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Health Center Compliance Manual

Webinar #1:

The Heart of Your Health Center: Need, Services, Service Delivery Model & Continuity of Care (Chapters 3, 4, 6, 7, 8, 12)

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This webinar series is co-sponsored by the National Association of Community Health Centers (NACHC)

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PRESENTER: MARCIE ZAKHEIM

- Partner at Feldesman Tucker Leifer Fidell, specializing in, among other things, federal grants and grant-related requirements (in particular the requirements related to Section 330 of the Public Health Service Act) and nonprofit corporation law
- Counsel to National Association of Community Health Centers, and numerous Primary Care Associations and health centers nationwide for over 20 years
- Provides advice and technical assistance services on compliance with federal statutes, regulations and requirements related to the operation, administration and governance of health centers and health center consortia; analyzes and provides comments/advice on legislation, regulations and policies impacting health centers and the health care industry in general; and assists with development of federal grant applications

AGENDA

- **Introduction to Health Center Program Compliance Manual and Site Visit Protocol**
- **Needs Assessment**
Program Requirement 1  Chapter 3
- **Services & Service Delivery Model**
Program Requirements 2, 4, 5 & 6 
Chapters 4, 6, 7 & 8
- **Contracts for Services**
Program Requirement 10  Chapter 12

COMPLIANCE MANUAL

- August 28, 2017: HRSA issued the final Health Center Program Compliance Manual – was effective immediately
- Separate chapters for each requirement
 - Legal authority – statutory/regulatory citations
 - Requirements – statutory/regulatory requirements
 - Demonstrating compliance – how health centers can demonstrate compliance with the requirements – must meet all elements
 - Related Considerations – areas for which health center retains discretion in making decisions on how to implement compliance elements
 - Not within HRSA’s purview to assess compliance
 - Not considered “musts” or even “should’s” – clarifies what centers “could” do in their sole discretion

COMPLIANCE MANUAL

- Aligns credentialing/privileging requirements and the quality improvement/assurance requirements with the FTCA deeming requirements for the same areas
- Includes chapter on health center program eligibility (eliminates designation of any new dual grantee and look-alike entities)
- Includes chapter on HRSA/BPHC's oversight process for monitoring compliance with Health Center Program Requirements
 - Remedies for non-compliance, including enforcement action(s)
 - When and how compliance with program requirements and past performance is considered in award or designation decisions
 - Similar to current Progressive Action Process

COMPLIANCE MANUAL

- Serves as consolidated resource and definitive guidance for interpreting Program Requirements and FTCA requirements
- Supersedes many current PINs / PALs (including SFDP, governance and budgeting/accounting), and “summary of health center program requirements”
- Deletes “Scope of Project” as a separate requirement – 18 requirements now
- Will not supersede
 - Scope guidance
 - Service area overlap policy (PIN 2007-09)
 - Emergency management program expectations (PIN 2007-15)
 - FTCA Manual and deeming PALs
 - UDS Manual and resources

COMPLIANCE MANUAL

- Applies only to activities included in the health center's scope of project
- Does not provide guidance on requirements in areas beyond HRSA purview (such as 340B, Medicaid, Medicare)
- Pay attention to the Related Considerations section – reflects implementation areas that HRSA explicitly delegated to health center discretion (important when talking with reviewers!)
- Webpage:
 - Compliance Manual
 - Frequently Asked Questions
 - Responses to Comments received by HRSA during the notice and comment period (2017)

<https://www.bphc.hrsa.gov/programrequirements/compliancemanual/index.html>

COMPLIANCE MANUAL: PROGRAM REQUIREMENTS COMPARISON

#	Site Visit Guide (FY 2015)	#	Compliance Manual
		1	Health Center Program Eligibility
		2	Health Center Program Oversight
1	Needs Assessment	3	Needs Assessment
2	Required and Additional Services	4	Required and Additional Services
3	Staffing	5	Clinical Staffing
4	Accessible Hours of Operation/Locations	6	Accessible Locations and Hours of Operation
5	After Hours Coverage	7	Coverage for Medical Emergencies During and After Hours
6	Hospital Admitting Privileges and Continuum of Care	8	Continuity of Care and Hospital Admitting
7	Sliding Fee Discounts	9	Sliding Fee Discount Program
8	Quality Improvement/Assurance Plan	10	Quality Improvement/Assurance
9	Key Management Staff	11	Key Management Staff
10	Contractual / Affiliation Agreements	12	Contracts and Subawards

