part B: Service Sites and indicate the approximate number of months that the site is open during the year.

⁸ Note the statutory requirement in section 330(k)(3) of the PHS Act that "primary health services of the center will be available and accessible in the catchment area of the center promptly, as appropriate, and in a manner which assures continuity." In addition, note the regulatory requirement in 42 CFR 51c.303(m) that community health centers "must be operated in a manner calculated ... to maximize acceptability and effective utilization of services."

d) Special Instructions for Recording Mobile Van Sites

A fully-equipped mobile van that is staffed by health center clinicians providing direct primary care services (e.g., primary medical or oral health services) at various locations on behalf of the grantee is considered a service site. Mobile vans must meet the definition of a service site above, except that services do not need to be provided on a regularly scheduled basis, although this is encouraged to provide continuity and access to care for the target population. A grantee should separately list each mobile van (i.e., Mobile Van #1, Mobile Van #2, etc.) as a site on Form 5 – Part B: Service Sites. The specific locations where the van provides direct health care services do not need to be listed.

Vans that are not equipped or utilized for direct patient care are not service sites. These vans may be used by a grantee to transport patients or staff or to support and facilitate outreach or other enabling services. These vans should be listed on Form 5 – Part C: Other Activities (discussed in detail below), in the application for Federal support with a brief description of how the van is used.

e) Intermittent Sites

Grantees may utilize intermittent sites to provide direct primary health care services to the target population. Intermittent sites meet the definition of a service site above but operate on a regular scheduled basis for a short period of time (two months or less) at locations that change frequently as necessary to continue services to the target population. Generally, these sites are established to assure access to care for more mobile populations, such as homeless persons or migrant or seasonal farmworkers and their families, who may not be in one area for an extended period of time and, therefore, may not access services at a grantee's permanent or seasonal sites. Often, intermittent sites are established at migrant camps or homeless shelters that are open for only a short time to bring health care services directly to the target population and will be closed and re-opened at a new location as the population moves or the availability of space changes. The following are examples of potential locations for intermittent sites: 1) Shelters - Family, Adult, Homeless, Runaway Youth; 2) Day Shelters, Soup Kitchens, or Homeless Service Centers; 3) Outdoor Encampments; 4) Migrant Camps.

Grantees should list intermittent sites as a category on Form 5 – Part B: Service Sites. The specific locations where the grantee establishes an intermittent site to provide the services do not need to be listed; however, the number of such locations should be indicated on Form 5 – Part B: Service Sites and should be updated at least annually in the grantee's application for Federal support.

f) Migrant Voucher Screening Sites

Migrant Voucher Programs are established when there is insufficient sustained demand in an area for health care services from migrant and seasonal farmworkers

to warrant establishing a permanent or seasonal service site. Often migrant voucher grantees do not provide direct health care services; rather, the grantee may establish a screening site(s) where the clinical needs of a patient are assessed and then a referral for care is made to a local provider through an established contractual arrangement. The local provider will provide the primary care services to those individuals who are referred by the voucher program. Under these arrangements, services are provided on behalf of the health center through a contractual arrangement; however, services under the contracts are generally not provided on a regular scheduled basis but instead on an as-needed basis.

Grantees should list each migrant voucher assessment/screening site as a category on Form 5 – Part B: Service Sites. As the functions of migrant voucher screening sites are predominantly administrative, where little clinical services are provided, the assessment/screening sites should be listed as administrative sites. Those voucher locations which meet the requirements of a service site should be listed as administrative/service site. The specific locations where the grantee maintains contracts for direct services do not need to be listed; however, the number of such locations should be indicated on Form 5 – Part B: Service Sites and should be updated at least annually in the grantee’s application for Federal support.

g) Other Activities

Grantees often provide activities that are included in the scope of project at locations that: (1) do not meet the definition of a service site, (2) are conducted on an irregular timeframe/schedule and (3) offer a limited activity from within the full complement of health center activities included within the scope of project. These activities and locations, where clinicians and project staff go from time-to-time to seek out, engage and serve persons eligible for the project’s services, are covered under the scope of the project; however, compiling an exhaustive list of such activities and locations is impractical and, therefore, should be included as general categories of activities at various locations as part of the approved scope of project.

“Other activities” may also include (1) locations for off-site activities required by the health center and documented as part of the employment agreement or contract between the health center and a provider (e.g., health center physicians providing coverage at the hospital emergency room or participating in hospital call coverage for unassigned patients in order to maintain their hospital admitting privileges) and/or (2) locations where the only services delivered do not generate encounters (i.e., filling prescriptions, taking X-rays, conducting street outreach or providing health education, etc.).

Some examples of other activities include:

- Immunizations. Providing immunizations at 15 different senior centers. Grantees should list the activity as “immunizations,” the location as “senior centers” and the frequency as appropriate (e.g., four times per year).

- **Admitting.** Following the health center's patients to the hospital (admitting privileges). Grantees should list the activity as "admitting," the location as "hospital" and the frequency as appropriate (e.g., as required for on call arrangement, three times per week) and indicate in the description the specific hospital(s) with which the health center has such arrangements and whether health center providers see non-health center patients as part of his/her admitting privileges.
- **Medical Rounds.** Grantees should list the activity as "medical rounds," the location as "hospital" and the frequency as appropriate (e.g., as required for patient care, twice per week) and indicate in the description the specific hospital(s) with which the health center has such arrangements and whether the health center providers see non-health center patients as part of his/her admitting privileges.
- **Home Visits.** If it is the policy of the grantee that providers occasionally make home visits to health center patients, the grantee should list the activity as "home visits," the location as "patients' homes" and the frequency as appropriate (e.g., as required for patient care, five times per month).
- **Health Fairs.** If it is the policy of the grantee to occasionally participate in health fairs, the grantee should list the activity as "health fairs," the location as appropriate (e.g., various schools, community service centers) and the frequency as appropriate (e.g., three times per year).
- **Non-Clinical Outreach.** If it is the policy of the grantee that staff conduct outreach where no clinical services are offered, the grantee should list the activity as "non-clinical outreach," the location as appropriate (e.g., community neighborhoods, schools, community service centers) and the frequency as appropriate (e.g., weekly).
- **Portable Clinical Care.** If it is the policy of the grantee that providers conduct clinical care as part of a mobile team (for example, as part of a primary care street outreach team to serve a homeless individuals or utilizing portable dental equipment to provide oral health services at schools), the grantee should list the activity as "portable clinical care," the types of locations as appropriate (e.g., street, temporary shelters, schools, soup kitchens, labor camps) and the frequency as appropriate (e.g., weekly).
- **Health Education.** Grantees should list the activity as "health education," the location as appropriate (e.g., community service centers, schools) and the frequency as appropriate (e.g., six times per year).

