NACHC Comments on Draft BPHC Compliance Manual

Final - 11/22/2016
# Table of Contents

Table of Contents ........................................................................................................................................... 2

Overarching Comments .................................................................................................................................... 11

1. Ensure that important policy interpretations contained in existing PINs and PALs remain in effect after the Compliance Manual is finalized, either by fully incorporating these interpretations into the Manual or by leaving the current documents in effect. ........................................................................ 11

2. Indicate in the Compliance Manual that HRSA maintains the authority to issue new interpretative policy guidelines as necessary in the future, likely in the form of PINs and PALs. ........................................................................................................ 13

3. Provide health centers adequate time to come into Compliance with new expectations established in the finalized Compliance Manual. In particular, health centers that already have OSVs scheduled at the time the final Manual is published should be “grandfathered in” under the expectations set forth in the Site Visit Guide in effect at that time. ......................................................................................... 13

4. Clarify the relationship between the Compliance Manual and the current OSV Guide during the period between when the Compliance Manual is finalized and the revised OSV “protocol” is published. ...................................................................................................................................... 14

Introduction .................................................................................................................................................... 16

Applicability ................................................................................................................................................... 16

1. Provide grant applicants 120 days after the receipt of an award to come into compliance with all requirements laid out in the Compliance Manual, as opposed to expecting them to be compliant at the time of application. ........................................................................................................... 16

Purpose ......................................................................................................................................................... 16

1. Keep PINs 97-27 and 98-24 (Affiliation Agreements) in effect in their entirety, to ensure that health centers’ governance and day-to-day management remain firmly under the control of their community-based, patient-majority boards. ........................................................................................................... 16

2. Provide a framework for health centers to understand and remember which PINs and PALs remain in effect. ......................................................................................................................................................... 20

3. Clarify whether HRSA will issue new PINs and PALs in the future, and if so, in what areas. 21

4. Establish a regular schedule for updating and seeking public comment on the Compliance Manual. ................................................................................................................................................................. 21

Structure of the Health Center Program Compliance Manual .............................................................................. 22

1. Permit health centers to demonstrate “alternative means of demonstrating compliance” with requirements before a condition is automatically applied ................................................................................................................ 22

Additional Health Center Responsibilities ........................................................................................................ 22
Chapter One: Eligibility ................................................................................................................. 24
First Paragraph ............................................................................................................................. 24
  1. Clarify the legislative authority which makes tribes, tribal organizations, and Urban Indian
     organizations eligible to apply for Section 330 grants, and give this category of eligible entities more
     prominence in the discussion. ........................................................................................................ 24
Additional Eligibility Requirements for Look-Alike Designation ................................................. 25
  1. Eliminate the reference to “income” in the context of 340B. ....................................................... 25
  2. Do not prohibit health centers from applying and receiving approval for dual Grantee/Look-
     Alike Status. ........................................................................................................................................ 25
Chapter Two: Oversight .................................................................................................................. 28
Program Oversight .......................................................................................................................... 28
  1. Provide clarity around “expected performance goals” that could lead to grant conditions, and how
     performance against these goals will be evaluated, to ensure that HRSA involvement is consistent
     with a grantee/grantor relationship ........................................................................................................ 28
Progressive Action Process ........................................................................................................... 28
  1. Permit health centers to demonstrate “alternative means of demonstrating compliance” with
     requirements before a condition is automatically applied ................................................................. 28
  2. Once a condition is imposed, explicitly state that reconsideration of the condition due to
     inaccuracy of the initial interpretation and non-compliance finding is an available option ............ 29
  3. Clarify which conditions will not be subject to (a) a 120-day implementation phase; or (b) the initial
     Phase One 90-day response time ........................................................................................................ 30
Chapter Three: Needs Assessment .................................................................................................... 32
General .................................................................................................................................................... 32
  1. When discussing Needs Assessment, explicitly reference the unique needs of statutory special
     populations, including but not limited to homeless individuals and migratory and seasonal
     agricultural workers (MSAWs) and their families ............................................................................. 32
Demonstrating Compliance ............................................................................................................... 32
  1. Clarify if HRSA has expectations regarding the minimum frequency for a comprehensive
     needs assessment, and if so, specify them ......................................................................................... 33
Chapter Four: Required and Additional Services ........................................................................... 34
Demonstrating Compliance ............................................................................................................... 34
Table of Contents

1. Reference those PINs that will remain in effect in the list of additional responsibilities........... 22
2. If the Chapter on FTCA is finalized, the FTCA Manual and future annual deeming application
   PALs should reference the requirements in Chapter 21 of this Compliance Manual, and include no
   new or additional requirements ........................................................................................................... 22

Chapter One: Eligibility .................................................................................................................... 24
First Paragraph ................................................................................................................................... 24
  1. Clarify the legislative authority which makes tribes, tribal organizations, and Urban Indian
     organizations eligible to apply for Section 330 grants, and give this category of eligible entities more
     prominence in the discussion. ............................................................................................................. 24
Additional Eligibility Requirements for Look-Alike Designation ................................................... 25
  1. Eliminate the reference to “income” in the context of 340B. ......................................................... 25
  2. Do not prohibit health centers from applying and receiving approval for dual Grantee/Look-
     Alike Status. ..................................................................................................................................... 25
Chapter Two: Oversight ....................................................................................................................... 28
Program Oversight .............................................................................................................................. 28
  1. Provide clarity around “expected performance goals” that could lead to grant conditions, and how
     performance against these goals will be evaluated, to ensure that HRSA involvement is consistent
     with a grantee/grantor relationship ...................................................................................................... 28
Progressive Action Process ............................................................................................................... 28
  1. Permit health centers to demonstrate “alternative means of demonstrating compliance” with
     requirements before a condition is automatically applied ................................................................. 28
  2. Once a condition is imposed, explicitly state that reconsideration of the condition due to
     inaccuracy of the initial interpretation and non-compliance finding is an available option .......... 29
  3. Clarify which conditions will not be subject to (a) a 120-day implementation phase; or (b) the initial
     Phase One 90-day response time ...................................................................................................... 30
Chapter Three: Needs Assessment ..................................................................................................... 32
General .................................................................................................................................................. 32
  1. When discussing Needs Assessment, explicitly reference the unique needs of statutory special
     populations, including but not limited to homeless individuals and migratory and seasonal
     agricultural workers (MSAWs) and their families .......................................................................... 32
Demonstrating Compliance ................................................................................................................. 32
  1. Clarify if HRSA has expectations regarding the minimum frequency for a comprehensive
     needs assessment, and if so, specify them ...................................................................................... 33
Chapter Four: Required and Additional Services ............................................................................ 34
Demonstrating Compliance ................................................................................................................. 34
Table of Contents

1. Clarify that services provided directly by the health center can be provided by employees, volunteers and independent contractors who work primarily for the health center and who are included as and considered part of the health center’s “core” staff.................................................. 34
2. Clarify that the health center is generally responsible to bill for services provided by a third party via a formal contract/agreement, subject to limitations in law.................................................. 35
3. Explicitly state that formal contracts/agreements must specify “how the health center’s policies and/or procedures will apply”.................................................................................................................. 35
4. Avoid using the term “pays for” to describe different delivery models.................................. 36
5. Include a specific cross-reference to the Chapter 9 requirement that if an in-scope service is provided only through a formal referral arrangement, the agreement must specify that the referral provider will offer discounts.................................................................................................................................................. 36
6. Explicitly state that informal referral arrangements are not subject to the requirements outlined in this Compliance Manual ........................................................................................................................................................................ 37
7. Clarify that the requirement to provide interpretation and translation services applies only to health centers whose patient populations include a “substantial proportion of individuals of limited English-speaking ability”. Also, clarify how “substantial proportion” is to be defined........ 37
8. State explicitly that health centers are not required to provide all required services at each site. 39

Chapter Five: Clinical Staffing ................................................................................................................................. 40

Demonstrating Compliance ............................................................................................................................................ 40
1. Clarify what is meant by a “staffing plan” and any expectations around frequency of updates.......................................................... 40
2. Clarify whether the “staffing plan” referenced in Chapter 5 is the same as the current Form 2 Staffing, which is reported in UDS. If so, delete the reference to referral providers as a component of the staffing plan........................................................................................................................................ 40
3. Remove the new requirement to verify clinicians’ “mental health status”; if this is not possible then provide examples of acceptable methods of verification.................................................................................................................. 41
4. Clarify that health centers may accept assurances from referral providers that they have been credentialed, and are not required to credential these providers themselves........................................................................................................ 41

Chapter Six: Accessible Locations and Hours of Operation .......................................................................................... 43

Demonstrating Compliance ............................................................................................................................................ 43
1. Clarify if HRSA has specific expectations around if and how health centers should document the factors impacting the accessibility of their sites, including how to measure time and distance. 43

Chapter Seven: Coverage for Medical Emergencies During and After Hours ................................................................ 44

Demonstrating Compliance ............................................................................................................................................ 44
1. Replace the term “basic life support skills” with a clinical standard that is broadly understood and easily demonstrated............................................................................................................................................... 44
Chapter Eight: Continuity of Care and Hospital Admitting ................................................................. 45

Demonstrating Compliance ................................................................................................................... 45

1. Clarify that arrangements for hospital admissions must be in writing, but are not limited to formal contracts; also clarify that only one such arrangement is required. ................................................. 45

2. Encourage - but do not require - health centers to have provisions in their hospital agreements under which the hospital must notify the health center when any of its patients are admitted or visit the emergency department. ........................................................................ 45

3. Clarify, in either the Compliance Manual or the OSV guide that formal written referral agreements between hospitals and health centers for the admission and hospitalization of health center patients are not required to include sliding fee discounts for rounding services provided to health center patients as part of the hospitalization. ................................................................. 47

Chapter Nine: Sliding Fee Discount Program ...................................................................................... 48

General ................................................................................................................................................ 48

1. Retain valuable guidance on the development and implementation of the Sliding Fee Discount Program by not rescinding PIN 2014-02, and using it as a “complementary” guidance to be used in conjunction with the Compliance Manual ........................................................................... 48

Demonstrating Compliance .................................................................................................................. 49

1. Clarify the status of the requirements from PIN 2014-02 regarding nominal fee, eligibility reassessments, and the number of discount classes between 101- 200% FPL. ................................................. 49

2. Revise the examples of distinct, permissible SFDSs to clarify that different SFDSs can be based on either broad service types or distinct sub-categories within such service types .......... 50

3. Clarify that different SFDS are permissible for services provided through established delivery sites versus those provided by mobile outreach teams. ................................................................................ 50

4. Clarify whether there is a standard for how frequently health centers must evaluate the effectiveness of their SFDS, and if so, what it is ................................................................................. 51