#	Site Visit Guide (FY 2015)	#	Compliance Manual
		13	Conflict of Interest (moved from #19)
11	Collaborative Relationships	14	Collaborative Relationships
12	Financial Management and Control Policies	15	Financial Management and Accounting Systems
13	Billing and Collections	16	Billing and Collections
14	Budget	17	Budget
15	Program Data Reporting Systems	18	Program Monitoring and Data Reporting Systems
16	Scope of Project	NA	(Incorporated into other requirements, as appropriate)
17	Board Authority	19	Board Authority
18	Board Composition	20	Board Composition
19	Conflict of Interest Policy		(Moved to #13)
		21	Federal Tort Claims Act (FTCA) Deeming Requirements

SITE VISIT PROTOCOL

- Site Visit Guide was replaced by a new Site Visit Protocol (SVP), which is aligned with the Health Center Program Compliance Manual
 - Issued early January – effective for Operational Site Visits, New Grantee Site Visits and FQHC Look-Like Designation Site Visits on or after January 22, 2018
 - More proscriptive on reviewers than prior Site Visit Guides – see below
- For each Chapter, the following are identified
 - Statutory and regulatory authority (consistent with the Manual)
 - Primary and secondary reviewers

SITE VISIT PROTOCOL

- For each Chapter, the following are identified (cont.)
 - Documents lists: (1) documents sent prior to site visit; and (2) documents provided on-site – NO OTHER DOCUMENTS SHOULD BE REQUESTED
 - Which “Demonstrating Compliance” elements from the Manual will be assessed off-site by HRSA and which will be assessed on-site by review team
 - Assessment methodology (policy/procedure review, samples of files and records, interviews, site tours) that should be used by the reviewers to determine compliance with each on-site element
 - Questions to determine site visit findings

<https://www.bphc.hrsa.gov/programrequirements/svguide.html>

IMPACT ON OPERATIONAL SITE VISITS

- OSV is still a 3 day on-site audit of a health center's compliance with the requirements of the Compliance Manual
 - Three reviewers (admin/governance, clinical, financial) who are consultants acting as "authorized representatives of HRSA"
 - Either project officer or another person from HRSA operations divisions will be on site
 - Elements of on-site process unchanged from prior process – entrance conference, facility visits, document reviews, interviews and exit conference
 - Should be able to make minor revisions to policies (if board is available to approve) and procedures while review team is on site – no revisions after they leave!

IMPACT ON OPERATIONAL SITE VISITS

- Reviews should be more objective
 - Has the center established and implemented required policies, procedures, etc. that include all elements/bullets for “Demonstrating Compliance” sections of Manual and SVP?
 - SVP is more proscriptive with respect to review process (documents, review methodologies)
 - Greater level of focus on health center implementation – not just compliance on paper – review of sample charts and records to assess implementation
 - Assessment should not discuss whether the reviewer thinks what you have in place is “good” or “bad”

IMPACT ON OPERATIONAL SITE VISITS

- Final reports should be issued by HRSA within 45 days of the site visit
 - Before finalizing the reports, HRSA will review the findings and may adjust the reports accordingly
 - Report will include findings and final compliance determinations
 - Non-compliance will result in grant conditions
 - Report will also be used by FTCA to support deeming decisions and identify TA needs – but no conditions on FTCA elements that are not also part of program requirements (credentialing and privileging, QI/A)