All “other activities,” their locations, estimated frequency and a brief description of the activity should be identified and briefly described on Form 5 – Part C: Other Activities in the annual application for Federal support. In addition, these activities should be described in the grant application, as they contribute to the provision of comprehensive primary care services. For items listed on Form 5-Part C, grantees should ensure that adequate and appropriate documentation has been secured to support and enable performance of these activities.

2. Services

a) Requirements and Discussion of Services

Section 330 funded health centers are required to provide, either directly or through an established arrangement, a set of primary health care services. These are defined in section 330 of the PHS Act as health services related to family medicine, internal medicine, pediatrics, obstetrics and gynecology, diagnostic laboratory and radiological services, pharmaceutical services as appropriate, and defined preventive health services. (For the complete list of required services see section 330(b)(1)(A) of the PHS Act). The specific amount and level of these services will vary by grantee based on a number of factors including, among others, the population served, demonstrated unmet need in the community, provider staffing, collaborative arrangements and/or licensing requirements.

Services provided by the grantee are defined for the organization/entity, not by individual site. Not all services must be available at every grantee service site; rather, the patients must have reasonable access to the full complement of services offered by the center as a whole, either directly or through formal established arrangements.

Because health centers provide service to diverse populations, health centers should assure services are provided in culturally and linguistically appropriate manner based on the target population(s).

Health centers may also provide “additional health services” defined in the section 330 statute as “services that are not included as required primary health services and that are appropriate to meet the needs of the population served by the health center...”⁹ Grantees are reminded that once a service is included in the approved scope of project, it must be available equally to all patients regardless of ability to pay and available through a sliding fee scale.¹⁰ Grantees, therefore, should thoroughly investigate the costs, benefits, and risks to the grantee before providing these services. In general, a grantee should demonstrate that all required primary health services are available to all patients before proposing to add additional health services.

⁹ Section 330(b)(2) of the PHS Act.

¹⁰ Section 330(k)(3)(G) of the PHS Act., 42 C.F.R. Part 51c.303(f).

Health centers often provide both clinical and non-clinical services. Generally, clinical services are those services related to the provision of direct care and include medical, dental, mental health, substance abuse, diagnostic laboratory and X-ray, and pharmacy services. Non-clinical services are those services that support and assist in the delivery of medical care and facilitate patient access to care, often described as enabling services. These include case management, outreach, transportation, translation and interpretation, health education and eligibility assistance.

The specific range of services that are available at a health center may vary based on provider qualifications and licensing requirements. Many professional, State and/or local certifying/licensing boards require and/or sanction levels or types of service based on a provider's qualifications. Similarly, State and/or local certifying bodies may require different accrediting or licensing standards for facilities. If a grantee determines that all professional, State, and local qualifications necessary for a grantee provider to provide a specific service have been met, and State and local standards/accreditation requirements of the facility have also been fully met, the procedures or levels of service sanctioned by the certifying board are included in the grantee's scope of project. For example, if the grantee employs an obstetrician who performs colposcopy, that service would be appropriate to be included in the scope of the center's project because that procedure is a normal part of the practice of obstetrics and is recognized as such under State certifying boards.

As a reminder, all providers of medical, dental, and mental health services (whether required or additional services) must be properly credentialed and privileged (i.e., appropriately trained and licensed) to perform the activities and procedures expected of them by the grantee. It is the responsibility of the grantee to ensure that all necessary credentialing of providers and licensing of the facility(ies) to provide a service, are completed before requesting that a service be included in the scope of project. (See PIN 2002-22 for additional guidance on the credentialing of providers.)

b) Delivery Method and Scope of Project

In order to ensure the availability of comprehensive services for their patients, health centers may utilize one or more of the following delivery methods to provide a service:

(1) Direct by Grantee and/or Formal Written Agreement

When a service is provided directly by the grantee (Form 5-Part A, Column I) or through a formal written contract/agreement (Form 5-Part A, Column II), the grantee is accountable for providing and/or paying/billing for the direct care. Services provided by the grantee may include, but are not limited to, those rendered by salaried employees, certain contractors, National Health Service Corps staff, and sub-recipients. In most cases, services delivered by the grantee are provided on-site at a service delivery location listed on Form 5- Part B: Service Sites. If the service is provided

by formal written agreement, the agreement must describe how the service will be documented in the patient record and if applicable, how the grantee will pay and/or bill for the service.

(2) Formal Written Referral Arrangement

Under a formal written referral arrangement (Form 5-Part A, Column III), the grantee maintains responsibility for the patient's treatment plan and will be providing and/or paying/billing for appropriate follow-up care based on the outcome of the referral. These referral arrangements should be formally documented in a written agreement that at a minimum describes the manner by which the referral will be made and managed and the process for referring patients back to the grantee for appropriate follow-up care.

Under these types of formal referral arrangements, if the actual service is provided and paid/billed for by another entity, then the SERVICE IS NOT included in the grantee's scope of project. However, establishment of the referral arrangement and any follow-up care provided by the grantee subsequent to the referral is considered to be part of the grantee's scope of project. For example, a grantee may have a referral arrangement for diagnostic X-ray with a hospital. As part of the referral arrangement, the hospital performs the diagnostic X-ray, bills the patient for the services and provides feedback and/or results to the grantee for appropriate follow-up care. The diagnostic X-ray service would NOT be part of the grantee's scope of project but the establishment of the referral and follow-up care provided by the grantee would be part of the grantee's scope of project.

(3) Informal Referral Arrangements or Agreements

Under informal referral arrangements or agreements (these arrangements are not captured on Form 5-Part A and are not a part of the grantee's scope of project), a grantee refers a patient to another provider who is responsible for the treatment plan and billing for the services provided and no grant funds are used to pay for the care provided. These informal arrangements/agreements are not required by HRSA to be documented in a written agreement and do not require the other provider to refer patients back to the grantee for appropriate follow-up care. For services provided by informal referral arrangements or agreements, the referral and the service and any follow-up care provided by the other entity, are considered outside of the grantee's scope of project.