5. State in main body of text that health centers may offer discounts to persons with incomes above 200% FPG if it has access to other grants or subsidies that support patient care ................... 51

6. Delete the required contractual language regarding the application of the sliding fee discount schedule in detail, which could suggest that contractors can bill patients directly. ................. 52

7. Revise the section on applying the SFDS rules to formal referral arrangements to indicate that such rules apply when the only way in which an in-scope service is provided is through such arrangement ................................................................................................................................. 53

8. State explicitly that health centers are permitted to subsidize the cost of services provided by referral to ensure that patient charges adhere to the SFDS rules ........................................................................ 54

9. State explicitly that discounts offered by formal referral providers are compliant, even if they do not meet the SFDS structural requirements in this Compliance Manual, provided that they offer discounts equivalent to (or greater than) the health center’s discounts. ........................................ 54
10. Clarify that privately-insured patients who qualify for the SFDS must pay no more than what they would have paid under their applicable SFDS income level.................................................55
11. Add language to this chapter indicating that different discounting rules apply to “Supplies and Equipment” than to services. Also note that, as discussed in Chapter 16, prescription drugs should be included under required “pharmaceutical services” rather than improperly classified under “Supplies and Equipment.” .................................................................56
12. Add language about optional payment incentives from PIN 2014-02 in this Chapter. ........56

Chapter Ten: Quality Improvement/Assurance..................................................................58

Requirements..............................................................................................................58
  1. Clarify that the management issues to be addressed in QI/QAs plan are limited to clinical management issues. ....................................................................................................................58

Chapter 11: Key Management Staff...............................................................59

Demonstrating Compliance ..................................................................................59
  1. Make clear that health center CEOs must work full-time for the health center, unless HRSA explicitly approves otherwise......................................................................................................59

Related Considerations ........................................................................................61
  1. Do not permit health centers to enter into HRSA-approved contracts for their CEOs as part of the regular course of business, except under unusual circumstances requiring case-by-case approval, as doing so could create a “back door” for hospitals and other entities to gain a foothold into the program, undermining health centers’ core identity as community-based and patient-based organizations............................................................................................................61
  2. Clarify that prior HRSA approval is still required for contracts involving individual members of the key management team (other than the CEO, which is addressed above).......................................................64

Chapter 12: Contracts and Subawards ...............................................................65

Requirements and Demonstrating Compliance ..................................................65
  1. Make clear that Part 75 Uniform Administrative Requirements (including, but not limited to, procurement requirements) do not apply to contracts for which payment is made only with nongrant funds (i.e., program income and other operational funding). .................................................................65
  2. Remove the “General” sections under Requirements and Demonstrating Compliance in order to avoid suggesting that certain requirements applicable to one category also apply to the other. Instead, place all relevant provisions in the appropriate subsections on either Contracts or Subawards (or both) as applicable.................................................................67

Requirements - General .......................................................................................68
  1. Clarify that the requirement for prior HRSA approval of contracts for the delivery of health care services under the Federal award applies only to those contracts for “substantive programmatic work.” ..................................................................................................................69

Requirements - Subawards: Monitoring and Management ....................................69
### Table of Contents

1. Delete requirement for health centers to ensure subrecipients’ compliance with FTCA requirements at the time the subaward is made. ................................................................. 69
2. Clarify the specific FTCA requirements that a health center must monitor in its subrecipients… 70

Demonstrating Compliance - General ........................................................................................................... 70
1. Clarify whether prior approval is needed for contracts for non-CEO key management positions, and for contracts involving the majority of primary care providers or the majority of core primary care services. ......................................................................................................................... 70

Related Considerations .................................................................................................................................. 71
1. Similar to the earlier recommendation, create separate sub-sections under “Related Considerations” to address Contracts and Subawards.................................................................................. 71

Chapter 13: Conflict of Interest ..................................................................................................................... 73

Overarching Comments .................................................................................................................................... 73
1. NACHC supports HRSA’s plan to separate the Conflict of Interest requirements from the Governance section, as these issues apply throughout a health center. .................................................................................. 73
2. Add the term “board member” to provisions under both the “Requirements” and the “Demonstrating Compliance” sections that address requirements for “officers,” in order to encompass the full Board of Directors. ............................................................................................................................ 73

Requirements .................................................................................................................................................. 73
1. Expand the requirement to maintain standards of conduct to include officers, board members and agents. ................................................................................................................................. 73
2. Remove the word “contractor” from the definition of “agent” in second footnote......................... 74
3. Remove the word contractors from the footnote addressing organizational conflicts of interest......................................................................................................................................................... 74

Demonstrating Compliance .............................................................................................................................. 75
1. Require written disclosure of both actual and apparent conflicts of interest......................... 75
2. Clarify that written standards of conduct must apply to the selection, award, or administration of contracts paid for in whole or in part with HHS grant funds. ...................................................... 75

Related Considerations .................................................................................................................................... 76
1. Add a bullet stating that “A health center’s standards of conduct should include a statement referencing the health center’s procurement policies.” ............................................................ 76
2. Clarify that health center officers, employees, or agents may accept unsolicited gifts from contractors if they are of “nominal value.” ...................................................................................... 76

Chapter 14: Collaborative Relationships ........................................................................................................ 78

Demonstrating Compliance .............................................................................................................................. 78
1. Clarify any specific expectations as to how a health center must “document its efforts” to collaborate with nearby providers and program.................................................................................................. 78
2. Remove or qualify the expectation that letters of support from providers serving similar patient populations in the service area must address areas of coordination or collaboration. ....... 78

Chapter 15: Financial Management and Accounting Systems .......................................................... 80
General............................................................................................................................................... 80

1. Explain what elements of PIN 2013-01 are not addressed in this Compliance Manual but will remain in effect once the Compliance Manual is finalized.................................................. 80

Requirements.................................................................................................................................... 80

1. Include citations to 45 CFR 75.302, the key regulatory requirement for financial management systems under the grant management regulations, in the discussion of requirements for health centers’ financial management systems................................................................................. 80

2. Clarify the intent of the reference to 45 CFR 75.305.................................................................. 81

4. State clearly that expenditures of program income funds (“non-Grant funds”) by federally-funded health centers are not subject to the Federal Cost Principles................................................................. 81

5. For health centers that expend less than $750,000 of Federal award funding in a fiscal year, verify whether the Single Audit Act overrides the Section 330(q) audit requirement; if 330(q) is not overridden, expressly state the authority for applying this requirement to these health centers... 82

Demonstrating Compliance ...................................................................................................................... 83

1. State clearly that expenditures of program income funds (“non-Grant funds”) by federally-funded health centers are not subject to the Federal Cost Principles.................................................. 83

2. For health centers that expend less than $750,000 of Federal award funding in a fiscal year, verify whether the Single Audit Act overrides the Section 330(q) audit requirement; if 330(q) is not overridden, expressly state the authority for applying this requirement to these health centers... 83

Chapter 16: Billing and Collections ..................................................................................................... 85

Demonstrating Compliance ...................................................................................................................... 85

1. Add language about payment incentives from PIN 2014-02, in order to explicitly mention cash incentive plans and to provide guidance around factors to consider and requirements for implementing such incentives. ............................................................................................................. 85

Demonstrating Compliance & Related Considerations ............................................................................ 86

1. Delete prescription drugs dispensed to patients from “Supplies and Equipment” and include them under required pharmaceutical services, which are subject to the health center’s sliding fee discount schedule. ..................................................................................................................... 86

Chapter 17: Budget ................................................................................................................................. 88

No comments ........................................................................................................................................ 88

Chapter 18: Program Monitoring and Data Reporting Systems ............................................................ 89

No comments ........................................................................................................................................ 89

Chapter 19: Board Authority ................................................................................................................... 90
**Table of Contents**

General..............................................................................................................................................90

1. Maintain valuable guidance on the public entity model by either incorporating Section IV of PIN 2014-01 in its entirety into the Governance chapters, or else not rescinding the PIN.................90

Requirements ........................................................................................................................................91

1. Clarify that the bylaws are written operating rules for the board, not the health center. ....91
2. Clarify if governing boards will continue to be required to evaluate the performance of the CEO/Project Director, and if so, how frequently. .........................................................................................91
3. Clarify if and how governance requirements set forth solely in regulations apply to grantees who receive only 330(h) and/or 330(i) funds. .........................................................................................92

Demonstrating Compliance ....................................................................................................................92

1. Ensure that Executive Committees can act independently of the full Board in time-sensitive situations, provided that it acts in a manner consistent with the priorities established by the full Board........................................................................................................................................92
2. If HRSA will continue to have expectations around required provisions for the Board bylaws above and beyond the regulatory authorities, state these expectations explicitly in Chapter 19 of the Compliance Manual. .................................................................................................................................93
3. Resolve the inconsistency between the Requirements section and the Demonstrating Compliance section regarding approval of the budget. ........................................................................................................94
4. Clarify that while the board is required to approve the decision to enter into a contract or subaward for a substantial portion of the health center’s services, it is not required to approve the actual agreement ................................................................................................................................95
5. Acknowledge that not all health centers have capital expenditure plans.................................95
6. Explicitly recognize that while boards are responsible to approve financial management and personnel policies, they are not required or expected to approve operating procedures ..........95

Chapter 20: Board Composition ................................................................................................................97

Requirements ..............................................................................................................................................97

1. Clarify if and how governance requirements set forth solely in regulations apply to grantees who receive only 330(h) and/or 330(i) funds. .........................................................................................97

Demonstrating Compliance ....................................................................................................................97

1. Delete the requirement that, to be eligible to be a patient Board member, an individual must receive an in-scope service at a site approved under the HRSA Scope of Project; replace this with the language from PIN 2014-01 requiring such individuals to receive at least one in-scope service that generated a health center visit. ..................................................................................................................97
2. Clarify that the requirement prohibiting “contractors” from serving on the health center board applies solely to “independent contractors” who work primarily for the health center as part of its staff (and not to “individual contractors”.).........................................................................................................................98
Table of Contents

3. Eliminate the 51 percent quorum requirement from under “Demonstrating Compliance” and move it to “Related Considerations”. ........................................................................................................... 100

4. For Health Centers seeking a waiver of the patient majority board requirement, clarify the standard and the documentation required to demonstrate the unsuccessful attempts to recruit a majority of special population board members, and distinguish this from “undue hardship.”........ 100

Chapter 21: FTCA Deeming Requirements ........................................................................................................... 102

Cross-Cutting.................................................................................................................................................................. 102

1. Delete the chapter on FTCA from the Compliance Manual, and include the term “Section 330” in the title of the document................................................................................................................ 102

2. Establish a single, consolidated set of requirements and expectations for credentialing and privileging, quality improvement/assurance and risk management that apply to both the health center (§330) and FTCA (§233) programs. Reference these requirements and expectations in both the Section 330 Compliance Manual and the FTCA Manual. ................................................................. 103

3. If the Chapter on FTCA is included in the final Compliance Manual, revise the FTCA Manual and future annual deeming application PALs to indicate that requirements for deeming are limited to those outlined in the Compliance Manual. In particular, clarify the status of the credentialing and privileging standards in PIN 2001-16 and 2002-22................................................................. 103

Demonstrating Compliance ........................................................................................................................................... 104

1. Clarify what is meant by mitigating risk “consistent with the HRSA-approved scope of project”. .................................................................................................................................................. 104

Appendix A: Health Center Program Non-Regulatory Policy Issuances That Remain in Effect............. 106

1. Provide a framework for health centers to understand and remember which PINs remain in effect. ............................................................................................................................................... 106

Glossary............................................................................................................................................................................ 106

1. See recommendation in Chapter One, first paragraph, about including the statutory definition of “tribal organization” and “Urban Indian organization” in the Glossary. ........................................... 106

2. Expand the definition of Migratory and Seasonal Agricultural Worker to include aged and disabled agricultural workers and their families, consistent with statute. ........................................... 106

3. Clarify that the requirement to establish temporary housing for work purposes applies to migratory agricultural workers but not seasonal agricultural workers. ........................................... 107
Overarching Comments

Please note that these comments apply to the entire draft Compliance Manual, and are not directly linked to specific wording or Chapters.

