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De-Mystifying the Compliance Manual and Its Impact on the Program Requirements

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- Partner at Feldesman Tucker Leifer Fidell, specializing in, among other things, Federal grants and grant-related requirements (in particular the requirements of and related to Section 330 of the Public Health Service Act) and nonprofit corporation law;
- Counsel to National Association of Community Health Centers, numerous Primary Care Associations and health centers nationwide for over 20 years; and
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Introduction to the Health Center Program Compliance Manual and HRSA Review Process

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COMPLIANCE MANUAL

- August 28, 2017: HRSA issued the final Health Center Program Compliance Manual – was effective immediately
- Updated on August 20, 2018 for alignment with statutory changes, including (but not limited to)
  - CEO must be directly employed
  - Greater focus on demonstration of financial policies
  - Greater focus on quality of care
  - Full compliance to secure a 3 year project period (based on the SAC application – not the Operational Site Visit) … more on this later

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COMPLIANCE MANUAL

- Separate chapters for each requirement
  - Legal authority – statutory/regulatory citations
  - Requirements – statutory/regulatory requirements
  - Demonstrating compliance elements – how health centers can demonstrate compliance on an element by element basis
  - Related Considerations – areas for which health center retains <u>discretion</u> in making decisions on how to implement compliance elements

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COMPLIANCE MANUAL

- Includes chapter on HRSA/BPHC oversight process, consistent with Progressive Action Process, including remedies for non-compliance and enforcement actions
- Aligns credentialing/privileging requirements and the quality improvement/assurance requirements with the FTCA deeming requirements for the same areas
- Supersedes many current PINs / PALs (including SFDP, governance, budgeting/accounting, affiliations) – BUT NOT
  - Scope of Project guidance
  - FTCA Manual and deeming PALs
  - UDS
  - Service Area Overlap policy (PIN 2007-09)
  - Emergency Management Program Expectations (PIN 2007-15)

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COMPLIANCE MANUAL

- Eliminates Scope of Project as separate requirement – but scope is still important!
  - Scope of Project forms the basis of each health center's program
  - Scope of Project sets the context for the Operational Site Visit – only in-scope activities, sites, etc. are included in the review
  - Form 5A is assessed under "Required and Additional Health Services" and Form 5B is assessed under "Accessible Locations and Hours of Operation"

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COMPLIANCE MANUAL

- Does not provide guidance on requirements in areas beyond Bureau of Primary Health Care purview (such as 340B, Medicaid, Medicare)
- 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

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SITE VISIT PROTOCOL

- Site Visit Guide was replaced by Site Visit Protocol (SVP)
  - Fully aligned with the Health Center Program Compliance Manual
  - New SVP aligned with Compliance Manual changes – was effective September 6, 2018

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SITE VISIT PROTOCOL

- For each Chapter, the following are identified:
  - Statutory and regulatory authority (consistent with the Manual)
  - Primary and secondary reviewers
  - Document lists: (1) documents sent prior to site visit; and (2) documents provided on-site – NO OTHER DOCUMENTS SHOULD BE REQUESTED (but health center can provide additional documents if necessary to demonstrate compliance)
  - Demonstrating Compliance elements and whether they will be assessed off-site by HRSA or on-site by review team

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SITE VISIT PROTOCOL

- For each Chapter, the following are identified (cont.)
  - Individuals (by positions) to be interviewed while on-site
  - Assessment methodologies (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 (aligned with the Compliance Manual elements)

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

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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
  - **NEW: under new process, can no longer make minor revisions to policies and procedures while review team is on site – HRSA should provide 2-week "grace" period after OSV to make changes before findings are finalized, included in OSV report and imposed as conditions**

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IMPACT ON OPERATIONAL SITE VISITS

- Compliance assessments based on the health center's particular documentation, taking into account health center's discretion in implementing each compliance element as long as basic requirements are met
- 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 ***by element for each Chapter*** (over 90 elements in total – detailed in condition library on BPHC website)
  - Non-compliance will result in grant conditions

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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?
  - More proscriptive with respect to review process (uniform documents, review methodologies)
  - Greater level of focus on implementation / utilization of operating procedures – not just compliance on paper – review of sample charts, files, records
  - Assessment should not discuss whether the reviewer thinks what you have in place is "good" or "bad" – no personal opinions

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IMPACT ON OPERATIONAL SITE VISITS

- Anticipated benefits of the Site Visit Protocol – should:
  - Improve health center's site visit preparation
  - Improve accuracy and consistency of on-site review and reviewer reports
  - Provide greater clarity and transparency regarding what reviewers will assess, how assessments will occur, which health center staff will be interviewed and what constitutes compliance
  - **Ultimately, improve health center's overall and ongoing compliance – timelines in the SVP can serve as basis for incorporating 330 compliance into annual compliance workplan**