Required primary health services must be provided directly by the grantee or through an established arrangement¹¹ such as through a formal agreement or through a formal referral arrangement. In addition, required services provided directly by the grantee or by formal agreements or formal referral arrangements must be offered on a sliding fee scale and available equally to all

¹¹ Section 330 (a)(1) of the PHS Act.

patients regardless of ability to pay. Therefore, informal referral arrangements are not acceptable for the provision of a required service.

Grantees should ensure that all agreements/contracts/arrangements with other providers and organizations comply with section 330 requirements and administrative regulations for the Department of Health and Human Services.¹² Grantees should also ensure that providers for any formal arrangements/agreements are properly credentialed and licensed to perform the activities and procedures expected of them by the grantee.

Note: FTCA and 340B Drug Pricing coverage does not extend to all types of contractual and referral arrangements. Health centers should refer to FTCA-related guidances, listed on page 26 of this PIN, and to Federal Register, Vol. 61, No. 207, page 55156-8, "Patient and Entity Eligibility" for clarification of the 340B Drug Pricing benefit for referrals. Remember, FTCA and 340(B) each has its own independent requirements that must be met for participation.

c) Recording Services and Delivery Method

The services provided by a grantee under the section 330 grant and the method in which they are provided must be documented on Form 5 – Part A: Services Provided. Services are reported on Form 5-Part A: Services Provided in aggregate for the grantee, not on a site-by-site basis. Since more than one delivery method may apply for a given service, more than one type of service delivery method may be indicated on the Form. Grantees must indicate at least one delivery method for each required service listed on Form 5-Part A. Only those services listed on this Form from the most recent annual application for Federal support or approved change in scope request are considered to be part of a grantee's scope of project.

Service delivery methods should be updated at least annually in the grantee's application for Federal support. If services are provided, regardless of method, at a location that meets the definition of service site, the location should be listed on Form 5 – Part B: Service Sites.

3. Providers

a) Requirements and Discussion of Providers

Providers are individual health care professionals who deliver services to health center patients on behalf of the health center. They assume primary responsibility for assessing the patient and documenting services in the patient's record. Providers include only those individuals who exercise independent judgment as to the services rendered to the patient during an encounter.

¹² 45 C.F.R. Part 74.

Grantees utilize a variety of mechanisms for provider staffing in order to maximize access to comprehensive, efficient, cost-effective, and quality health care.¹³ For instance, grantees may directly employ or contract with individual providers, may have arrangements with other organizations or may utilize volunteers. Grantees are encouraged to carefully consider the benefits and risks associated with each type of staffing arrangement because of the impact it may have on management and operations. It is preferable that grantees directly employ providers; however, there can be certain situations under which it may be necessary and appropriate for grantees to engage in alternative arrangements. Grantees must ensure that for all contracted clinical staff or volunteers, there is a separate, written agreement.

As a reminder, all providers of medical, dental and mental health services must be appropriately trained and properly credentialed and licensed to perform the activities and procedures expected of them by the grantee. It is the responsibility of the health center to ensure that all necessary credentialing of providers has been completed. (See PIN 2002-22 for additional guidance on the credentialing of providers.)

b) Instructions for Recording Providers

The type and number of clinical providers including volunteers and other staff must be listed on Form 2: Staffing Profile. Providers and other staff are reported in aggregate for the grantee, not on a site-by-site basis. Providers should be updated at least annually in the grantee's application for Federal support.

c) FTCA Considerations

Please note that the definition of "provider" under the scope of project may not be consistent with the definition of provider under FTCA. Individuals covered by FTCA may include others, such as lab and radiology technicians, as described in section 224 of the PHS Act. Likewise, not all provider arrangements in the scope of project are covered by FTCA. For example, volunteer providers, physicians contracted under a professional corporation or employed by another corporation, as well as interns/residents/medical students not employed by the health center may be included as part of scope of project, but are not covered under FTCA. If providers are employees of another company, the health center would still need to have a separate written agreement with the providers.

Also of note, moonlighting, defined as engaging in professional activities outside of the provider's employment responsibilities to the primary employer (in this case the health center), is not a part of the grantee's approved scope of project. Therefore, neither the grantee nor the moonlighting provider may receive FTCA coverage for moonlighting activities.

¹³ For health centers funded under section 330(e) and/or section 330(g), please see PIN 98-24, Amendment to PIN 97-27, Regarding Affiliation Agreements of Community and Migrant Health Centers, for further discussion of affiliation arrangements.

4. Service Area

a) Requirements and Discussion of Service Area

The concept of a service or “catchment” area has been part of the Health Center Program since its beginning. Although in general, the service area is the area in which the majority of the health center’s patients reside, health centers may use other geographic or demographic characteristics to describe their service area. The Health Center Program’s authorizing statute requires that each grantee periodically review its catchment area to:

- (i) ensure that the size of such area is such that the services to be provided through the center (including any satellite) are available and accessible to the residents of the area promptly and as appropriate;¹⁴
- (ii) ensure that the boundaries of such area conform, to the extent practicable, to relevant boundaries of political subdivisions, school districts, and Federal and State health and social service programs; and
- (iii) ensure that the boundaries of such area eliminate, to the extent possible, barriers to access to the services of the center, including barriers resulting from the area's physical characteristics, its residential patterns, its economic and social grouping, and available transportation.

Public Health Service Act sec. 330(k)(3)(J)

This periodic assessment of service area should be incorporated into a grantee’s annual application for Federal support. Routine patient origin studies/analyses will help to ensure that the reported service area is accurate.

The service area should, to the extent practicable, be identifiable by county and by census tracts within a county. Describing service areas by census tracts enables analysis of service area demographics. Service areas may also be described by other political or geographic subdivisions (e.g., county, township, zip codes as appropriate). Starting with calendar year (CY) 2005 Uniform Data System (UDS) data, grantees annually report information on the aggregate geographic area in which its patients reside. This enables grantees and HRSA to better identify service areas. The service area must be federally designated as a Medically Underserved Area in full or in part or contain a federally designated Medically Underserved Population (MUP).¹⁵

b) Recording Service Area

The service area for the grantee must be listed by census tracts and zip codes on Form 5 – Part B: Service Sites. Census tracts and zip codes for the service area are reported on a site-by-site basis. In general, those census tracts and/or zip codes

¹⁴ Primary health services of the center must also be provided “in a manner which assures continuity.” (PHS Act, section 330(k)(3)(A).)