1. Ensure that important policy interpretations contained in existing PINs and PALs remain in effect after the Compliance Manual is finalized, either by fully incorporating these interpretations into the Manual or by leaving the current documents in effect.

- **Comment:** NACHC sincerely appreciates HRSA’s extensive efforts to clarify and consolidate information about what health centers must do in order to ensure compliance with the fundamental requirements of the Section 330 Health Center Program. Having a central repository for this critical information – and eventually having the Operational Site Visit (OSV) protocol updated to reflect this information and reduce the potential for varying interpretations – will be very beneficial to health centers.

Overall, we think the Draft Compliance Manual does an excellent job of describing the statutory and regulatory requirements applicable to health centers. However, **we are concerned that in several key areas, the Manual focuses narrowly on statutory and regulatory requirements, and eliminates HRSA’s appropriate, long-standing interpretations of these requirements – interpretations which are critical to ensuring the integrity and effectiveness of the health center model.**

As you are aware, HRSA has a decades-long history of issuing sub-regulatory policy guidance -- generally in the form of Policy Information Notices (PINs) and Program Assistance Letters (PALs) -- in which the agency lays out its interpretations of the Section 330 program’s statutory and regulatory requirements. These interpretations have played a central role in assisting health centers to operate efficiently, effectively and in a manner that is consistent with the program’s statute, regulations, and intent.

The draft Compliance Manual states that some PINs and PALs will remain in effect after the Manual is finalized, while others will be superseded. For some that will be superseded, it is clear that the important policy interpretations they contain have been adequately incorporated into this Manual (generally under “Demonstrating Compliance” or “Related Considerations”), which is consistent with the goal of consolidating policy documents. However, **some PINs and PALs that are slated to be superseded contain important policy interpretations which are not adequately incorporated into the draft Compliance Manual, and which -- if no longer in effect once the Manual is finalized -- will create significant confusion and risk for health centers, threatening the integrity and effectiveness of the overall program.**

While we will discuss specific PINs in our detailed comments, we are particularly concerned about the proposals to supersede:

- PINs 1997-27 and 1998-24 - Affiliation Agreements
- PIN 2014-02 - Sliding Fee Discount
Overarching Comments

- PIN 2014-01: Health Center Program Governance (particularly Section IV on public health centers)
- PIN 1994-07: Migrant Voucher Program Guidance
- The Comparative Summary of Requirements for Credentialing and Privileging “Licensed or Certified Health Care Practitioners” from PIN 2002-22: Credentialing and Privileging

HRSA is on solid legal ground to maintain the policy interpretations contained in these PINs, and can do so by either fully incorporating them into the Manual or leaving the current documents in effect. As the health center program grantor agency, HRSA is well within its purview to issue interpretative policies in order to establish the operational framework of the program. The Administrative Procedures Act gives Federal agencies the right to issue interpretive rules, policy statements, and other guidance documents any time after a final rule is published. In these sub-regulatory documents, the agency may “explain how it interprets an existing regulation or statute, how a rule may apply in a given instance, and what things a health center must do to comply.” [1] In addition, under the long-standing doctrine known as the Chevron deference, courts will defer to HRSA’s interpretations provided that they are not “arbitrary, capricious, or manifestly contrary to the statute.”

NACHC understands the importance of holding health centers accountable based on legally defensible requirements; however, distinctions can be made between standards that reflect statutory/regulatory requirements and those that reflect HRSA’s interpretive guidance. For years HRSA has followed this approach with great success, and their interpretations have never been subjected to legal challenge. Given the importance of the interpretations contained in these PINs to the overall Health Center Program, it is both unnecessary and inadvisable to eliminate them.

- **Recommendation:** HRSA should ensure that important policy interpretations contained in existing PINs and PALs remain in effect after the Compliance Manual is finalized, either by fully incorporating these interpretations into the Manual or by leaving the current documents in effect.

Specifically, please see our recommendations regarding the Affiliation Agreement PINs (1997-27 and 1998-24), the Sliding Fee Discount PIN (2014-02), Section IV of the Governance PIN (2014-01), and the “Comparative Summary of Requirements for Credentialing and Privileging Licensed or Certified Health Care Practitioners” from PIN 2002-22. The recommendations regarding the Affiliation PINs are located in our comments for the Introduction and Chapter 11; the recommendations about the other items are located in our comments for Chapters 9, 19, and 21, respectively.

(Please note that we have not included a specific recommendation about the Migrant Voucher Program PIN, as it is much broader than a single requirement. However, our rationale for retaining this PIN is similar to that for the other PINs – namely, that it contains valuable policy information about how to develop, establish and manage migrant voucher programs that is not available in any other official document.)
2. **Indicate in the Compliance Manual that HRSA maintains the authority to issue new interpretative policy guidelines as necessary in the future, likely in the form of PINs and PALs.**

   - **Comment:** As discussed in the previous comment, HRSA is well within its purview to issue interpretative policies in order to establish the operational framework of the program. The Administrative Procedures Act (APA) gives the agency the right to issue interpretive rules, policy statements, and other guidance documents, which, if challenged, will be afforded deference by the courts under the Chevron doctrine, provided that such policies are not “arbitrary, capricious, or manifestly contrary to the statute.”

   This right, however, should not be applied solely to justify the retention of past PINs and PALs. Given the rapid evolution of the healthcare industry (both recently and in the future), health centers will continue to face fast-changing environments in which they operate. The implementation of the Affordable Care Act has demonstrated that such changes come with their own sets of challenges, especially when viewed in the context of a compliant Section 330-supported program. Insofar as this Compliance Manual is intended as a clarification and consolidation of current information regarding health centers compliance with the fundamental requirements of the Section 330 Health Center Program, it cannot anticipate what the future may hold. As such, HRSA should continue to exercise its policymaking authority under the APA and the Chevron doctrine to issue new policy interpretations in the future, which will assist health centers in adapting to these changes while maintaining compliance with Section 330 requirements.

   - **Recommendation:** Insofar as the Compliance Manual is intended to consolidate existing PINs and PALs to the extent possible, HRSA should not be precluded from issuing new PINs and PALs in the future should circumstances require good, clear policy interpretations. Whether those new policies supplement or supersede information provided in the Compliance Manual should be determined on a case-by-case basis, based in part on the reason for the new issuance.

3. **Provide health centers adequate time to come into Compliance with new expectations established in the finalized Compliance Manual.** In particular, health centers that already have OSVs scheduled at the time the final Manual is published should be “grandfathered in” under the expectations set forth in the Site Visit Guide in effect at that time.

   - **Comment:** While much of the draft Compliance Manual is consistent with current HRSA policies and expectations, there are several areas where new standards for compliance are or may be established. For example:

     - Chapter Six (Accessible Locations and Hours of Operations) incorporates standards for determining compliance with the “accessible locations” requirement that have not previously been issued in HRSA guidance.
     - Chapter Eight (Continuity of Care and Hospital Admitting) includes a notification requirement under the standards for continuity of care and hospitalization that previously was considered a “best practice.”
Chapter 20 (Board Composition) requires that patient board members receive one or more services at an in-scope site. The addition of “in-scope site” is a change from the current policy, which was issued only 2½ years ago.

These are just a few of the instances where standards for compliance were expanded, modified or newly established in a manner that would require health centers to revise their internal procedures, their external arrangements with other providers within the community, or both. Health centers will need time to adopt these changes; thus, it is unrealistic to expect them to be in compliance immediately upon the publication of the final Compliance Manual. This situation will be particularly relevant for those health centers that already have upcoming OSVs scheduled at the time the final Manual is released, as they will have already begun preparing for the OSV in advance of the Manual publication based on current policies.

**Recommendation:** Provide health centers adequate time to come into compliance with the new standards included in the Compliance Manual. In particular, to the extent that the current standards are different from - or less restrictive than - those included in the final Compliance Manual, health centers with OSVs already scheduled at the time the final Compliance Manual is published should be “grandfathered in” under the current standards and policies.

4. **Clarify the relationship between the Compliance Manual and the current OSV Guide during the period between when the Compliance Manual is finalized and the revised OSV “protocol” is published.**

**Comment:** NACHC sincerely appreciates that HRSA plans to revise the current OSV Guide into an OSV “protocol” that will reflect the contents of the final Compliance Manual, and will reduce variations in interpretations among OSV reviewers. However, we recognize that preparing the new OSV protocol will take a substantial period of time after the Compliance Manual is finalized, and we are concerned that during the interim period, there could be confusion and differing interpretations regarding which documents’ expectations apply, particularly during OSVs.

**Recommendation:** As stated previously, we recommend that those health centers with OSVs already “on the calendar” at the time the final Compliance Manual is published be grandfathered in under the current standards and policies. We are also concerned about health centers that will be informed of their OSV date -- and start preparing for it - during the period between the publication of the final Compliance Manual and the release of the revised OSV protocol. For those health centers, we request that HRSA continue to utilize the prior Site Visit Guide and the standards and policies incorporated therein, thus affording health centers the stability and consistency necessary for preparation. Further, we recommend that HRSA provide explicit, written guidance for both health centers and OSV reviewers acknowledging the use of the prior standards until the new OSV protocol is issued. At a minimum, HRSA should provide explicit, written guidance for both health centers and OSV reviewers regarding which standards those health centers should be held to during their OSVs.
Introduction

Applicability

1. Provide grant applicants 120 days after the receipt of an award to come into compliance with all requirements laid out in the Compliance Manual, as opposed to expecting them to be compliant at the time of application.