CHAPTER 3: NEEDS ASSESSMENT

- What are the Authorities?
 - *Section 330(k)(2) and Section 330(k)(3)(J) of the PHS Act; and 42 CFR 51c.104(b)(2-2), 42 CFR 56.104(b)(2) and (b)(4), and 42 CFR 51c.303(k)*
- What are the Requirements?
 - Must define and annually review the boundaries of the service area, including the identification of the medically underserved population(s) served, to ensure that
 - Size is such that services are available and accessible to residents of service area promptly and as appropriate
 - Boundaries conform, to the extent practicable, to relevant political subdivisions, school districts, and areas served by federal and state health and social service programs
 - Boundaries eliminate, to the extent possible, barriers resulting from physical characteristics, residential patterns, economic and social groupings, and available transportation

CHAPTER 3: NEEDS ASSESSMENT

Site Visit Guide: Program Requirement #1

- Health center must have a defined service area consistent with UDS patient origin data, which is updated when appropriate (no details provided on either frequency or thresholds)

Compliance Manual: Chapter 3

- Must identify and annually review the service area based on where current/proposed populations reside as documented by Form 5B zip codes, consistent with patient origin data in UDS reports
 - Form 5B zip codes should include the zip codes in which at least 75% of patients reside (as identified in UDS)

CHAPTER 3: NEEDS ASSESSMENT

- SVP – Element a: Service Area Identification / Annual Review
 - Assess whether the health center uses patient origin data and whether there is a process in place to review service area at least annually
 - Off site review by HRSA of whether the service area listed on Form 5B is correct based on patient origin data

CHAPTER 3: NEEDS ASSESSMENT

- What are the Requirements?
 - Must assess the need for health services in the service area based on population served (or proposed to be served) that takes into account:
 - Available health resources in relation to the size of the service area and its population, including appropriate ratios of primary care physicians in various practices
 - Health indices for the population
 - Economic factors affecting the population's access to health services
 - Demographic factors affecting the population's need and demand for health services

CHAPTER 3: NEEDS ASSESSMENT

Site Visit Guide: Program Requirement #1

- Health center must have a written needs assessment for the target population (no details provided on either factors or frequency)

Compliance Manual: Chapter 3

- Must conduct needs assessment of the current or proposed population at least once every three years – must utilize most recently available data and must address
 - Factors associated with access to care and utilization
 - Most significant causes of morbidity and mortality
 - Other unique needs / characteristics impacting health status or access/utilization
- Explicit discretion to determine appropriate methodology, how to complete assessment, whether to include other factors

CHAPTER 3: NEEDS ASSESSMENT

- SVP – Element b: Update of Needs Assessment
 - Assess whether center can provide at least one example of how it utilized needs assessment results to inform and improve service delivery
 - Off site review by HRSA of whether needs assessment was conducted utilizing the appropriate factors

CHAPTER 4: REQUIRED & ADDITIONAL HEALTH SERVICES

- What are the Authorities?
 - *Section 330(a)-(b), Section 330(h)(2), and Section 330(k)(3)(K) of the PHS Act; and 42 CFR 51c.102(h) and (j), 42 CFR 56.102(l) and (o), and 42 CFR 51c.303(l)*
- What are the Requirements?
 - Must provide (or arrange the provision of) all required primary, preventive and enabling services
 - If receiving funds (or look-alike designation) for homeless population, must provide (or arrange provision of) full service package PLUS additional substance abuse services as required by statute
 - May provide additional/specialty health services that are appropriate for the needs of the population served by the center, subject to HRSA review and approval

CHAPTER 4: REQUIRED & ADDITIONAL HEALTH SERVICES

- What are the Requirements? (cont.)
 - All “in-scope” services (required and additional services included on Form 5A) must be provided through one or more service delivery methods – directly, by established written contracts / cooperative agreements (which may include formal written referral arrangements)

CHAPTER 4: REQUIRED & ADDITIONAL HEALTH SERVICES

Site Visit Guide: Program Requirement #2

- Health center must provide access to all required services and in-scope additional and specialty services, either directly or by established written contracts or referrals
- Set forth basic requirements for contracts and referrals – not a lot of detail

2017 Compliance Manual: Chapter 4

- Service obligation is the same but expands contract and referral descriptions consistent with scope guidance on delivery methods
- Form 5A Column I: Direct services must be provided by employees or volunteers
 - Employee is an individual who receives a salary on a regular basis and a W-2, and health center withholds applicable taxes and benefit contributions
 - Health center pays and bills for services