¹⁵ This requirement is not applicable to health centers requesting or receiving funding only under section 330(g), (h), and/or (i) of the PHS Act, since those centers are applying to serve populations already recognized as underserved.

listed on this Form from the most recent annual application for Federal support and/or approved change in scope request form the basis for determining service area for a grantee's scope of project. The service area for each service site should be updated at least annually in the grantee's application for Federal support.

5. Target Population

a) Requirements and Discussion of Target Population

Health centers are required to serve a "medically underserved, or special medically underserved population."¹⁶ Each health center must define an underserved population from within the established service area to which it will direct its services. The underserved populations often face barriers in accessing health care services and disparities in their health status which are addressed through the health center operation.

This target population is usually a subset of the entire service area population, but in some cases, may include all residents of the service area if it is determined that the entire population of the service area is underserved, and lacking access to adequate comprehensive, culturally competent quality primary health care services. Although a grantee may serve diverse populations at several sites, the target population is reported in aggregate at the grantee level not on a site-by-site basis.

Section 330(e) grantees are required to make services available to all residents of the health center's service area, regardless of the individual's ability to pay.¹⁷ Health centers may also extend services to those residing outside the service area. However, HRSA recognizes that health centers must operate in a manner consistent with sound business practices. Nonetheless, health centers should address the acute care needs of all who present for service, regardless of residence.

Some health centers receive funding to target a special population within a community. There are three such special populations: migrant and seasonal agricultural workers and their families, persons who are homeless, and/or residents of public housing. Grantees receiving special populations funding (i.e., grants under only section 330(g), (h), and/or (i) of the PHS Act) are not subject to the requirement to make services available to all residents of the service area.¹⁸ However, these grantees are expected to address the acute care needs of anyone who presents for service. Individuals who are not members of the special population(s) served by a special populations-only grantee may then be referred to more appropriate settings for their non-acute health care needs.

¹⁶ Section 330(a)(1) of the PHS Act.

¹⁷ Section 330(a)(1)(B) of the PHS Act.

¹⁸ Section 330(a)(2) of the PHS Act.

b) Recording Target Population

Information on the grantee's target population must be listed on Form 4: Community and Target Population Characteristics. Demographic, income, insurance status and other information on the service area and target population should be recorded on this Form in aggregate for the grantee as a whole, not on a site-by-site basis, and should be updated at least annually in the grantee's application for Federal support.

IV. CHANGE IN SCOPE REQUESTS

Some changes in the approved scope of project require prior approval from HRSA before being initiated; others may be implemented by the grantee without prior approval. In all cases, any changes proposed and/or implemented by a grantee must assure continued compliance with the applicable statutory, regulatory and policy requirements. In reviewing a request to change the approved scope of project, HRSA will consider whether the request furthers the mission of the health center by increasing or maintaining access, and improving or maintaining the quality of care for the target population. Requests must not result in the diminution of the grantee's total level or quality of health services currently provided to the target population. Additionally, grantees are reminded that a request to change the approved scope of project must not shift resources away from providing approved services for the target population, and must be accomplished without additional Health Center Program funding. As appropriate, changes in the approved scope of project also must assure continued service to a Medically Underserved Area (MUA) or a Medically Underserved Population (MUP). (Please note, a service site does not have to be located in an MUA in order to serve people living in the area.)

A. CHANGE IN SCOPE REQUESTS THAT REQUIRE PRIOR APPROVAL

1. Types of Change in Scope Requests that Require Prior Approval

Based on applicable section 330 program regulations, 42 CFR Part 51c.107(c), 45 CFR Parts 74 and 92, and HHS Grants Policy Statement, prior approval is required for significant changes in the approved budget or program plan including scope of project.¹⁹ The following five types of changes are considered significant and, therefore, require prior approval from HRSA:

- **Adding a service site** not included on Form 5 – Part B: Service Sites, of the grantee's most recent application for Federal support or approved change in scope request.
- **Adding a service** not included on Form 5 – Part A: Services Provided, of the grantee's most recent application for Federal support or approved change in scope request.
- **Relocating a service site** that was included on Form 5 – Part B: Service Sites, of the grantee's most recent application for Federal support or approved change in scope request.

¹⁹ Any activity that results in significant re-budgeting also requires prior approval. See DHHS Grants Policy Statement (HHS GPS): page II-55. <ftp://ftp.hrsa.gov/grants/hhsgrantspolicystatement.pdf>.

- **Deleting a service site** that was included on Form 5 – Part B: Service Sites, of the grantee’s most recent application for Federal support or approved change in scope request.
- **Deleting a service** that was included on Form 5 – Part A: Services Provided, of the grantee’s most recent application for Federal support or approved change in scope request.

Grantees should include in their change in scope request a detailed discussion of any potential impact on the total approved section 330 project budget, services provided, number of patients served, and number and type of providers. Any unique circumstances that are expected to impact the ability of the grantee to meet the expectations for change in scope requests must be fully explained and documented.

Note: Any request for change in scope of project must be accomplished without additional section 330 funds. Requests for change in scope of project must be approved by the Board of Directors of the grantee with approval documented in the Board minutes prior to submission to HRSA.

Because of the importance of the scope of project, it is expected that grantees will submit any change in scope request requiring prior approval **at least 60 days in advance of their desired implementation date**, to the extent practicable, following the process described in Section V of this PIN (see page 24).