   - **Wording (first paragraph):** “This draft... Compliance Manual applies to all health centers that apply for or receive federal award funds... as well as... look-alikes.” (This language – or something very similar – appears twice in the first paragraph under “Applicability.”)

   - **Comments:** This language suggests that the all requirements in the Compliance Manual would apply to an organization that is applying for Section 330 funding, at the time that it submits its application. This is inconsistent with current HRSA policy, which provides newly funded grantees 120 days after the receipt of an award to come into compliance with the core Nineteen Program Requirements. It is also unrealistic, as organizations that are not already Section 330 grantees or look-alikes will not be able to adhere to all requirements prior to becoming operational. In addition, operational look-alikes are not required to comply with some of the financial management requirements related to the receipt of grant funds (i.e., the HHS Administrative Requirements), since they do not receive such funds.

   Section 330(k)(3) outlines the requirements that must be met by applicants that seek to receive Section 330 grants. This section regularly uses the future tense to refer to requirements (e.g., “the required primary health care services... will be available;” “the health center will demonstrate its financial responsibility”), thereby indicating that Congress did not intend for applicants to meet all requirements at the time of application.

   - **Recommendation:** As is current practice, provide newly funded grantees 120 days after the receipt of an award to come into compliance with all requirements laid out in the Compliance Manual. If there are specific requirements that must be met at the time of application, these should be individually identified and highlighted in this Compliance Manual or in the applicable grant application.

Purpose

1. Keep PINs 97-27 and 98-24 (Affiliation Agreements) in effect in their entirety, to ensure that health centers’ governance and day-to-day management remain firmly under the control of their community-based, patient-majority boards.

   - **Wording (third paragraph):** “Health Center Program non-regulatory policy issuances that remain in effect after the issuance of this Compliance Manual are listed in Appendix A. With the exception of these policies, the Compliance Manual supersedes other previous Health Center
Program non-regulatory policy issuances ... Such previously published issuances include, but are not limited to: ...PINS 1997-27 and 1998-24: Affiliation Agreements of Community and Migrant Health Centers and Amendment to PIN 1997-27 Regarding Affiliation Agreements of Community and Migrant Health Centers.”

- **Comments:** One of the most fundamental characteristics of Community Health Centers -- as well as Migrant, Homeless, and Public Housing Health Centers -- is that their governance and day-to-day management are firmly under the control of their community-based, patient-majority boards, and are not unduly influenced by outside parties. In an era when the healthcare sector is consolidating rapidly, health centers are frequently approached by outside groups -- both friendly and unfriendly -- that wish to exert control over the Health Center. The interpretive policies contained in PINS 97-27 and 98-24 (collectively, the Affiliation Policies) have played a key role in assisting health centers in navigating these waters; they have facilitated health centers’ understanding of the importance of maintaining their autonomy; educated health centers about the structural and corporate mechanisms that could be employed through collaborative efforts, which could jeopardize their independence; and functioned as a powerful tool for helping health centers “ward off unwanted suitors.”

We are unclear if HRSA’s proposal to supersede the Affiliations PINS is due to an opinion that the agency lacks legal authority to issue/retain these policies, or a belief that the important policies in these PINS are currently incorporated in the draft Compliance Manual. However, we strongly disagree with both these views, as discussed below.

**HRSA has clear legal authority to issue interpretive policies, and health centers appreciate these interpretations:** As discussed in our “Overarching Comment”, under the Administrative Procedures Act, Federal agencies have the legal authority to establish clear policies that interpret statutory and regulatory requirements - not simply restate them - as long as these interpretations do not set new legal standards or impose new requirements and are not “arbitrary, capricious, or manifestly contrary to the statute.” As program grantor agency, HRSA is well within its purview to issue interpretive policies in order to establish the operational framework of the Health Center Program.

In this case, Section 330(k)(3)(B) requires that health centers will 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.” (42 USC §254b(k)(3)(B)). This requirement, however, is just one of several requirements set forth in Section 330(k), all of which must be met by applicants seeking Section 330 grant awards and by grantees seeking to retain their Section 330 funds. While collaboration is one element of a health center project, health centers can never lose sight of maintaining compliance with all requirements. As noted above, the Affiliation Policies are essential interpretive guidance for ensuring such compliance by assisting health centers in protecting themselves from third party involvement that could compromise autonomy and thus compliance.

Further, Section 1905(l)(2)(B)(iii) of the Social Security Act (SSA) defines a look-alike as “an entity which... based on the recommendation of the Health Resources and Services Administration within the Public Health Service, is determined by the Secretary to meet the requirements for receiving such a grant, including requirements of the Secretary that an entity may not be owned, controlled, or operated by another entity.” While the statutory requirement applies
Introduction

solely to look-alike entities, insofar as look-alikes are required to comply with the Section 330 requirements, one could apply this prohibition to grantees as well.

In addition, it should be noted that in the almost two decades since these policies were issued, there have been no legal challenges to them. Further, as noted above, in the highly-unlikely event that a challenge did arise, under the longstanding doctrine known as the Chevron deference, the courts will defer to HRSA’s interpretations provided that they are not “arbitrary, capricious, or manifestly contrary to the statute” (which the interpretations in the Affiliations PINs clearly are not.)

Finally, HRSA should note that health centers appreciate the existence of these policies, as they are helpful tools in their on-going efforts to remain independent and community-focused in an era of rapid consolidation. Many health center directors report that when they are approached by a hospital or group practice seeking to “partner” in ways that raise questions about independence, they simply send them the Affiliation PINs - which often leads to an immediate change in approach or in some cases loss of interest by the potential partner. Therefore, eliminating these policies will make it significantly harder and more time-consuming for health centers to maintain their hallmark independence.

The draft Compliance Manual does not adequately reflect the overarching principle, or the full set of interpretations, contained in the Affiliation PINs: PIN 97-27 provides health centers (and their collaborative partners) with a cohesive and comprehensive policy that codifies the importance of health centers maintaining the autonomy and the integrity of the health center project and the independence of the individual health center. The PIN clearly expresses HRSA’s concerns that certain health center affiliation arrangements could lead to a degree of third party involvement in the health center that might compromise the center’s compliance with legal and policy requirements, in particular requirements pertaining to autonomy and integrity of the health center project. Such actions could, in turn, jeopardize the center’s eligibility for Section 330 funds and/or FQHC status. PIN 97-27 also defines “affiliations” to include “contractual arrangements, joint ventures (e.g., partnerships, limited liability corporations, various kinds of networks), and corporate integration (e.g., parent-subsidiary models, acquisitions, mergers)” and addresses the specific requirements/prohibitions resulting from the overarching policy within four areas of critical concern: corporate structure, governance, management and finance, and health services/clinical operations.

NACHC recognizes that parts of PIN 97-27 appear to be codified in various chapters of the Compliance Manual. For example, some (but not all) of the limitations on third party involvement and influence on health center governance have been incorporated into two separate Chapters. Specifically, Chapter 19 on Board Authority states the following:

“In cases where a health center collaborates with other entities in fulfilling the health center’s HRSA-approved scope of project, such collaboration or agreements with other entities do not restrict or infringe upon the health center board’s required authorities and functions ...”

Similarly, Chapter 20 on Board Composition states that the:
“board member selection and removal process does not permit any other entity, committee or individual ... to select either the board chair or the majority of health center board members, including a majority of the non-patient board members.”

A footnote to that section also prohibits an outside entity from removing a board member who was not selected by that entity. Combined, these prohibitions reflect the main governance limitations in PIN 97-27.

In other instances, parts of PIN 97-27 have been modified prior to inclusion in the Compliance Manual. For example, Chapter 12 appears to require prior approval by HRSA if the health center wants to contract for the majority of its primary care providers but neglects to mention prior approval of contracts for individual key management (other than the CEO) such as the CFO and CMO. The Compliance Manual also appears to supersede long-standing policy addressed in PIN 97-27, which, absent unusual circumstances, prohibits the health center from having a CEO who does not work full-time for the health center and/or from contracting for the CEO. Specifically, PIN 97-27 states the following:

“Executive Director: By law, the health center must select and directly employ an Executive Director (i.e., Chief Executive Officer). In some health centers, this position may be combined with that of Finance Director or Medical Director ... The individual who fills the Executive Director position is expected to work full-time for the health center.”

(Our concerns with what appears to be new policy regarding the employment arrangements of the CEO are discussed in greater detail in the comments on Chapters 11 and 12).

Of note, the draft Compliance Manual is silent regarding one of the most important principles in PIN 97-27 - the prohibition on corporate structures that would impact a health center’s ability to maintain full independence and autonomy, such as parent-subsidiary models (with the health center as the subsidiary) or models under which another organization becomes the health center’s “sole corporate member.” Under these models, the parent or sole corporate member could (and in the vast majority of cases is legally bound under State law to) retain certain authorities vested by statute and regulation to the health center Board. PIN 97-27 is the sole guidance that explicitly prohibits such models unless the health center retains all required authorities. Therefore, eliminating PIN 97-27 -- especially without incorporating this critical prohibition into the Compliance Manual -- “leaves the door wide open” for these types of arrangements, which threaten the core character and integrity of the health center model.

In addition, the requirements of PIN 98-24 (the amendment to PIN 97-27) also do not appear to be included in the Compliance Manual. PIN 98-24 sets forth the criteria and process for obtaining a “good cause” exception allowing health centers to contract for key management and the majority of primary care providers. As noted above, the Compliance Manual incorporates some (but not all) of these contracting limitations; however, approval criteria are conspicuously absent.

Regardless of whether and the extent to which portions of PIN 97-27 and PIN 98-24 have been adapted into (or omitted from) the Compliance Manual, the Manual does not include perhaps the most important feature of the Affiliation Policies - the explanation of the “Overarching Principle” that health centers must be independent organizations that maintain autonomy in order to protect the integrity of the health center program. This principle, as codified in general policy statements, is vital to ensuring that the health center model is not jeopardized by
deviations that could harm the program, such as potentially allowing another organization to gain a foothold into a health center’s governance/management or allowing non-compliant organizations to “back door” into the program. Further, including some of the requirements from PIN 97-27 but not those policy statements (or for that matter, the criteria from PIN 98-24 discussed above) adds a level of difficulty and confusion for health centers in maintaining the “line” beyond which centers should not cross or risk losing autonomy.