CHAPTER 4: REQUIRED & ADDITIONAL HEALTH SERVICES

Site Visit Guide: Program Requirement #2

- Contracts must include (1) how service will be documented in patient record; (2) how health center will bill for service and provide payment to contractor; and (3) how health center's policies and procedures will apply to the contracted service

2017 Compliance Manual: Chapter 4

- Form 5A Column II: services are provided on behalf of the health center by third party pursuant to contract
 - Contractor can be entity or individual and includes sub-recipients
 - Health center pays the contractor and bills for care
- Written agreement: retains (1) and (2) from prior guidance

CHAPTER 4: REQUIRED & ADDITIONAL HEALTH SERVICES

Site Visit Guide: Program Requirement #2

- Contracts must include (1) how service will be documented in patient record; (2) how health center will bill for service and provide payment to contractor; and (3) how health center's policies and procedures will apply to the contracted service

Compliance Manual: Chapter 4

- Written agreement must also include (cont.)
 - Specific language regarding application of sliding fee discounts consistent with Chapter 9 (Sliding Fee Discount Program)
 - Additional terms, including oversight and monitoring, addressed in Chapter 12 (Contracts and Subawards)

CHAPTER 4: REQUIRED & ADDITIONAL HEALTH SERVICES

Site Visit Guide: Program Requirement #2

- Referral agreements must at a minimum describe (1) how referral will be made and managed; and (2) process for tracking and referring patients back to center for follow-up care – also must include specific language regarding availability of sliding fee discounts, consistent with requirement #7
- Services provided by referral must be available equally to all health center patients

Compliance Manual: Chapter 4

- Form 5A Column III: services is provided and billed by third party –
 - Health center is responsible for making the referral to the other provider and for any follow-up care it provides
- Referral agreement elements remain the same - available equally to all is implied but not explicit

CHAPTER 4: REQUIRED & ADDITIONAL HEALTH SERVICES

Site Visit Guide: Program Requirement #2

- No statements of explicit discretion

Compliance Manual: Chapter 4

- Explicit discretion whether to
 - Offer additional and specialty services (Board decision)
 - Prioritize availability of in-scope additional services to patients who use the health center as primary care medical home

CHAPTER 4: REQUIRED & ADDITIONAL HEALTH SERVICES

Site Visit Guide: Program Requirement #2

- Findings regarding inaccuracies in how services are listed on Form 5A are documented under Program Requirement #16 for Scope of Project

Compliance Manual: Chapter 4

- Eliminates Scope of Project as a separate requirement – findings regarding inaccuracies with Form 5A will be documented under Chapter 4

CHAPTER 4: REQUIRED & ADDITIONAL HEALTH SERVICES

- SVP – Element a: Providing and Documenting Services within Scope of Project
 - For Column I services, team will tour one or more sites to determine if all services are provided and confirm delivery of services through patient records
 - For Column II services, team will review
 - All written contracts for Required Services that are provided only under Column II
 - Sample of up to 3 contracts for Additional Services provided only under Column II
 - Sample of records of patients who received services under Column II in last 12-24 months

CHAPTER 4: REQUIRED & ADDITIONAL HEALTH SERVICES

- SVP – Element a: Providing and Documenting Services within Scope of Project
 - For Column III services, team will review
 - All written referral MOUs for Required Services that are provided only under Column III
 - Sample of up to 3 referral MOUs for Additional Services provided only under Column III
 - Operating procedures/processes for tracking and managing referrals to ensure follow-up care
 - Sample of records of patients who received services under Column III in last 12-24 months

CHAPTER 4: REQUIRED & ADDITIONAL HEALTH SERVICES

- SVP – Element a: Providing and Documenting Services within Scope of Project
 - Assessment will focus on
 - Are services provided as indicated on Form 5A?
 - Does center have written contracts/MOUs in place for services under Column II and III?
 - Do the contracts/MOUs include required provisions?
 - Can the center produce patient records that document receipt of Column II and III services?
 - For referrals, does the center have operating procedures to manage referrals and do patient records demonstrate appropriate follow-up care was provided?