2. Special Instructions for Adding a Service Site²⁰

a) Adding Sites in the Same Building, Complex or Campus

Health centers may identify an opportunity to add a new location that meets the definition of a service delivery site (see page 5) within the same building or complex/campus where they are already have an established service delivery site providing services to the target population. In such an instance, a health center must complete a change in scope for prior approval to add the new site if the site would have a separate physical address including a different suite/office/building number. For example, a change in scope of project is required if a grantee operates a site at 345 Main Street, Suite #4 and will be adding a new site at 345 Main Street, Suite #12. If the location does not create a separate physical address, no change in scope is required.

b) Adding Migrant Voucher Screening Sites

If a grantee needs to add a new migrant voucher screening site, the grantee must submit a change in scope request for prior approval to add the new screening

²⁰ All approved change in scope requests to add a new service site must be reported to the State Medicaid Agency and the Medicare Fiscal Intermediary within 90 days of approval. See Section VI of this PIN for further information regarding notification to the State Medicaid Agencies and the Medicare Fiscal Intermediary.

location. No change in scope request is necessary to add/delete the specific locations where the grantee maintains contracts for direct services.

c) Changing from Intermittent to Permanent or Seasonal Sites

Grantees may determine that demand for primary care services from the target population at an intermittent site exceeds their expectation to provide services at that location for only a short period of time. If a grantee determines that the intermittent site should be operated for more than the expected period of time for an intermittent site (two months or less), and the site meets the definition of a service site (see page 5), the grantee must complete a change in scope request to add the location as a permanent or seasonal service site.

d) Sites Offering a Single Service

Although grantees are not required to provide all services at all service sites, patients must have reasonable access to the full complement of comprehensive services offered by the health center as a whole. The establishment of a single service or limited service site must be in a location that allows reasonable access to the full complement of services from the health center or access to the required services on a sliding fee scale basis through formal arrangements with other providers in the community.

3. Special Instructions for Adding a Service

While grantees may deliver a service by several different methods, a service will only be included in the grantee's scope of project if it is delivered directly by the grantee or through a formal written agreement such as a contract, purchase agreement, and/or written arrangement as recorded Form 5- Part A, Services, Columns I and II. **Although the arrangement with another provider under a formal referral arrangement (recorded under Column III on Form 5 – Part A) is within a grantee's scope of project, the actual service provided by the other provider under the arrangement is not included in a grantee's scope of project;** therefore, if a grantee has been providing a service only through a formal or informal referral arrangement and wishes to begin providing this service directly or through formal agreement as part of their scope of project (e.g., the service is **ONLY** recorded in Column III and is being moved to Columns I and/or II on Form 5- Part A), the grantee **MUST** submit a change in scope request to add the service to the scope of project and begin providing this service.

Cases where a grantee moves a service(s) from one site to another site in the approved scope of project do not require prior approval. However, in doing so, grantees should assure that the population accessing the service at the original site will continue to have reasonable access to the service once it is relocated.

4. Special Instructions for Relocation of a Site

Health centers may engage in different types of relocations to maximize access to services for the target population. In some cases, this may involve complete relocation, and in others, only partial relocation.

Grantees moving **all** clinical services from an approved permanent or seasonal service site to a new location must submit a request for prior approval to relocate the service site. Requests for relocation will be examined to assure continued access for the populations served by the service site to be relocated. Such requests should demonstrate that the relocation furthers the mission of the health center by increasing or maintaining access and improving or maintaining the quality of care for the target population currently served by the grantee. Requests for relocation must not result in the diminution of the grantee's total level or quality of health services currently provided to the target population.

Cases where a grantee is moving only a portion of its current clinical services from an approved permanent or seasonal service site to a new location that is not a part of the approved scope of project, are not considered a relocation of the service site but rather, the addition of a new service site. In this situation, the grantee must submit a change in scope request to add a service site for the new location as the existing site will continue to operate as a service site, meeting the definition described above in III.B.1. (see page 5).

Changes in locations for intermittent sites (when operated for two months or less) are not considered relocations and, therefore, do not require prior approval. However, if an intermittent site becomes a permanent or seasonal site (i.e., will be operated for more than two months), the grantee must submit a change in scope request to add the site as a permanent or seasonal site.

5. Special Instructions for Deleting a Site or Service

There may be circumstances that require grantees to cease operation of a site or the provision of a particular service. Because of the potential implication on access to care for the target population, any request to delete a service or service site from a grantee's scope of project will not be approved without a full examination of the issues surrounding the perceived need to delete the site or service. Grantees are reminded that the deletion of a site or a service must not result in elimination or reduction in access to required services under section 330 of the PHS Act for populations currently served by the health center. Grantees must demonstrate that the requested deletion will not reduce access to services or the ability of current patients to receive the same level of care. As a reminder, grantees must provide all required services directly or through an established arrangement (i.e., a formal written contract/agreement or a formal written referral arrangement); therefore, a grantee may not request to delete a required service.

6. Special Considerations for Changes in Scope of Project

a) Future Federal Funding to Support a Change in Scope Request

A key requirement for every change in scope request is that the grantee must document that the requested change can be fully accomplished with no additional Federal support. In other words, in a request to add a site or service a grantee must demonstrate that adequate revenue will be generated to cover all expenses as well as an appropriate share of overhead costs incurred by the health center in administering the new site or service. If additional Federal funds will be necessary to fully implement the proposed change in scope, it will not be approved. Grantees that require additional Federal grant support to implement the proposed change should consider competitive funding opportunities. Specific eligibility for additional Federal support will be included in each announced funding opportunity.

Grantees considering submitting a change in scope to add a service delivery site that will be the basis for later submission of a competitive grant application (i.e., for Expanded Medical Capacity) should proceed with care. As stated previously, a change in scope request must include only the level of services that can be maintained without additional Federal support. Grantees are strongly advised against establishing a new service or site that is dependent on new future grant support, since such support is not guaranteed.

b) Financial Impact

While many grantees have undertaken changes to their scope of project to improve their financial viability, changes in scope of project that are not carefully planned may pose high risks. A complete financial analysis of the impact of a change in scope is imperative to ensure long-term viability of the health center. In particular, grantees should examine the overall costs of the activity and the potential for reimbursement as part of this analysis. **Approval of a change in scope request is contingent on submission of a budget demonstrating break-even (worst case scenario) or the potential for generating additional revenue.** Grantees are strongly encouraged to thoroughly review any change in scope request that could result in a significant increase or decrease in the total budget of the health center. Because unforeseen events may occur making original projections inaccurate, grantees should continually monitor the progress of their requested change in scope and be prepared to take action should revenues fail to meet or exceed expenses. Additional revenue obtained through the addition of a new service or site must be invested in activities that further the objectives of the approved health center project, consistent with and not specifically prohibited by section 330(e)(5)(D)(3).

c) Impact on Neighboring Health Centers

Health centers should coordinate and collaborate with other section 330 grantees, FQHC Look-Alikes, State and local health services delivery projects, and programs in the same or adjacent service areas serving underserved populations to create a

community-wide service delivery system. Section 330 of the PHS Act specifically requires that applicants for health center funding have 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.”²¹ The goal of collaboration is to utilize the strengths of all involved organizations to best meet the overall health care needs of the area’s underserved population. In addition, continued collaboration among providers will help to ensure that organizations are aware of and, where possible, maximize the benefits of, all organizations.