Finally, requiring health centers to dig through various chapters of the Compliance Manual to ascertain which components of the prior Affiliation Policies still apply significantly dilutes the strength of the prohibitions and prior approval requirements by not linking them to the “Overarching Principle” to protect the autonomy and integrity of the health center. In contrast, maintaining separate Affiliation Policies demonstrates the significance of the principles and policies contained therein - not only to the health centers but also to those third parties who desire to compromise the health center model. In this case, \textit{the total reflected in the Compliance Manual is less than the sum of the parts contained in the separate Affiliation Policies.}

\begin{itemize}
\item \textbf{Recommendation:} NACHC strongly urges HRSA to maintain PINs 97-27 and 98-24 in effect in their current form after the Compliance Manual is finalized, and to refer to them in sections of the Manual that touch on those issues. For example, rather than incorporating some (but not all) of the limitations on third party involvement and influence on health center governance into both Chapters 19 and 20, a reference in those Chapters would suffice (\textit{e.g.}, “Information on the restrictions around third party involvement in health center governance can be found in HRSA Policy Information Notice (PIN) 97-27”). Similar references could be incorporated into Chapter 1 (regarding maintaining a corporate structure that does not allow another entity to control the health center’s governance/management), Chapter 11 (regarding employment of the health center’s CEO) and Chapter 12 (regarding contracting for the majority of primary care providers and key management staff), the latter of which would include references to both PINs 97-27 and 98-24.

If it is necessary to modify the PINs to distinguish between requirements and interpretive guidance, HRSA should use its policy-making authority to make such clarifications. At a minimum, HRSA should incorporate into the Compliance Manual the full contents of PINs 97-27 and 98-24, including the overarching policy statements regarding the autonomy and integrity of the health center model, and establish a separate chapter on this issue, so that health centers do not have to dig through the Manual to identify all related sections.

\end{itemize}

2. \textbf{Provide a framework for health centers to understand and remember which PINs and PALs remain in effect.}

\begin{itemize}
\item \textbf{Wording (third paragraph):} “Health Center Program non-regulatory policy issuances that remain in effect after the issuance of this Compliance Manual are listed in Appendix A.”

\item \textbf{Comment:} NACHC is unclear how HRSA determined which PINs and PALs will be superseded by this Compliance Manual, as opposed to which will remain in effect. We considered a range of possibilities – \textit{e.g.}, that all PINs that were finalized without an opportunity for public comment were being superseded, or that all those with significant information beyond what is included in
this Compliance Manual are being kept. Nonetheless, none of these tests appear to apply uniformly and we are unable to determine which criteria were determinative in deciding which PINs and PALs will be rescinded versus which will remain in effect. Without a framework to understand which ones will – and will not — be effective after the Compliance Manual is finalized, there will be significant confusion among health centers.

- **Recommendation:** Provide a framework or explanation to assist health centers in understanding which current PINs and PALs will remain in effect after the Compliance Manual is finalized (e.g., “All PINs related to scope of project remain in effect.”) Also, whenever possible, please explain why certain PINs and PALs were superseded while others were not superseded by the Compliance Manual.

3. Clarify whether HRSA will issue new PINs and PALs in the future, and if so, in what areas.

- **Wording (third paragraph):** “Health Center Program non-regulatory policy issuances that remain in effect after the issuance of this Compliance Manual are listed in Appendix A.”

- **Comment:** Given the lack of clarity around why some PINs will remain in effect while others will be rescinded, it is also unclear if HRSA will issue new PINs and PALs in the future.

- **Recommendation:** As noted above, NACHC believes there is an important role for good, clear policy that interprets the statutory and regulatory requirements which form the framework of the health center program. Further, as the health center program grantor agency, HRSA is well within its purview to issue interpretative policies, provided that they are consistent with the longstanding doctrine known as the Chevron deference, which requires courts to defer to HRSA’s interpretations provided that they are not “arbitrary, capricious, or manifestly contrary to the statute.” Thus, we recommend that HRSA not abandon its policy-making role and rather, continue to issue good, clear policies that set forth HRSA’s interpretation of the requirements. In that regard, clarify if HRSA will publish new PINs and PALs in the future. If so, what is the distinction between issues that will be addressed in the Compliance Manual and those that will be addressed in PINs, PALs, and other sub-regulatory guidance?

4. Establish a regular schedule for updating and seeking public comment on the Compliance Manual.

- **Wording (fifth paragraph):** “HRSA will update or amend the Compliance Manual as needed to provide further clarification of program policies.” (p.7)

- **Comment:** We recognize that updates to the Compliance Manual may be needed over time. However, insofar as the Compliance Manual (which will be codified in the Health Center Site Visit Protocol) will function as the basis for health center reviews, to assist health centers keep track of changes, it would be very helpful for updates to be made on a consistent and predictable schedule, and for public comment to be solicited before updates that constitute new policies are finalized. For example, HRSA could implement an annual update cycle, with changes announced in the summer; health centers submitting comments in the early fall; HRSA
finalizing the updates/new policies in late fall; and effective dates no sooner than the start of the new year.

- **Recommendations:** Establish a standard timeframe for proposing updates, seeking public comment for updates that constitute new policies, finalizing updates/new policies, and making them effective, so that health centers can predict when to expect and implement changes.

**Structure of the Health Center Program Compliance Manual**

1. **Permit health centers to demonstrate “alternative means of demonstrating compliance” with requirements before a condition is automatically applied.**

   - **Wording (Note under Demonstrating Compliance):** “Health centers that fail to demonstrate compliance as described in this Manual will receive a condition of award/designation. In responding to such conditions, health centers could demonstrate their compliance...by the health center proposing an alternative means of demonstrating compliance with the specified Requirements, which would include submitting an explanation and documentation that explicitly demonstrates compliance.”

   - **Comment and Recommendation:** This issue is discussed under Chapter Two, Progressive Action; please see that section.

**Additional Health Center Responsibilities**

1. **Reference those PINs that will remain in effect in the list of additional responsibilities.**

   - **Wording:** “Health centers (including look-alikes) may be subject to the distinct statutory, regulatory, and policy requirements of other Federal programs such as, but not limited to: ...”

   - **Recommendation:** Given that some PINs will remain in effect even after the Compliance Manual is finalized, we recommend noting this in a bulleted list of other requirements that may remain in effect. We also recommend including a link to the list of PINs that will remain in effect (which is located in Appendix A). On a related note, as discussed previously, we strongly urge HRSA to include the Affiliation PINs (97-27 and 98-24) on the list of those PINs that will remain in effect.

2. **If the Chapter on FTCA is finalized, the FTCA Manual and future annual deeming application PALs should reference the requirements in Chapter 21 of this Compliance Manual, and include no new or additional requirements.**

   *Please see the comments on Chapter 21 (under “Cross-Cutting”) for a further discussion of this issue.*
- **Wording:** “Health centers (including look-alikes) may be subject to distinct statutory, regulatory, and policy requirements of other Federal programs such as ...the Health Center FTCA Program (with the exception of the deeming requirements included in this Manual).” (emphasis added)

- **Comment:** This language indicates that the deeming requirements in the Compliance Manual will supersede those in the FTCA Manual and the annual PALs describing the deeming process. Nevertheless, the FTCA Manual is included in Appendix A as one of the documents that will not be superseded by the Compliance Manual.

- **Recommendation:** It appears that HRSA intends for the deeming requirements in the Compliance Manual to supersede those described in the FTCA Manual and future annual deeming application PALs. While our preference is for HRSA to remove the FTCA Chapter from this Compliance Manual (see comments on Chapter 21), if this is not possible, then both the FTCA Manual and future PALs must be revised to indicate that any requirements they contain are superseded by, and limited to, those contained in this Compliance Manual.
Chapter One: Eligibility

First Paragraph

1. Clarify the legislative authority which makes tribes, tribal organizations, and Urban Indian organizations eligible to apply for Section 330 grants, and give this category of eligible entities more prominence in the discussion.

- **Wording:**
  - *(First paragraph)* “Specifically, organizations applying for funding as health centers or designation as look-alikes must be private non-profit entities or public agencies.”
  - *(Middle of second page)*: “Tribal or Urban Indian organizations, as defined under the Indian Self-Determination Act or the Indian Health Care Improvement Act, are eligible to apply for Health Center Program funding or designation and would demonstrate their eligibility by providing documentation of such status.”

- **Comment:** While the Compliance Manual does mention that tribal organizations and Urban Indian organizations are eligible to apply for Section 330 grants, this language appears as an afterthought, given that it is mentioned only in italics, and following a detailed discussion of eligibility for non-profit organizations and public entities.

Also, we are unclear if the term “tribal organizations” includes single tribes, given that the term generally refers to organizations representing more than one tribe. Our understanding is that the standard language used to refer to these categories of entities—such as in Section 1902 (l)(2)(B) of the SSA—is “tribes, tribal organizations, and Urban Indian organizations.”

- **Recommendation:** We recommend giving more prominence to tribes, tribal organizations, and Urban Indian organizations as entities that are eligible to apply for Section 330 grant funds. Specifically:
  - If these types of organizations can be classified as either non-profit or public entities, then they should be discussed under — and clearly linked to — the appropriate heading. If they are eligible under separate authority, then they should be given their own section/heading, similar to non-profit and public entities.
  - The sentence in the first paragraph should be revised to include these entity types (e.g., “Organizations applying...must be private non-profit entities, public agencies, tribes, tribal organizations or Urban Indian organizations”).
  - The reference to tribal organizations should be expanded to include “tribes.”

Finally, we encourage HRSA to include the statutory definition of “tribal organization” and “Urban Indian organization” in the Glossary, and to link to these definitions in this chapter. For reference, here are the statutory definitions:

- **Tribal organization:** Per the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b(l)): “tribal organization” means the recognized governing body of any Indian tribe; any legally established organization of Indians which is controlled, sanctioned, or chartered by such governing body or which is democratically elected by
the adult members of the Indian community to be served by such organization and which includes the maximum participation of Indians in all phases of its activities: 

*Provided*, That in any case where a contract is let or grant made to an organization to perform services benefiting more than one Indian tribe, the approval of each such Indian tribe shall be a prerequisite to the letting or making of such contract or grant.

- Urban Indian Organization: Per 5 USC § 1603(29), the term “Urban Indian organization” means a non-profit corporate body situated in an urban center, governed by an urban Indian controlled board of directors, and providing for the maximum participation of all interested Indian groups and individuals, which body is capable of legally cooperating with other public and private entities for the purpose of performing the activities described in section 1653(a) of this title.

### Additional Eligibility Requirements for Look-Alike Designation

1. **Eliminate the reference to “income” in the context of 340B.**
   - **Wording:** “2.a....(for example, Federally Qualified Health Center reimbursement, 340B drug pricing income)”
   - **Recommendation:** We request that HRSA change the word “income” (as in “340B drug pricing income”) to either “savings” or “benefits,” as this more accurately represents the way in which health centers and other covered entities benefit under 340B, as well as direction that health centers have received directly from HRSA leadership.