CHAPTER 4: REQUIRED & ADDITIONAL HEALTH SERVICES

- What are the Requirements?
 - If serving a substantial portion of patients with Limited English Proficiency (LEP) must
 - Develop a plan and make arrangements for interpretation and translation that are responsive to the needs of such patients to the extent practicable (linguistically and culturally appropriate)
 - Provide guidance to staff members with respect to cultural sensitivities and bridging cultural and linguistic differences

CHAPTER 4: REQUIRED & ADDITIONAL HEALTH SERVICES

Site Visit Guide: Program Requirement #2

- Limited English Proficiency (LEP) – must take “reasonable steps to provide meaningful access” – required specific methods (Used the term “specifically” as opposed to “for example”)

Compliance Manual: Chapter 4

- Limited English Proficiency (LEP) – must develop a plan and make arrangements for interpretation and translation that are responsive to the needs of such patients to the extent practicable (linguistically and culturally appropriate)
 - Provides examples but leaves actual method to discretion of health center
 - Requires resources and training for staff

CHAPTER 4: REQUIRED & ADDITIONAL HEALTH SERVICES

- SVP – Element b: Ensuring Access for Limited English Proficiency Patients
 - Assess whether center provides access to interpretation and whether it can provide an example of key document translated into different languages
- SVP – Element c: Providing Culturally Appropriate Care
 - Assess whether the center can provide an example of how it delivers services in a culturally appropriate manner

CHAPTER 6: ACCESSIBLE LOCATIONS AND HOURS OF OPERATION

- What are the Authorities?
 - *Section 330(k)(3)(A) of the PHS Act; and 42 CFR 51c.303(a) and 42 CFR 56.303(a)*
- What are the Requirements?
 - Required services must be available and accessible in the service area promptly, as appropriate, and in a manner that ensures continuity of services to the residents of the area

CHAPTER 6: ACCESSIBLE LOCATIONS AND HOURS OF OPERATION

Site Visit Guide: Program Requirement #4

- Health center provides services at locations that assure accessibility and meet the needs of the population – not a lot of detail beyond this

Compliance Manual: Chapter 6

- Health center sites must be accessible to patients relative to where the population lives – Examples
 - Areas immediately accessible to public housing
 - Shelters
 - Migrant camps
- Consider access barriers (including physical characteristics, residential patterns and economic/social groupings) and travel distance and time

CHAPTER 6: ACCESSIBLE LOCATIONS AND HOURS OF OPERATION

Site Visit Guide: Program Requirement #4

- Health center provides services at times that assure accessibility and meet the needs of the population to be served

Compliance Manual: Chapter 6

- Total number and scheduled hours of operation across all service sites must be responsive to needs of patients by facilitating ability to schedule appointments and access to full range of services within the scope

CHAPTER 6: ACCESSIBLE LOCATIONS AND HOURS OF OPERATION

- SVP – Element a: Accessible Service Sites
 - Assess whether the center has taken into consideration the factors listed in the Manual (access barriers and distance/time to travel to and between sites) when locating sites, including whether center facilitates access to services provided only at limited # of sites for the entire patient population
- SVP – Element b: Accessible Hours of Operation
 - Assess whether center has taken into consideration patient needs when establishing hours of operation

CHAPTER 6: ACCESSIBLE LOCATIONS AND HOURS OF OPERATION

Site Visit Guide: Program Requirement #4

- Findings regarding inaccuracies in how sites are listed on Form 5B are documented under Program Requirement #16 for Scope of Project

Compliance Manual: Chapter 6

- Eliminates Scope of Project as a separate requirement – findings regarding inaccuracies with Form 5B will be documented under Chapter 6 (SVP, Element c)
- Explicit discretion to determine
 - Method for obtaining patient input
 - How to measure and consider distance and travel time
 - How to support patient access to various sites
 - Which services to provide at each site