When a change in scope of project (e.g., the addition or relocation of a service site) is proposed, it is essential that a grantee consider the population(s) served by other existing providers of care, including other section 330 funded health centers, and the impact of the proposed change in scope on the viability of these neighboring health centers. Meeting the health care needs of the community and target population, ensuring that limited Federal grant dollars are used efficiently and effectively to provide access to as many underserved people as possible and the potential impact of a change in scope request on a neighboring health center(s) are key in decisions related to service area overlap.

The potential for service area overlap through a change in scope request will prompt further review, analysis and resolution before HRSA will be able to make a final decision on a health center’s request. When a proposed change in scope has the potential to create a service area overlap, documentation of support, and/or cooperation from a neighboring health center(s) in the form of a Board of Directors-endorsed letter is desirable. If the health center is not able to document the support of other local providers for its request, it should provide an explanation for the lack of such documentation. In cases where there may be a service area overlap, additional information such as patient origin studies/analyses or an onsite visit may be necessary prior to a final HRSA decision. (See Service Area Overlap PIN, 2007-09 dated March 12, 2007 available at <http://www.bphc.hrsa.gov/policy/pin0709.htm>.)

7. Criteria for Prior Approval of a Change in Scope Request

All requests for change in scope of project requiring prior approval (see in Section IV.A. of this PIN on page 16), will be reviewed to determine if the request:

- 1) will not require any additional section 330 funding to be accomplished;
- 2) does not shift resources away from providing services for the current target population;
- 3) furthers the mission of the health center by increasing or maintaining access and improving or maintaining quality of care for the target population;

²¹ Section 330(k)(3)(B) of the PHS Act.

- 4) is fully consistent with section 330 of the PHS Act and Health Center Program Expectations including appropriate governing board representation for changes in service sites and populations served;
- 5) provides for appropriate credentialing and privileging of providers;
- 6) does not eliminate or reduce access to a required service;
- 7) does not result in the diminution of the grantee's total level or quality of health services currently provided to the target population;
- 8) continues to serve a Medically Underserved Area (MUA) in whole or in part, or Medically Underserved Population (MUP)²² [Please note that a service site does not have to be located in an MUA to serve it];
- 9) demonstrates approval from the health center's Board of Directors, with approval documented in the Board minutes; and
- 10) does not significantly affect the current operation of another health center located in the same or adjacent service area, preferably, but not necessarily, by documenting support to the extent possible from any neighboring health centers.

B. OTHER CHANGE IN SCOPE REQUESTS

The following changes are not considered significant²³ and, therefore, do not require prior approval. Each grantee is expected to discuss any such changes and/or updates in the next application for Federal support.

- **Adding a service to a site where both the service and site are already within the approved scope of project.** If a grantee currently provides a service within the scope of project, no prior approval is necessary to add the service to a service site already in the approved scope of project. For example, a grantee provides mental health services at one service site and chooses to add that service to another service site already within the approved scope of project; no request for prior approval of the change is necessary. The service and service site must be previously documented on Form 5 – Part A: Services Provided and Form 5 – Part B: Service Sites, respectively, of the grantee's most recent application for Federal support or approved change in scope request.
- **Change in the number of intermittent sites,** previously documented on Form 5 – Part B: Service Sites, of the grantee's most recent application for Federal support

²² Required for health centers funded under section 330(e).

²³ Based on applicable section 330 program regulations, 42 CFR Part 51c.107(c), 45 CFR Parts 74 and 92, and HHS Grants Policy Statement.

or approved change in scope request. The number of such sites should be updated at least annually in the application for Federal support.

- **Change to providers** listed on Form 2: Staffing Profile of the grantee's most recent application for Federal support or approved change in scope request. Only those requests affecting providers that are linked with changes in sites or services require prior approval. No change in scope request is required in cases where a grantee changes the type of provider used to provide a service under the approved scope of project. For example, if the grantee has been providing mental health services using a social worker and decides to add a psychologist, and there is no change in the services provided (i.e., mental health), the grantee does not need to request prior approval to make this change.
- **Change to the hours of operation of a service site** previously approved on Form 5 – Part B: Service Sites, of the grantee's most recent application for Federal support or approved change in scope request. The hours for each site should be updated at least annually in the application for Federal support.

Note that any change in scope of project must be accomplished without additional section 330 funds.

C. CHANGE IN SCOPE DURING EMERGENCIES FOR HEALTH CENTERS

During an emergency, health centers are likely to play an important role in delivering critical services and assisting in the local community response. **Health centers deemed under FTCA should refer to PIN 2007-16, "Federal Tort Claims Act (FTCA) Coverage for Consolidated Health Center Program Grantees Responding to Emergencies."** (See <http://www.bphc/policy/pin0716/>.)

For the purposes of this section, an "emergency" or "disaster" is defined as an event affecting the overall target population and/or the community at large, which precipitates the declaration of a state of emergency at a local, State, regional, or national level by an authorized public official such as a governor, the Secretary of the U.S. Department of Health and Human Services, or the President of the United States. Examples include, but are not limited to: hurricanes, floods, earthquakes, tornadoes, wide-spread fires, and other natural/environmental disasters; civil disturbances; terrorist attacks; collapses of significant structures within the community (e.g., buildings, bridges); and infectious disease outbreaks and other public health threats.

In situations where an emergency has not been officially declared, but the health center is unable to operate, HRSA will evaluate on a case-by-case basis whether extraordinary circumstances justify a determination that the situation faced by the health center constitutes an "emergency."

HRSA recognizes that during an emergency, health centers are likely to participate in an organized State or local response and provide primary care services at temporary

locations. Temporary locations include any place that provides shelter to evacuees and victims of an emergency. It also includes those locations where mass immunizations or medical care is provided as part of a coordinated effort to provide temporary medical infrastructure where it is most needed. These temporary locations will be considered part of a health center's scope of project if all of the following conditions are met:

1. Services provided are on a temporary basis;
2. Temporary locations are within the health center's service area or neighboring counties, parishes, or other political subdivisions adjacent to the health center's service area;
3. Services provided by health center staff are within the approved scope of project; and
4. All activities of health center staff are conducted on behalf of the health center.