2. **Do not prohibit health centers from applying and receiving approval for dual Grantee/Look-Alike Status.**
   - **Wording:** “Organizations will not be permitted to apply for ‘dual status,’ whereby an organization receives both a Federal award under section 330 and look-alike designation.” (p. 11)
   - **Comment:** This language and the preceding requirement #3 for look-alike organizations indicate that HRSA will no longer allow health center organizations to obtain “dual status,” under which some sites are look-alike sites while others are included within the grant scope of project. Further, while this language appears to impact only those organizations desiring to apply for dual status after the Compliance Manual is finalized, it is unclear whether current dual-status arrangements will be allowed to continue.

Although there are not a significant number of “dual status” health centers, the reasons health centers choose this option are appropriate and varied. For example, some health centers choose this option for strategic purposes, i.e., by leaving one or more sites under the look-alike status rather than the grant scope of project, those sites remain eligible for New Access Point funds. Others choose this option for more practical reasons having to do with organizational structure or their specific operations.
Legal justification: HRSA cites Section 1905(l)(2)(B) of the SSA as the basis for its decision to eliminate dual status the provision. However, this language refers to the definition of a Federally Qualified Health Center (FQHC), which is a term that is used in the Medicaid, Medicare, and CHIP programs to determine eligibility for specific reimbursement systems (i.e., PPS) under these programs. In contrast, the requirements in this Compliance Manual are to be limited to those established under Section 330 of the Public Health Service Act (PHS) – a completely separate law and authority, which is relevant to the FQHC definition only to the extent that the SSA references the Section 330 requirements in establishing its requirements for FQHC eligibility.

The distinctions between a Section 330 health center and an FQHC are emphasized by the following points:

- It is possible to be an FQHC without being either a grantee or look-alike under Section 330. Specifically, Section 1902(l)(2)(B) of the SSA states that the following type of organization is eligible to be an FQHC despite having no connection to Section 330: “an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act (Public Law 93-638) or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act for the provision of primary health services.”

- CMS defines an FQHC at the site level, whereas HRSA defines a Section 330 health center at the organizational level. For example, if a health center organization has 8 permanent and seasonal sites, HRSA considers it to be a single “health center,” while CMS (specifically Medicare) considers it to be eight separate “FQHCs”. As HRSA is well aware, this is far from a theoretical distinction, as the fact that Medicare considers each permanent and seasonal site to be a distinct FQHC is the basis for its requirement that each site be enrolled separately in Medicare.

Not only do we contend that it is inappropriate to apply the SSA definition of a FQHC to determine requirements for Section 330 health centers, but we also disagree with HRSA’s interpretation of the SSA definition. The portion of the SSA definition of a FQHC cited in the Compliance Manual includes three distinct types of organizations - a direct grantee of Section 330 funds, an entity that receives Section 330 funds through a direct grantee (a sub-recipient), and an entity that does not receive Section 330 funds but is determined to meet the requirements for such receipt (a FQHC Look-Alike). It appears that HRSA has chosen to interpret the FQHC definition so that the grantee and look-alike options are mutually exclusive. However, there is no indication that Congress intended such a result. Thus, the basis for HRSA’s proposed interpretation is unclear.

In addition, interpreting the grantee and look-like options as mutually exclusive is contrary to HRSA’s current interpretation. If HRSA has decided to establish and implement a new interpretation of the statute that fundamentally differs from the prior, long-standing interpretation, the appropriate vehicle for doing so would be a proposed rule-making, not a sub-regulatory policy document.

Finally, allowing such change in interpretation would be a slippery slope – if HRSA is now determining that the grantee and look-alike options are mutually exclusive, could HRSA next interpret the statute so that the grantee and subrecipient options are mutually exclusive as
well? There are several centers that have both a direct grant and a sub-award. In fact, use of the dual grantee/sub-recipient status is an approach that HRSA has approved to help alleviate service area overlap concerns. It also is a method by which funds can remain in the community when an existing grantee fails and its grant must be awarded to another entity. Further, Section 330 grantees often receive additional grants that are intended to be sub-awarded to other grantees as well as used by the direct recipient, such as certain Health Care for the Homeless grants and Health Center Controlled Networks grants. Allowing HRSA to eliminate grantee/look-alike dual status options could lead to elimination of the grantee/sub-recipient dual status, with potentially grave consequences.

- **Recommendation:** Consistent with the statutory PHS Act Section 330 definition of a health center (rather than the SSA definition of an FQHC), HRSA should continue to allow health centers to apply for, and receive, dual grantee/look-alike status, provided that the health centers can demonstrate that they are:
  - accounting for the grant and the look-alike projects separately, and
  - not co-mingling the grant funds and benefits solely available to grantees (such as FTCA) with the look-alike project.

At a minimum, HRSA must grandfather those health centers that currently have grantee/look-alike dual status.
Chapter Two: Oversight

Program Oversight

1. Provide clarity around “expected performance goals” that could lead to grant conditions, and how performance against these goals will be evaluated, to ensure that HRSA involvement is consistent with a grantee/grantor relationship.

   • **Wording** *(third paragraph, first and third bullets):* “HRSA may impose specific award conditions if an applicant/designee...
     - Demonstrates undue risk in such areas as....Ability to effectively implement statutory, regulatory, or other requirements imposed on non-federal entities
     - Fails to meet *expected performance goals*” *(emphasis added)*

   • **Comments:** We are concerned about the term “expected performance goals” in the third bullet. Depending on how broadly these “expected performance goals” are identified, this statement could potentially provide HRSA a level of involvement in health centers’ day-to-day issues that would be more consistent with a cooperative agreement than a grant.

   As indicated in the first bullet of this section, HRSA has the ability to impose conditions when a health center “demonstrates undue risk” related to, among other things, an inability to implement “statutory, regulatory, or other requirements” (which we interpret as encompassing the Program Requirements outlined in this Compliance Manual). This suggests that the term “expected performance goals” refers to activities that are above and beyond statutory, regulatory and programmatic requirements - raising the question of what types of goals it would encompass, and whether there are any limits on how extensive or detailed they could be. In turn, this raises questions about the types of involvement that are appropriate for HRSA in a grantor-grantee relationship.

   • **Recommendation:** Provide clarity in the Compliance Manual text about the types of “expected performance goals” that, if unmet, could result in conditions. For example, what will be the process and criteria for determining which goals could lead to conditions? How will these goals be established and documented, and how will they be communicated to health centers?

Progressive Action Process

1. Permit health centers to demonstrate “alternative means of demonstrating compliance” with requirements before a condition is automatically applied.

   • **Wording:**
     - **Progressive Action Process, first paragraph:** “In responding to such conditions, health centers would demonstrate their compliance by either submitting documentation to HRSA, which demonstrates compliance as described in Chapters 3-20 of this Manual, or by
Chapter Two: Oversight

providing an alternative means of demonstrating compliance with the specified requirements, which would include submitting an explanation and documentation that explicitly demonstrates compliance.

- **Introduction, Structure of Manual, Note under Demonstrating Compliance:** “Health centers that fail to demonstrate compliance as described in this Manual will receive a condition of award/designation. In responding to such conditions, health centers could demonstrate their compliance... by the health center proposing an alternative means of demonstrating compliance with the specified Requirements, which would include submitting an explanation and documentation that explicitly demonstrates compliance.”

- **Comments:** NACHC appreciates HRSA’s recognition that health centers may be able to demonstrate compliance with program requirements in other ways than those listed in the Compliance Manual. However, we are concerned that HRSA intends to automatically place a condition on a health center’s award/designation if it does not meet the standards outlined in the Compliance Manual, before giving the health center an opportunity to present its alternative.

- **Recommendation:** Given both the workload and the potential negative impacts of having a condition, as well as the administrative burden for both the health center and for HRSA in removing such conditions, NACHC recommends that health centers be given a brief window to present their “alternative means of demonstrating compliance” before a condition is placed.

2. **Once a condition is imposed, explicitly state that reconsideration of the condition due to inaccuracy of the initial interpretation and non-compliance finding is an available option.**

- **Wording:**
  - **First paragraph:** “In responding to such conditions, health centers would demonstrate their compliance by submitting documentation to HRSA, which demonstrates compliance as described in Chapters 3-20 of this Manual, or by providing an alternative means of demonstrating compliance ....”
  - **Third paragraph, first bullet:** “Phase One provides ninety (90) days for the health to submit appropriate documentation that the specified program requirement has been met or that the health center has developed an adequate action plan...”

- **Comment:** The language above fails to recognize a request for reconsideration of the condition as an option for resolution of the condition. As has been demonstrated throughout the Operational Site Visit process of the last few years, there are instances under which a finding of noncompliance may result from a reviewer’s incorrect or inaccurate interpretation of a requirement. If such inappropriate interpretation is not detected prior to the issuance of the Notice of Award, a standard condition is placed on the grant based solely on the requirement being classified as “not met” and not taking into account the detailed (inaccurate) findings that served as the bases of this classification. At that point, the initial inappropriate interpretation and findings typically remain undetected and health centers that are deemed noncompliant due to inaccuracy are put into the same position as those that are truly noncompliant. From experience, those centers are then placed in a position of having to modify their existing
Chapter Two: Oversight

policies, procedures, systems, etc., even though they may be compliant - a situation which should not be allowed to occur if the health center can demonstrate that the initial interpretation and findings upon which the condition was based were inaccurate or incorrect from the outset.

This could be particularly problematic for health centers operating special population-only programs, such as Migrant Voucher programs and Health Care for the Homeless programs, as many OSV reviewers may not be familiar with the innovative approaches such programs often must establish to implement and demonstrate compliance with the program requirements. Given the complexities of serving these populations, these grantees are at higher risk of receiving conditions inappropriately due to a reviewer’s incorrect or inaccurate interpretation of how a requirement should be met.

We note that the “Progressive Action Overview” section states that program conditions describe, among other things, the “method for requesting reconsideration of the condition, if applicable.” However, there is no mention of the reconsideration option in the description of the Progressive Action Process.

- **Recommendation:** To avoid situations under which health centers are forced to unnecessarily modify policies, procedures, systems, etc., that are already compliant, HRSA should explicitly include as an option a process for reconsideration of the initial findings of noncompliance which resulted in the condition. This process should be referenced in the description of the Progressive Action Process.

3. **Clarify which conditions will not be subject to (a) a 120-day implementation phase; or (b) the initial Phase One 90-day response time.**

- **Wording:**
  - *Footnote:* “a limited number of conditions do include an implementation phase. This is because the corrective actions needed to address these conditions would not require a health center to make programmatic and organizational changes or necessitate documentation of compliance.”
  - *Fourth paragraph:* “For example, in Phase One, for most conditions, a health center is given 90 days ...”