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POTENTIAL CONSEQUENCES OF NON-COMPLIANCE

- New Notice of Award with special award conditions related to findings of non-compliance, such as drawdown restrictions and potential ineligibility to compete for supplemental grants
  - NOTE: Conditions after OSV will not result in changes to project period unless significant non-compliance
- Conditions at time of Service Area Competition (SAC): HRSA will provide a certain amount of time after submission of SAC to resolve non-compliance through EHB
  - NOTE: this also applies if no competing grant application is submitted during SAC and non-compliance is identified during the SAC review

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POTENTIAL CONSEQUENCES OF NON-COMPLIANCE

- Any 1 condition in effect when SAC is awarded (either unresolved carry over from OSV or a new condition from the SAC) will result in 1-year project period
  - New OSV will be scheduled within 2-4 months of the project period start date
  - Health center will be required to submit an overall plan for compliance within 120 days of the award AND will be required to respond to the specific conditions imposed consistent with the current Progressive Action Process

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POTENTIAL CONSEQUENCES OF NON-COMPLIANCE

- If unresolved during year or if new condition is imposed under second SAC, will result in a second 1- year project period
- If unresolved during second 1-year project period or if new condition would be imposed under third SAC, **HRSA will not award a third 1-year project period and may announce new competition for the service area**
- No more than two 1-year renewals also applies to Look-alike redesignations

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"Hot" Areas of Concern

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SCOPE OF PROJECT

- "Scope of Project" = five elements (services, sites, providers, target population, service area), which together define the center's legal commitment
  - Activities supported under the total approved section 330-grant related project budget (federal funds, program income and other funds) or Look-Alike designation
  - Activities for which scope-related benefits are available (check specific rules for those benefits for exceptions)
  - Activities to which programmatic requirements apply
- Scope reflects what the health center currently does – not what it intends to do in the future
- For links to scope materials: https://www.bphc.hrsa.gov/programrequirements/scope.html

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SCOPE OF PROJECT: SERVICES

- **Services (Form 5A):** full complement of required and HRSA-approved additional / specialty services **provided directly or through established arrangements**, which must be available and accessible to all patients regardless of ability to pay
  - Not all services must be available at each site – every patient must have access to full complement of services offered by the health center as a whole
  - Applicable HRSA Guidance: (1) *Service Descriptors for Form 5A: Services Provided*; and (2) *Service Delivery Methods*

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FORM 5A: REQUIRED SERVICES

- Must be provided by every health center, either directly **or by written contract/referral arrangement** – must have a "check mark" in at least one of the three columns of Form 5A
- *Service Descriptors* guidance lists
  - Minimum elements of the service (floor below which you are not compliant)
  - What services may also be included
  - What services are not included (ceiling, above which would require separate CIS)

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FORM 5A: ADDITIONAL / SPECIALTY SERVICES

- May be provided, based on need and other relevant factors; must support and be related to primary care furnished to health center's patient population
- For additional services "pre-populated" on Form 5A, *Service Descriptors* guidance lists
  - What services may be included (floor below which you are not compliant)
  - What services are not included (ceiling, above which would require separate specialty services CIS)
- Specialty services are NOT included in *Service Descriptors* guidance

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FORM 5A: MODE OF DELIVERY

- Column I Direct: always in scope
  - Provided by health center employee or volunteer
  - An 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 direct care
- Column II Formal written contract/agreement: always in scope
  - Services are provided on behalf of the health center, regardless of whether service is furnished at health center facility or at contractor's site
  - Contractor can be an individual or an entity (including sub-recipients)
  - Health center pays the contractor and bills for the care

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FORM 5A: MODE OF DELIVERY

- Column III Formal written referral arrangement: service is not in-scope, but the arrangement and any follow-up care provided by the health center is in scope
  - Services are provided by another provider on its own behalf, which provider bills for the services rendered to health center patients
  - Health center retains responsibility for making the referral and for follow-up care provided by the center
- What's NOT included on Form 5A? Informal referrals for continuity of care purpose
- For each mode of delivery, the HRSA *Service Delivery Method* guidance lists key elements and distinctions as defined by HRSA

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SCOPE OF PROJECT: SITES

- Locations at which services are provided to a defined service area or target population – must be listed on Form 5B to be "in-scope"
  - Permanent, seasonal, intermittent, mobile vans
  - Must meet all of the following conditions (exceptions for seasonal and intermittent):
    - Visits are documented in a patient's medical record
    - Providers exercise independent judgment
    - Services are provided directly by or on behalf of center and board retains control and authority
    - Services are provided on a regularly scheduled basis
  - If site does not meet site definition, include on Form 5C – not Form 5B