To assure that the emergency response at temporary locations is considered part of the center's scope of project, the health center must provide the following information to its HRSA Project Officer by phone, e-mail, or fax: (1) health center name; (2) the name of a health center representative and this person's contact information; and (3) a brief description of the emergency response activities. Health centers must submit this information as soon as practicable but no later than 15 calendar days after initiating emergency response activities. HRSA will determine on a case by case basis whether extraordinary circumstances justify an exception to this 15-day requirement. If the HRSA Project Officer is not available, the health center should contact the BPHC's main phone line at 301-594-4110.

If a health center needs to continue operating at a temporary location beyond 90 days from the onset of the emergency, the health center must submit a formal change in scope request to add the site. Health centers are expected to submit the formal request with sufficient time for HRSA processing.

V. PROCESS FOR CHANGE IN SCOPE OF PROJECT REQUESTS

All grantees considering a change in scope are encouraged to carefully review this PIN prior to initiating a request. In considering a change in scope, all grantees should review the proposal with their Board of Directors and consult with their Project Officer.

A. MECHANISM TO SUBMIT REQUESTS FOR PRIOR APPROVAL

An electronic process through HRSA's Electronic Handbook (EHB) has been developed for obtaining prior approval for the five types of change in scope of project requests requiring prior approval (see page 16 of this PIN). The EHB is designed to streamline the grants administration process and enable grantees to communicate with HRSA and conduct activities electronically. The EHB can be accessed from anywhere on the Internet using a standard web browser <https://grants.hrsa.gov/webexternal/>. When a grantee initiates a change in scope request, the EHB will assign a tracking number.

Grantees may create and submit a change in scope request in one session, or create and save part of a request, using the assigned tracking number to return as many times as necessary to complete the request before submitting it for HRSA review.

B. CHANGE IN SCOPE DETERMINATIONS AND TIMELINE

Because of the importance of scope of project, it is expected that grantees will request prior approval at least 60 days in advance of their desired implementation date for changes in scope for service delivery sites and services provided. There may be circumstances where submitting a change in scope request early may not be possible; however, the goal is to minimize these occurrences through careful planning. Timely submission of a change in scope request is important to ensure Medicaid and Medicare FQHC reimbursement, FTCA coverage, and 340B Drug Pricing benefits for the specific site/service, as appropriate.

If additional information or clarification is needed, the Project Officer will notify the grantee of the deficiencies of the request through the EHB, and the grantee will be given 60 days to provide the additional information. If the requested information is not provided by the grantee by the end of 60 days, the change in scope request will be denied and the grantee will be notified of this decision through the EHB. If a request is denied, the grantee will have to submit a new request for prior approval in order to implement the change in scope.

Due to the varying complexity of requests, in some cases it may be necessary to extend the HRSA review period if additional analysis, such as an on-site consultation, is warranted. In those cases, the grantee will be notified through the EHB within the initial 60 day review period of the potential delays in processing the request.

HRSA will indicate the final decision within 60²⁴ days of a complete change in scope request in one of the following two ways:

- 1) Notice of Grant Award (NGA) indicating approval; or
- 2) an email through EHB indicating disapproval.

C. EFFECTIVE DATE OF APPROVAL

The effective date of an approved change in scope will be no earlier than the date of receipt of a complete request for prior approval. In cases where a grantee is not able to determine the exact date by which a change in scope (i.e., adding a site or service) will be fully accomplished, grantees will be allowed up to 120 days following the date of the NGA indicating approval for the change in scope to implement the change (e.g., open the site or begin providing a new service). Therefore, grantees should carefully consider their ability to accomplish the requested change within this anticipated timeframe prior to submitting a request. If a grantee does not or is unable to implement the requested change in scope within 120 days of approval, the grantee must immediately notify the Project Officer in

²⁴ Please see PIN 2009-03 available at <http://bphc.hrsa.gov/policy/pin0903.htm> on the revision made to PIN 2008-01.

writing with an appropriate justification for the unanticipated delay and a detailed plan for completing the requested scope change. The BPHC will consider, on a case by case basis, exceptions to the 120 implementation requirement only if the grantee provides sufficient and compelling justification of the unique and unavoidable circumstances that will prevent the grantee from meeting this expectation.

As a reminder, all grantees should ensure that any application for Federal support documents the total scope of project and all activities added through an approved change in scope of project during the preceding budget period.

VI. ADDITIONAL SCOPE OF PROJECT POLICY ISSUES

A. SCOPE OF PROJECT AND FTCA COVERAGE

FTCA coverage is limited to staff and services that are documented as being within the approved scope of project and included in provider employment agreements or contracts.

The requirements and other information regarding FTCA coverage and the deeming process can be found in the following PINs and PALs:

- PIN 1999-08, "Health Centers and The Federal Tort Claims Act"
- PIN 2001-11, "Clarification of Policy for Health Centers Deemed Covered Under the Federal Tort Claims Act for Medical Malpractice"
- PIN 2001-16, "Credentialing and Privileging of Health Center Practitioners"
- PIN 2002-22, "Clarification of Bureau of Primary Care Credentialing and Privileging Policy Outlined in Policy Information Notice 2001-16"
- PIN 2002-23, "New Requirements for Deeming under the Federally Supported Health Centers Assistance Act"
- Program Assistance Letter (PAL) 99-15, "Questions and Answers on the Federal Tort Claims Act Coverage for Section 330, Deemed Grantees"
- PAL 2005-01, "Federal Tort Claims Act Policy Clarification on Coverage of Corporations under Contract with Health Centers"
- PAL 2001-25, "Procedures for General Inquiries on Federal Tort Claims Act Coverage"
- PIN 2005-19, "Federal Tort Claims Act Coverage for Deemed Consolidated Health Center Program Grantees Responding to Hurricane Katrina."
- PIN 2007-16, "Federal Tort Claims Act (FTCA) Coverage for Health Center Program Grantees Responding to Emergencies"

These PINs and PALs can be found online at <http://bphc.hrsa.gov/policy/>.