- **Comment:** Both instances cited above indicate that some circumstances may result in deviations from certain elements of the typical Progressive Action Process. In the first instance, HRSA indicates that there are some conditions that would not include an implementation phase. However, it’s unclear how the example provided in the Compliance Manual (“a condition requiring a health center to provide an updated needs assessment”) fits the circumstances described in the Manual. In the second instance, HRSA indicates that there may be conditions for which an initial 90 days is not provided, but no examples are provided. Both of these situations are vague at best, which could result in both confusion among health centers and inconsistent application by HRSA.
• **Recommendation:** To avoid confusion and inconsistency, HRSA should specify the circumstances under which health centers would not be provided either a 120-day implementation phase or an initial 90-day response time.
Chapter Three: Needs Assessment

General

1. When discussing Needs Assessment, explicitly reference the unique needs of statutory special populations, including but not limited to homeless individuals and migratory and seasonal agricultural workers (MSAWs) and their families.

   • Wording:
     - **Requirements, first sub-bullet:** “services to be provided through the center (including any satellite service sites) are available and accessible to the residents of the area promptly and as appropriate;”
     - **Demonstrating Compliance, second bullet, first sub-bullet:** Factors associated with access to care and health care utilization (for example, geography, transportation, unemployment, income level, educational attainment);
     - **Related Considerations, second bullet:** “The health center may choose to include an additional focus on a specific underserved subset of the service area population (for example, low-income individuals; homeless children; lesbian, gay, bisexual, and transgender individuals; persons living with HIV/AIDS; elderly persons), as

   • Comment: These bullets do not explicitly recognize the unique needs of the statutory special populations, including migratory and seasonal agricultural workers (and their families) and homeless individuals and families, and how these unique needs might impact a needs assessment. Such impact may be relevant regardless of whether a center receives targeted funding for such special population(s) or whether, as if often the case, the health center services members of the special population(s) as part of the general community.

   • Recommendation: Add the language highlighted below to
     - **Requirements, first sub-bullet:** “services to be provided through the center (including any satellite service sites) are available and accessible to the residents of the area (including transient populations such as migratory and seasonal agricultural workers and their families, homeless individuals and families) promptly and as appropriate;”
     - **Demonstrating Compliance, second bullet, first sub-bullet:** “Factors associated with access to care and health care utilization (for example, geography, transportation, occupation, transience, unemployment, income level, educational attainment);”
     - **Related Considerations, second bullet:** “The health center may choose to include an additional focus on a specific underserved subset of the service area population (for example, low-income individuals; agricultural workers; homeless adults and/or children; lesbian, gay, bisexual, and transgender individuals; persons living with HIV/AIDS; elderly persons)....”

Demonstrating Compliance
1. Clarify if HRSA has expectations regarding the minimum frequency for a comprehensive needs assessment, and if so, specify them.

- **Wording (second bullet):** "The health center completes or updates a needs assessment of the current or proposed population ... the needs assessment utilizes the most recently available data ..."

- **Comment:** The requirement regarding the needs assessment does not specify if HRSA has expectations regarding the frequency for conducting such assessment. Should it be conducted once every project period (similar to strategic planning) with annual updates? Does HRSA expect a full needs assessment annually (similar to the assessment of the service area, which by regulation should be conducted annually)? Currently, there are differing opinions among HRSA reviewers as to how often the assessment should be conducted. The Health Center Program Site Visit Guide also does not address frequency – it merely inquires whether the health center has a documented needs assessment.

- **Recommendation:** To avoid future confusion in the field and among reviewers, if HRSA has expectations regarding the minimum frequency for health centers to conduct a comprehensive needs assessment (which ideally would be no more than once every three years consistent with the typical project periods), such frequency should be specified in the Compliance Manual. On the other hand, if no such expectations exist, the Compliance Manual should include a statement explicitly affording health centers flexibility to determine the appropriate frequency based on their and their communities’ specific facts and circumstances, perhaps in the “Related Considerations” section.
Chapter Four: Required and Additional Services

Demonstrating Compliance

1. Clarify that services provided directly by the health center can be provided by employees, volunteers and independent contractors who work primarily for the health center and who are included as and considered part of the health center’s “core” staff.

   - **Wording:** Footnote: “For purposes of the HRSA-approved scope of project (Form 5A), services provided ‘directly’ are those provided by employees and volunteers. HRSA/BPHC utilizes Internal Revenue Service (IRS) definitions to differentiate contractors and employees. Typically, an employee receives a salary on a regular basis and a W-2 from the health center with applicable taxes and benefit contributions withheld along with coverage for unemployment compensation.” (emphasis added)

   - **Comment:** Determining whether services are provided directly based on the tax classification of the individual furnishing such services is inconsistent with current health center staffing models. Many “independent contractors” work primarily for the health center and both the individual and the health center consider themselves to be furnishing direct services on behalf of the health center. These persons do not have a separate employer functioning as the contracted entity, typically do not see patients independent of the health center, provide the services at the health center site, and are included as and considered part of the health center’s core “staff.” While the IRS still uses a modified “right to control” test to determine whether an individual is an employee or an independent contractor for tax classification purposes, such test should not be definitive with respect to whether an individual is providing services directly for the health center. Rather, a more appropriate and consequential test would be one based on the nature of the relationship between the health center and the individual furnishing the services.

There are several reasons for a person to be an independent contractor rather than an employee – for example, a physician may practice in a state that does not exempt the health center from the corporate practice of medicine and thus the physician cannot be “employed” by the health center. Alternatively, the person may want to maintain independent contractor status so that he/she can provide some consulting work outside of the health center (with the center’s permission - similar to “moonlighting” by an employee). Regardless of the “form,” the substance of the relationship between the health center and the individual furnishing the services differs from that of an “individual contractor” who contracts with the center to provide a distinct service (whether clinical, administrative or otherwise), does not work primarily for the health center (and may not even provide services at the health center’s site), and is not included as or considered part of the health center’s core “staff.”
Chapter Four: Required and Additional Services

Also note that failing to include independent contractors as providers of “direct services” will impact staffing models and/or Form 5A for many health centers and is not workable from an operational standpoint.

- **Recommendation:** Revise this footnote and related language to indicate that services provided directly by the health center can be provided by independent - but not individual - contractors who work primarily for the health center and whose relationships with the health center are similar to those of employees.

2. **Clarify that the health center is generally responsible to bill for services provided by a third party via a formal contract/agreement, subject to limitations in law.**

- **Wording (first bullet, second sub-bullet):** “Services Provided to Health Center Patients on Behalf of the Health Center by a Third Party via a Formal Contract/Agreement: If a required or additional service is provided on behalf of the health center via a formal contract/agreement between the health center and a third party entity (including a subrecipient), this service is accurately recorded in Column II on Form 5A: Services Provided, reflecting that the health center pays for the care provided by the third party via the agreement. In addition, such contractual agreements for services include:
  - How the service will be documented in the patient’s health center record; and
  - How the health center will pay for the service.”

- **Comment:** This description neglects to include that, subject to limitations in statute or regulation, the health center “bills for” the care provided by the third party via the agreement. Such detail is included in the description of “Services Provided Directly by the Health Center.” Further, the Health Center Program Operational Site Visit Guide includes the following as a required provision for service contracts: “How the health center will pay and/or bill for the service.”

The failure to state that the health center also bills for services under “Services Provided... via a Formal Contract/Agreement” to the extent allowed by law, may be confusing to the reader. Further, by omitting this requirement, the arrangements may be subject to an interpretation that a contracted third party retains responsibility to bill for the services rendered to health center patients pursuant to the agreement, potentially using the health center’s billing numbers and thus its PPS rate (which is prohibited).

- **Recommendation:** State explicitly that the health center is responsible to bill for services provided by a third party via a formal contract/agreement subject to limitations in federal or state law.

3. **Explicitly state that formal contracts/agreements must specify “how the health center’s policies and/or procedures will apply”**.

- **Wording:** “Services Provided to Health Center Patients on Behalf of the Health Center by a Third Party via a Formal Contract/Agreement... (same as above.)

35
Chapter Four: Required and Additional Services

- **Comment:** The description does not state that the contract/agreement must specify “how the health center’s policies and/or procedures will apply,” as required under the Operational Site Visit Guide and as indicated by the Form 5A Column Descriptor Guide. Typically, contracts for services require that the contractor provide services consistent with the health center’s applicable policies and procedures. This requirement is consistent with the health center’s obligation to oversee and monitor contracted services. Further, it is important to ensure that contractors who are compensated by the health center to provide services on its behalf do so under the control of the health center by, among other things, requiring compliance with the health center’s standards.

- **Recommendation:** Explicitly state that formal contracts/agreements must specify “how the health center’s policies and/or procedures will apply”. This will ensure that contractors comply with the health center’s standards when furnishing services on its behalf.

4. Avoid using the term “pays for” to describe different delivery models.

- **Wording** *(first bullet, first and second sub-bullets, emphasis added):*
  - “Services Provided Directly by the Health Center... the health center pays for and bills for direct care”
  - “Services Provided... by a Third Party... reflecting that the health center pays for the care provided by the third party via the agreement... In addition, such contractual agreements for services include... How the health center will pay for the service.”

- **Comment:** Both sections indicate that the health center “pays for” the care. However, the term “pays for” has very different meanings under the two separate delivery models, so this double use could result in confusion.

- **Recommendation:** We suggest striking the term “pays for”, as follows:
  - Under “Services Provided Directly by the Health Center,” the footnote clarifies that the services are furnished through “employees and volunteers” (i.e., individuals directly compensated by the health center or volunteering on behalf of the health center) so the reference to “paying for” direct care if unnecessary and can be deleted. Note that should HRSA include independent contractors in the list of persons providing direct services, the reference to “paying for” direct care is still unnecessary since the health center would be “compensating” the independent contractor rather than paying for the services.
  - Under “Services Provided... via a Formal Contract/Agreement” we recommend replacing the “health center pays for the care provided by the third party via the agreement” with “health center provides compensation or a sub-award to the third party furnishing care via the agreement.”

5. Include a specific cross-reference to the Chapter 9 requirement that if an in-scope service is provided only through a formal referral arrangement, the agreement must specify that the referral provider will offer discounts.
• **Wording:** “Services Provided to Health Center Patients by Third Parties through Formal Referral Arrangements... such formal referral arrangements for services, at a minimum, address:
  - The manner by which referrals will be made and managed; and
  - The process for tracking and referring patients back to the health center for appropriate follow-up care (for example, exchange of patient record information, receipt of lab results).”

• **Comment:** This list does not include a cross-reference the requirement in Chapter Nine that the referral provider offer discounts at least consistent with the health center sliding fee discount program requirements. Including specific requirements for formal written referral agreements in multiple chapters without, at a minimum, an applicable cross reference could result in confusion when health centers are putting these requirements in place.

• **Recommendation:** Include a cross reference to the text in Chapter 9: Sliding Fee Discount Program, page 37, either in the body of the description or in a footnote.