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CONTRACTS AND REFERRALS

- HRSA requirements for in-scope services (required, additional and specialty) provided by contract (Form 5A, Column II) and/or formal referral (Form 5A, Column III) are addressed in multiple Chapters of the Compliance Manual and SVP
- Must be compliant with the elements in each chapter to ensure that the contracts/referrals pass muster
  - **Chapter 4: Required and Additional Health Services**
  - **Chapter 5: Clinical Staffing**
  - **Chapter 9: Sliding Fee Discount Program**
  - **Chapter 12: Contracts and Subawards**

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IN-SCOPE CONTRACTS UNDER COLUMN II

- Chapter 4 – at a minimum, written agreement must describe how:
    - Service will be documented in patient record
    - Health center will bill for service and provide payment to contractor

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IN-SCOPE CONTRACTS UNDER COLUMN II

- How is compliance with SVP assessed?
    - 3-5 patient records that document provision of various required and additional services offered only by formal written contracts (alternative – billing records)
    - Up to 3 written contracts for EACH required service and EACH additional service provided ONLY by contract (Column II)
    - 1 written contract for EACH required service and EACH additional service provided directly (Column I) and by contract (Column II)

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IN-SCOPE CONTRACTS UNDER COLUMN II

- Chapter 5 – at a minimum, ensure that contracted services are provided by providers/organizations that:
  - Verify provider licensure, certification or registration through defined credentialing process in accordance with applicable law, and
  - Complete privileging process that confirms competency and fitness to perform services
  - NOTE: Can review other provider's / organization's process in lieu of contractual provisions
- How is compliance with SVP assessed?
  - 2-3 samples of contracts or related documentation for Column II services (prioritize services offered only by Column II)

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IN-SCOPE CONTRACTS UNDER COLUMN II

- Chapter 9 – written agreement must ensure that patient fees are discounted consistent with the Sliding Fee Discount Program requirements
  - NOTE: since health center is paying contractor and billing payors and patients for service, advisable to include a provision that the center will bill consistent with its usual and customary billing and collection policies, including its SFDP
- How is compliance with SVP assessed?
  - Up to 3 written contracts for EACH required service and EACH additional service provided ONLY by contract (Column II)
  - 1 written contract for EACH required service and EACH additional service provided directly (Column I) and by contract (Column II)

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IN-SCOPE CONTRACTS UNDER COLUMN II

- Chapter 12 – written agreement must include:
  - Schedule of rates and methods of payment
  - Specific activities or services to be performed
  - Record retention and access to contractor's records and reports related to health center activities
  - Contractor's submission of information and data necessary for the center to meet its federal reporting requirements (such as UDS)
  - Audits
  - Property management (as applicable)
  - Health center oversight and monitoring
- How is compliance with SVP assessed?
  - Sample of up to 5 final contracts that support HRSA approved scope of project regardless of whether costs are allocated to the grant

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IN-SCOPE REFERRALS UNDER COLUMN III

- Chapter 4 – at a minimum, written agreement must describe:
  - How the referral will be made and managed
  - Process for tracking and referring patients back to the health center for appropriate follow-up care (including whether patient presents and exchange of patient record information and results of referral)

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IN-SCOPE REFERRALS UNDER COLUMN III

- How is compliance with SVP assessed?
  - Operating procedures for tracking and managing referred services
  - List of patients referred for one or more required services in past 12-24 months (and, if time permits, sample list of patients referred for one or more additional services that are provided ONLY by referral) and 3-5 records from list to assess referral process
  - Up to 3 written referrals for EACH required service and EACH additional service provided ONLY by referral (Column III)
  - One written referral for EACH required service and EACH additional service provided directly (Column I) and by referral (Column III)

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IN-SCOPE REFERRALS UNDER COLUMN III

- Chapter 5 – same as contracts under Column II, with review of referrals instead of contracts
- Chapter 9 – written agreement must ensure that patient fees are either discounted consistent with the Sliding Fee Discount Program requirements or at a greater discount
- How is compliance with SVP assessed?
  - Up to 3 written contracts for EACH required service and EACH additional service provided ONLY by referral (Column III)
  - 1 written contract for EACH required service and EACH additional service provided directly (Column I) and by referral (Column III)

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SLIDING FEE DISCOUNT PROGRAM

- Application: must apply to all in-scope services for which the center has distinct fees, regardless of type or mode of delivery
- Structure
  - Must have minimum of three payment levels based on gradations of income for patients earning annual incomes between 101%-200% of Federal Poverty Level (FPL)
  - Must have full discount – or at most nominal fee that is nominal from patients' perspective and meets definition in Manual and SVP – for patients earning annual incomes at or below 100% FPL
  - No regular discounts for individuals above 200% FPL unless center has non-330 source of funds to support
  - Can have multiple discount schedules based on services (broad service types or distinct subcategories) and/or delivery methods – no other factors!