CHAPTER 7: COVERAGE FOR MEDICAL EMERGENCIES DURING AND AFTER HOURS

- What are the Authorities?
 - *Section 330(b)(1)(A)(IV) and Section 330(k)(3)(A) of the PHS Act; and 42 CFR 51c.102(h)(4), 42 CFR 56.102(l)(4), 42 CFR 51c.303(a), and 42 CFR 56.303(a)*
- What are the Requirements?
 - Health center must have
 - Provisions for promptly responding to medical emergencies during the regularly scheduled hours of operation; and
 - Clearly defined arrangements for promptly responding to medical emergencies after regularly scheduled hours

CHAPTER 7: COVERAGE FOR MEDICAL EMERGENCIES DURING AND AFTER HOURS

Site Visit Guide: Program Requirement #5

- **Requirements addressed after hours coverage only**
 - must provide professional coverage for medical emergencies during hours when center is closed
- Must make patients aware of after-hours coverage (appropriate languages and literacy levels)

Compliance Manual: Chapter 7

- Expands emergency coverage to include prompt response to medical emergencies during the regularly scheduled hours of operation, including
 - At least one staff member at each site who is trained and certified in basic life support to ensure sufficient clinical capacity to respond to such emergencies
 - Operating procedures to respond to such emergencies

CHAPTER 7: COVERAGE FOR MEDICAL EMERGENCIES DURING AND AFTER HOURS

- SVP – Element a: Clinical Capacity for Responding to Emergencies During Hours of Operation
 - Assess whether the center has documentation that at least one staff member who is trained and certified in basic life support is present at each site
- SVP – Element b: Procedures for Responding to Emergencies During Hours of Operation
 - Assess whether center has appropriate operating procedures and whether the center can describe how it has or is prepared to respond to emergencies during hours (for example, staff training/drills)

CHAPTER 7: COVERAGE FOR MEDICAL EMERGENCIES DURING AND AFTER HOURS

Site Visit Guide: Program Requirement #5

- Must provide professional coverage for medical emergencies during hours when center is closed

Compliance Manual: Chapter 7

- After hours coverage can include formal arrangements with other providers and must include
 - Telephone or face-to-face access to clinician with qualification / training necessary to exercise independent professional judgment in assessing need for emergency care
 - Ability to refer patients for further consultation or to emergency rooms or urgent care facilities for further assessment or immediate care, as needed

CHAPTER 7: COVERAGE FOR MEDICAL EMERGENCIES DURING AND AFTER HOURS

Site Visit Guide: Program Requirement #5

- Must provide professional coverage for medical emergencies during hours when center is closed

Compliance Manual: Chapter 7

- Patients, including LEP patients, must be informed of and are able to access after-hours coverage based on receipt of instructions and information in appropriate languages, literacy levels and formats
- Must have documentation of after-hours calls and any necessary follow-up
- Explicit discretion to determine
 - Appropriate means to provide after-hours coverage
 - How to inform patients

CHAPTER 7: COVERAGE FOR MEDICAL EMERGENCIES DURING AND AFTER HOURS

- SVP – Element c: Procedures or Arrangements for After Hours Coverage
 - Assess whether the center has written operating procedure or documented arrangements for responding to emergencies after hours
 - Do patients at all sites receive information on accessing after hours care (determined through interviews – not document review)? Are barriers addressed, including language/literacy barriers?
 - Team will call the center to determine whether appropriate procedures (based on elements in Manual) are in place

CHAPTER 7: COVERAGE FOR MEDICAL EMERGENCIES DURING AND AFTER HOURS

- SVP – Element d: After Hours Call Documentation
 - “Hands-on” review – team will review three samples of after hours documentation in the patient records and the center’s systems for tracking, recording and storing after hours call documentation to determine whether calls are documented and necessary follow-up care is provided

CHAPTER 8: CONTINUITY OF CARE AND HOSPITAL ADMITTING

- What are the Authorities?
 - *Section 330(k)(3)(A) and 330(k)(3)(L) of the PHS Act; and 42 CFR 51c.303(a) and 42 CFR 56.303(a)*
- What are the Requirements?
 - Health center must provide required primary care services promptly and in a manner that assures continuity of services to patients within the catchment (service) area
 - Health center must develop an ongoing referral relationship with one or more hospitals