Questions concerning FTCA should be directed to:

FTCA Program
DHHS/HRSA/BPHC
5600 Fishers Lane, Room 15C-26
Rockville, MD 20857
Phone: 301-594-2469
Fax: 301-594-5224

Email: HealthCenterFTCA@hrsa.gov

B. SCOPE OF PROJECT AND FQHC MEDICAID PPS OR ALTERNATIVE METHODOLOGY REIMBURSEMENT

After a change in scope of project that may generate a FQHC Medicaid reimbursement (e.g., PPS or APM) adjustment is approved, it is the responsibility of the grantee to notify its State Medicaid Agency of the change(s) within 90 days following HRSA approval.

Most State Medicaid Agencies require a HRSA approved change in scope project to process requests for changes in Medicaid PPS or APM (e.g., rate for new starts or rate increase/decrease). **Please note that the change in scope of project for grantees discussed under this PIN is not the same as a change in the scope of services for increased/decreased reimbursement (PPS or APM) through Medicaid.** The CMS and State Medicaid Agencies define the term “change in the scope of services” to refer to a mechanism for adjusting the reimbursement rate of a FQHC due to “a change in the type, intensity, duration, and/or amount of services.” The HRSA approved change in scope modifies the services or sites in the grantee’s scope of project for the section 330 grant. It does not approve a “change in the scope of services” for State Medicaid reimbursement purposes. Grantees should contact their State Medicaid Agency for further information about their “change in the scope of services” policy and procedures.

C. SCOPE OF PROJECT AND MEDICARE FQHC COST-BASED REIMBURSEMENT

After a change in scope of project is approved, it is the responsibility of each grantee to notify its Medicare Fiscal Intermediary in a timely manner following the HRSA approval for the purposes of receiving the Medicare FQHC reimbursement rate.

In order for any new service delivery site(s) to be recognized by Medicare as a FQHC and be reimbursed the FQHC all-inclusive rate, a complete CMS 855A Form must be filed with the appropriate Medicare Fiscal Intermediary. (A copy of the CMS 855A Form is available at <http://www.cms.hhs.gov/cmsforms/downloads/cms855a.pdf>.) For each new site added to the approved scope of project, a health center must submit the CMS 855A Form, a copy of the HRSA Notice of Grant award that includes the address for applicable site(s) being enrolled, along with the necessary accompanying documents (see page 41 of CMS-855A) to the appropriate Fiscal Intermediary. In addition, the Medicare Fiscal Intermediary should be notified within 30 days of all site address changes and changes in ownership. All other changes to enrollment should be reported within 90 days.

A unique National Provider Identifier (NPI) number is necessary for each site when completing the CMS 855A Form. The NPI is a standard unique health identifier for health care providers and is assigned by the National Plan and Provider Enumeration System (NPPES). The NPI is necessary for HIPAA standard transactions under Medicare. Those transactions include the electronic claim, eligibility inquiry and response, claim status inquiry and response, payment and remittance advice, prior authorization/referral, and coordination of benefits transactions. **Grantees are required to obtain a NPI for each service site in order to bill Medicare, Medicaid and other payers.**

Complete instructions for completing the NPI application process is available at http://www.cms.hhs.gov/NationalProvdentStand/03_apply.asp#TopOfPage. Grantees can obtain a NPI number(s) in two ways: 1) by going to the CMS website at <https://nppes.cms.hhs.gov> to fill out an application on-line; or 2) by completing a paper application form (CMS-10114) available from <http://www.cms.hhs.gov/forms> or by calling the NPI Enumerator at 1-800-465-3203 to request a copy.

D. SCOPE OF PROJECT AND THE SECTION 340B DRUG PRICING PROGRAM

Health centers qualify as covered entities under the section 340B Drug Pricing Program. Please note, however, that while identification as a service site within a scope of project is necessary for participation in 340B, the program has its own requirements that must be met. For information on participating in the 340B Program, please call the Office of Pharmacy Affairs at 1-800-628-6297 or 301-594-4353, or visit the following website <http://www.hrsa.gov/opa>.

E. SCOPE OF PROJECT AND ACCREDITATION

Grantees accredited by an external accrediting body, e.g., the Joint Commission, are responsible for notifying the accrediting body of organizational changes if required by the accrediting body, as these may result in a requirement for an extension survey. Please refer to the accrediting body's policies and procedures for further guidance.

VII. CONTACT INFORMATION

If you have any questions or require further guidance on the scope of project policy detailed in this PIN, please contact the Office of Policy and Program Development at 301-594-4300. If you have questions or require additional assistance regarding the process for requesting prior approval of changes in scope, please contact your Project Officer.

Attachment 2

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
JFK Federal Building, Government Center
Room 2275
Boston, Massachusetts 02203



Division of Medicaid and Children's Health Operations / Boston Regional Office

November 19, 2012

Kathleen Brennan, Deputy Commissioner
Department of Social Services
25 Sigourney Street
Hartford, Connecticut 06106

Dear Deputy Commissioner Brennan:

I am responding to your September 6, 2012 letter in which you requested guidance about whether the state should reimburse based on a prospective payment system or the Medicaid fee schedule rate for inpatient rounding services delivered by physicians employed by federally qualified health centers ("FQHCs"). We understand this request for information was prompted by an inquiry from the Community Health Center Association of Connecticut (the Association).

We wish to confirm that rounding services provided by FQHC-employed physicians should be reimbursed the Medicaid fee schedule amount and believe this position is consistent with the criteria in the September 10, 1995 letter to California cited by the Association. CMS agrees with the state that rounding services are not "of the type commonly furnished in the clinic setting" precisely because they occur only when a patient is hospitalized. For this reason services provided in the inpatient setting do not qualify for PPS, regardless of whether the service is an evaluation or management service or something else.

CMS appreciates the opportunity to address this question and encourage you to continue working cooperatively with FQHCs to help promote access to care for the communities served by these clinics.

We hope this information is helpful to you and clarifies CMS' position. If you have any questions regarding this matter you may contact Marie Montemagno (617) 565-9157 or by e-mail at Marie.Montemagno@cms.hss.gov

Sincerely,

A handwritten signature in black ink that reads "Richard R. McGreal". The signature is written in a cursive, flowing style.

Richard R. McGreal
Associate Regional Administrator