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SLIDING FEE DISCOUNT PROGRAM

- Eligibility:
  - Must assess all patients for eligibility based on income and family size, unless patient declines / refuses to be assessed
  - Must have operating procedures for assessment / re-assessment, and records that it occurred (except when patient declines/refuses)
  - NOTE: significant discretion with respect to types of documentation; how to treat individuals who refuse to provide documentation; whether to use self-attestation and if so, how; frequency of re-assessment; whether to take into consideration unique characteristics of patient population in determining assessment procedure

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SLIDING FEE DISCOUNT PROGRAM

- Board-Approved Policies applied uniformly to all patients, which include:
  - Definitions of income and family – income defined as earnings over a given period of time used to support the patient/household based on criteria of inclusions and exclusions – does not include assets (explicit discretion to determine whether to consider patient population characteristics when developing definitions)
  - Eligibility based only on income and family and methods for conducting assessments (Note – does not address inclusion of documentation requirements – but implied)
  - Specific structures of sliding fee discount schedules
  - If electing to charge nominal fee, definition of nominal consistent with Manual and SVP

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SLIDING FEE DISCOUNT PROGRAM

- Providing Information to Patients: must have mechanisms to inform patients about availability of discounts
  - Examples provided include information at intake and publishing information on website – BUT explicit discretion to determine how to inform patients about discounts (including signage)
- Evaluation: must evaluate the sliding fee discount program in its entirety at least once every three years from perspective of reducing financial barriers to care – minimum elements
  - Collection of utilization data
  - Use of such data (and other applicable data, such as patient satisfaction survey results) to evaluate the effectiveness
  - Identify and implement changes as necessary

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SLIDING FEE DISCOUNT PROGRAM

- How is compliance with SVP assessed?
  - In general: (i) review of SFDP policies, procedures, all sliding fee discount schedules (and basis for multiple SFDS if using more than one), and other related documents; and (ii) interviews with appropriate staff and site tours
  - For establishing nominal fee: want to see board involvement
  - For eligibility: includes review of 5-10 records, files or other forms of documentation of patient income and family size, including both insured and uninsured
  - For patient information: includes review of mechanisms to provide such information
  - For evaluation: includes review of data reports and other evaluation materials

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SLIDING FEE DISCOUNT PROGRAM

- Discussions of optional payment systems to help patients pay (such as grace periods, payment plans, cash incentives), optional process to discharge patients or limit services for refusal to pay, and charges for supplies and equipment included under Chapter 16 (Billing and Collection)
  - Must have operating procedures if these options are selected
  - Must notify patients
  - (For payment systems) Must be accessible to all patients regardless of income level or sliding fee discount pay class

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FINANCIAL MANAGEMENT SYSTEMS

- Spread across multiple chapters: Chapter 12 (Contracts and Subawards); Chapter 13 (Conflict of Interest); Chapter 15 (Financial Management & Accounting Systems)
  - What do these chapters have in common?
    - Compliance Manual and SVP explicitly incorporates requirements of 45 CFR Part 75 (applicable to all DHHS grantees) – prior guidance implied incorporation of 45 CFR Part 75 but in many cases was not explicit
  - What does this mean for compliance?
    - Health centers MUST review and understand 45 CFR Part 75, incorporate requirements into their policies and procedures, and establish and implement systems consistent with the requirements

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GOVERNANCE: BOARD AUTHORITY

- Minor revisions / clarifications to existing authorities
  - Must have a quorum at monthly meeting
  - Explicit discretion to determine frequency of CEO evaluation
  - Must outline uses of grant and non-grant funds in budget
  - Must conduct long term strategic planning – including financial management and capital expenditure needs – once every three years
  - Policy evaluation and as necessary update must occur at least once every three years, including: sliding fee discount program, QI/A, billing and collection, financial management and accounting systems, personnel
- In addition to minutes, can use “other relevant documents” to demonstrate compliance – potential “other documents” listed in SVP as examples, but not definitive
- Must demonstrate that follow-up actions were taken as a result of performance and policy evaluations

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GOVERNANCE: COMPOSITION

- Changes / clarifications on patient board members
  - Must be currently registered patient who has accessed the center in last 24 months to receive at least one in-scope service that generated a visit at an in-scope site
  - In addition to legal guardians and sponsors of immigrants, a person who has legal authority to make health care decisions on behalf of a patient can represent that patient on the board
  - Demographic representation must be consistent with UDS
- Non-patient board members must represent either the community served or the health center's service area, defines as live or work in community/area OR have demonstrable connection

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GOVERNANCE: BYLAWS

- Requirements for Bylaws were narrowed from previous Site Visit Guide – Bylaws must include
  - Monthly meetings
  - Board authorities: selection/dismissal of CEO; approval of budget and applications; approval of services, locations, hours; evaluation of health center performance; establishment / adoption of operational policies; assurance of compliance
  - Board size and composition
  - Process of ongoing selection and removal of board members
  - Demonstrations that no other entity controls the center

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QUESTIONS?

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