CHAPTER 8: CONTINUITY OF CARE & HOSPITAL ADMITTING

Site Visit Guide: Program Requirement #6

- Health center physicians must have admitting privileges at one or more hospitals or there must be established arrangement between the health center and one or more hospitals for hospitalization, discharge planning and patient tracking
- Arrangements must cover all health center patients (all lifecycles)

Compliance Manual: Chapter 8

- Admitting requirements (direct or established arrangement) remain the same
 - Explicit discretion to determine whether to directly admit or have arrangements, and the number and type of hospitals with which to have admitting arrangements
- Silent on “lifecycles” – but still best practice

CHAPTER 8: CONTINUITY OF CARE & HOSPITAL ADMITTING

Site Visit Guide: Program Requirement #6

- Must have internal policies and procedures addressing hospitalization referrals (both planned and through ER), discharge follow-up, patient tracking including tracking of diagnostic test results not available at time of discharge

Compliance Manual: Chapter 8

- Must have and follow internal procedures, and if applicable must have **related provisions in formal arrangements** that address
 - Receipt and recording of medical information related to hospitalization (including diagnostic test results)
 - Discharge follow-up instructions
 - Follow-up actions by health center

CHAPTER 8: CONTINUITY OF CARE & HOSPITAL ADMITTING

Site Visit Guide: Program Requirement #6

- While not explicit, prior informal guidance indicated sliding fee must be available for hospitalist services (at a minimum, rounding)

Compliance Manual: Chapter 8

- HRSA response to comments on draft manual state that “only in-scope services provided to a health center patient in a hospital setting on behalf of the health center would be subject to the sliding fee discount program requirements. As such, services provided by the hospital or other non-health center providers in the hospital would not be subject to the sliding fee discount program requirements”

CHAPTER 8: CONTINUITY OF CARE & HOSPITAL ADMITTING

- SVP – Element a: Documentation of Hospital Admitting Privileges or Arrangements
 - Assess whether center has direct admitting privileges and/or formal arrangements with non-health center providers
- SVP – Element b: Procedures for Hospitalized Patients
 - Assess operating procedures/arrangements to determine if they include all terms listed in the Manual
- SVP – Element c: Post Hospitalization Tracking and Follow-up
 - “Hands-on” review – staff will navigate the team through 5-10 patient records to determine whether there is appropriate documentation of medical information from hospital visit, discharge plans, follow-up actions taken by the center

CHAPTER 12: CONTRACTS AND SUBAWARDS

- **NOTE: TODAY'S WEBINAR WILL REVIEW CHAPTER 12 REQUIREMENTS ADDRESSING CONTRACTUAL TERMS AND CONDITIONS ONLY**
- **PROCUREMENT REQUIREMENTS, SUBAWARD REQUIREMENTS AND OTHER 45 CFR PART 75 REQUIREMENTS WILL BE ADDRESSED IN WEBINAR #4 ON FEBRUARY 13, 2018 (*INTERNAL CONTROLS: MANAGING YOUR GRANT FUNDS*), PRESENTED BY TED WATERS**

CHAPTER 12: CONTRACTS AND SUBAWARDS

- What are the Authorities?
 - *Section 330(k)(3)(l) and Section 330(q) of the PHS Act; 42 CFR 51c.113, 42 CFR 51c.303(t), 42 CFR 56.114, 42 CFR 56.303(t); 45 CFR Part 75 Subpart D; and Section 1861(aa)(4)(A)(ii) and Section 1905(l)(2)(B)(ii) of the Social Security Act*
- What are the Requirements?
 - If contracting for substantive programmatic work under the health center program award, the health center must request and receive prior approval from HRSA

CHAPTER 12: CONTRACTS AND SUBAWARDS

- What are the Requirements? (cont.)
 - Health center contracts for the provision of in-scope health services must include a schedule of rates and method of payment
 - Health center must oversee contractors to ensure performance is in accordance with the terms, conditions and specifications of the contracts and to assure compliance with applicable federal requirements
 - Health center must retain financial records, supporting documents and statistical records pertinent to the contracted services under the health center program award for 3 years from date of submission of final expenditure report

CHAPTER 12: CONTRACTS & SUBAWARDS

Site Visit Guide: Program Requirement #10

- Included affiliation policy requirements that agreements must not limit autonomy or compromise health center's compliance with core requirements

Compliance Manual: Chapter 12

- Deletes affiliation standards regarding autonomy, etc.
- Incorporates affiliation policy requirements to seek HRSA prior approval for contracting for substantive programmatic work – includes contracts for
 - CEO
 - Entire key management team
 - Majority of health care providers from a single entityDoes not include contracts for supplies, materials, equipment or general support services

CHAPTER 12: CONTRACTS & SUBAWARDS

Site Visit Guide: Program Requirement #10

- Did not address specific required contract terms and conditions other than general oversight

Compliance Manual: Chapter 12

- Contracts for provision of in-scope services must include schedule of rates and methods of payment (consistent with Chapter 4)
- Other required terms: specific activities or services performed; oversight and monitoring of contractor performance; contractor's submission of information and data necessary for the health center to meet its federal reporting requirements; record retention and access to records and reports; audits; property management

CHAPTER 12: CONTRACTS & SUBAWARDS

Site Visit Guide: Program Requirement #10

- Required oversight of contractor performance but did not address specific oversight methodologies

Compliance Manual: Chapter 12

- Must have access to contractor records and reports related to health center activities
- Provides examples of methodologies to monitor contractual performance, BUT health center retains explicit discretion to determine appropriate methods and to settle contractual / administrative issues

CHAPTER 12: CONTRACTS & SUBAWARDS

- SVP – Element e: HRSA Approval for Contracting Substantive Programmatic Work
 - Based on review of complete list of all contracts and staff interviews, team will assess if the health center has contracts for substantive programmatic work and if so, whether there is documentation of HRSA's prior approval
- SVP – Element f: Required Contract Provisions
 - Team will review sample of up to 5 contracts that support the HRSA-approved scope of project (including Column II contracts), regardless of whether costs directly attributable to grant, and assess whether they include all provisions required by the Manual

CHAPTER 12: CONTRACTS & SUBAWARDS

- SVP – Element d: Contractor Reporting
 - Team will review 2-3 reports or records from contractors (especially those related to clinical services) and assess whether the center has access to records and reports necessary to oversee performance

QUESTIONS?

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DON'T MISS THE REST OF THE COMPLIANCE MANUAL SERIES!

Next week with Marcie Zakheim:

- [Making Care Affordable While Maximizing Reimbursement: The Sliding Fee Discount Program & Billing and Collection \(Chapters 9 and 16\)](#)

Tuesday, February 6th with Molly Evans:

- [Quality & Personnel Dynamics: Ensuring Appropriate Clinical Staffing to Provide High Quality Care \(Chapters 5 and 10\)](#)

Tuesday February 13th with Ted Waters

- [Internal Controls: Managing Your Grant Funds \(Chapters 12, 13 and 15\)](#)

Tuesday February 20th with Molly Evans:

- [Understanding the Roles of Management & Governance \(Chapters 11, 19 and 20\); the OSV Process As it Stands Today](#)

OTHER UPCOMING TRAINING EVENTS

Webinars

Feb 8 th @ 1 PM	HIPAA Breaches: Determining Whether a Breach Has Occurred and the Reporting Requirements
Mar 13 th @ 1 PM	Emergency Preparedness: Implementation Updates and Best Practices

Live Trainings

Feb 13 th – 14 th	Health Center Compliance Intensive: HIPAA Fundamentals <i>(designed for Compliance Officers and Privacy Officers)</i>	Washington, DC
Feb 21 st -23 rd	Federal Funding Academy	Austin, TX
Feb 27 th – 28 th	De-Mystifying the New Compliance Manual & Its Impact on the Program Requirements	Mesa, AZ
Feb 28 th – Mar 1 st	An In-Depth Look at the Federal Tort Claims Act (FTCA)	Mesa, AZ
Feb 28 th – Mar 1 st	340B Drug Discount Program: An Intensive Focus on Covered Entity Compliance	Washington, DC

For more information and to register:
 Email learning@ftlf.com or go to <https://learning.ftlf.com>