6. **Explicitly state that informal referral arrangements are not subject to the requirements outlined in this Compliance Manual.**

• **Wording:** “Services Provided to Health Center Patients by Third Parties through Formal Referral Arrangements...”

• **Comment:** As you are aware, health centers may have informal referral arrangements with other providers within the community for continuity of care purposes. These informal arrangements are not recorded separately on Form 5A, Column III as “providing a service by referral” (rather they are considered part of general medical care) and thus are not required to comply with the aforementioned requirements. Nevertheless, there have been several instances of OSV reviewers who have informed health centers that ALL referral arrangements (including informal specialty or other referrals) must comply with such requirements and must be listed in Column III of Form 5A, ultimately putting the center in the position of having to establish a compliant MOU or to discontinue the relationship.

• **Recommendation:** State explicitly in this Chapter (perhaps under Related Considerations) that informal referral arrangements are not subject to the requirements outlined in this Compliance Manual.

7. **Clarify that the requirement to provide interpretation and translation services applies only to health centers whose patient populations include a “substantial proportion of individuals of limited English-speaking ability”.** Also, clarify how “substantial proportion” is to be defined.

• **Wording (second bullet):** “Health center patients with limited English proficiency are provided with interpretation and translation (for example, through bilingual providers, on-site interpreters, language telephone line) that enables them to have reasonable access to health center services.”
Comment: The implementing regulations at 42 CFR 51c.303(l) specify that:

“In the case of a center which serves a population including a substantial proportion of individuals of limited English-speaking ability, have developed a plan and made arrangements responsive to the needs of such populations for providing services to the extent practicable in the language and cultural context most appropriate to such individuals, and have identified an individual on its staff who is fluent in both that language and in English and whose responsibilities include providing a guidance to such individuals and to appropriate staff members with respect to cultural sensitivities and bridging linguistic and cultural differences. If more than one non-English language is spoken by such group or groups, an individual or individuals fluent in those languages and English shall be so identified.” (emphasis added)

The Requirements section of Chapter 4 of the draft Compliance Manual reflects the regulatory language, indicating that this requirement applies to health centers that serve “a population that includes a substantial proportion of individuals of limited English-speaking ability ....” (emphasis added). Accordingly, the aforementioned language in the Demonstrating Compliance section of Chapter 4 is inconsistent not only with the health center regulations, but also with the Requirements section of this very Chapter insofar as it neglects to reflect that these requirements are specific to health centers that serve a “substantial proportion” of individuals of limited English-speaking ability. While it is desirable for all health centers serving individuals of limited English-speaking ability adopt such strategies, it is incorrect to suggest that it is required.

Further, it is unclear how HRSA defines “substantial” for purposes of meeting this requirement. This lack of clarity has resulted in confusion in the field and in particular, among OSV reviewers, who without additional guidance often impose their own standards based on the proportion they deem reasonable – ultimately, this confusion has resulted in differing standards with respect to compliance. While the health center regulations do not include a definition, there are guidelines applicable to HHS grantees under both the Office of Civil Rights (OCR) (Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons) and the Office of Minority Health (OMH) (The National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care). To ensure consistency with these guidelines, and to provide “objective” review standards for both health centers and OSV reviewers, HRSA should explicitly reference the OCR and OMH standards. If HRSA declines to include such references, at a minimum, it should explicitly state that what constitutes “substantial” will be determined in the sole discretion of the particular health center.

Recommendation: Clarify that the requirement to provide interpretation and translation services applies only to health centers meeting the “substantial proportion” threshold. We also request that this issue be clarified in the OSV guide, which presently suggests that these requirements apply to all health centers. Further, HRSA should explicitly reference the OCR and OMH guidelines in establishing an “objective” review standard to determine whether the “substantial” threshold has been met. Alternatively, HRSA should include an explicit statement that health centers are afforded flexibility to determine, in their sole discretion, what constitutes “substantial” in the context of a particular individual health center’s project.
8. State explicitly that health centers are not required to provide all required services at each site.

- **Wording:** *Not applicable.*

- **Comments:** Chapter 4 fails to include the important concept that not all services have to be provided at each site, as set forth in PIN 2008-01, page 9. (See below.) Without such a statement, there could be an incorrect expectation that health centers must make all in-scope services available at each site. This continues to be an area of confusion and misinterpretation by OSV reviewers.

- **Recommendation:** Add language addressing this issue either in the body of the chapter or as a footnote under Demonstrating Compliance. We suggest inserting the following text from PIN 2008-01, page 9:

  “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”
Chapter Five: Clinical Staffing

Demonstrating Compliance

1. Clarify what is meant by a “staffing plan” and any expectations around frequency of updates.
   • **Wording (first bullet):** “The health center’s staffing plan ensures that clinical and related support staff are in place to carry out all required and additional services included in the HRSA-approved scope of project.”
   
   • **Comment:** The bullet refers to a "staffing plan." It is unclear whether that refers to the Form 2 staffing profile submitted with the grant application or another document.

   • **Recommendation:** Please clarify if the term “staffing plan” refers to a specific document. If it applies to the Form 2 staffing profile submitted with the grant or designation application, please indicate if HRSA has expectations about if, and how often, it should be updated, given the length of time that may occur between the application and an Operational Site Visit. If HRSA does not have expectations about the frequency of updates, please indicate that health centers are afforded flexibility in this area to determine the appropriate frequency, perhaps based on substantial changes to their plans.

2. Clarify whether the "staffing plan" referenced in Chapter 5 is the same as the current Form 2 Staffing, which is reported in UDS. If so, delete the reference to referral providers as a component of the staffing plan.

   • **Wording (first bullet, continued):** “The health center’s staffing plan ensures that clinical and related support staff are in place to carry out all required and additional services included in the HRSA-approved scope of project. This staffing plan may include the use of contracted providers and/or referral providers.” *(emphasis added)*

   • **Comment:** The first sentence in this bullet states that the staffing plan should address “all required and additional services included in the HRSA-approved scope of project.” However, HRSA is clear in the footnotes in the Compliance Manual, as well as in the instructions for Form 5A, that the actual services provided via a “formal referral agreement” are not included in the health center’s HRSA-approved scope of project (although the existence of the referral arrangement is). Further, staffing FTEs as reported on Form 2 and for the Uniform Data Systems (UDS) reports do not include referral providers. Therefore, assuming that the staffing plan is to be limited to providers of in-scope services and consistent with the staffing that is reported on Form 2 and through UDS, it is inaccurate to state that the staffing plan may include referral providers. On the other hand, if the staffing plan referenced in the language above is intended to include providers of the services furnished via in-scope referral arrangements, the language linking it to "required and additional services included in the HRSA-approved scope of project"
could cause confusion as it appears to indicate that the actual services provided under the referral arrangements (and not solely the arrangements) would be considered in-scope.

- **Recommendation**: Please clarify whether the staffing plan referenced in the provision above is intended to be the same as the current Form 2 staffing and thus limited to employees and contractors providing in-scope services on behalf of and/or under the control and guidance of the health center and who are included in the health center’s UDS reports. If so, then HRSA should delete the reference to referral providers in the staffing plan. In contrast, if the staffing plan referenced above is intended to be broader than the current staffing plan and include providers of services of in-scope referral arrangements, please revise the phrase linking the plan to scope as follows: "to carry out all required and additional services included in the HRSA-approved scope of project as well as to ensure access to all in-scope referral arrangements."

3. **Remove the new requirement to verify clinicians’ “mental health status”; if this is not possible then provide examples of acceptable methods of verification.**

   - **Wording:**
     - *Under Requirements*: “The health center must utilize staff... that are qualified by training and experience to carry out the activities of the center.”
     - *Under demonstrating compliance (fourth bullet, first sub-bullet)*: “The health center has... privileging procedures would address.... [v]erification of health fitness, including physical and mental health status”.

   - **Comment**: We have two concerns about the expectation to verify clinicians’ “mental health status.” First, this is a significant expansion of the original statutory requirement, as well as current policy. The statute requires health centers to review and verify a provider’s “fitness” (Section 233(h)(2).) This language was expanded to “health fitness” in PIN 2002-22, and now to “physical and mental health status” in the draft Compliance Manual. We are unclear under what authority HRSA/OGC is expanding this language. In addition, health centers already have many questions regarding examples of acceptable methods to meet the PIN 2002-22 requirements for verification of general health fitness. Adding “mental health status” will cause these questions to increase dramatically.

   - **Recommendation**: Please remove requirement to verify clinicians’ “mental health status”; if this is not possible, then provide examples of acceptable methods for verifying providers’ mental health status.

4. **Clarify that health centers may accept assurances from referral providers that they have been credentialed, and are not required to credential these providers themselves.**

   - **Wording (sixth bullet)**: “The health center’s contracts with provider organizations (for example, group practices, staffing agencies) and formal, written referral agreements with other provider organizations, contain provisions that... Ensure that the providers are licensed, certified,
registered as verified through a credentialing process, in accordance with applicable federal, state, and local laws.”

- **Comment:** This bullet could be read to suggest that health centers are expected to credential both contractors and referral providers. While health centers are required to credential contractors, they should only be expected to require an assurance from referral providers.

- **Recommendation:** Clarify that health centers may accept assurances from referral providers that they have been credentialed, and are not required to credential these providers themselves.
Chapter Six: Accessible Locations and Hours of Operation

Demonstrating Compliance

1. Clarify if HRSA has specific expectations around if and how health centers should document the factors impacting the accessibility of their sites, including how to measure time and distance.

- **Wording (first bullet):** “the health center has considered the following factors to ensure the accessibility of its sites:
  - Access barriers (for example, barriers resulting from the area's physical characteristics, residential patterns, or economic and social groupings); and
  - Distance and time taken for patients to travel to or between service sites in order to access the health center’s full range of in‐scope services.”

- **Comment:** While these bullets outline the factors that health centers are expected to consider in order to ensure the accessibility of sites, neither address the extent to which these factors must be documented, or the form of such documentation. In particular, since there are several methods to measure “distance and time” for patients to travel to or between sites, it is unclear if HRSA has specific expectations in this area.

- **Recommendation:** If HRSA has specific expectations around these issues (i.e., if and how health centers must document the factors that impact accessibility and their efforts to consider them, as well as how time and distance are to be measured), please clarify them in the Compliance Manual. If there are no specific expectations, the Compliance Manual should include a statement explicitly affording health centers flexibility in determining and defining these factors, perhaps in the “Related Considerations” section.
Demonstrating Compliance

1. Replace the term “basic life support skills” with a clinical standard that is broadly understood and easily demonstrated.

   - **Wording:** “The health center has the clinical capacity to respond to patient medical emergencies ... during the health center’s regularly scheduled hours of operation by having at least one staff member certified in basic life support skills present at each HRSA-approved service site.”

   - **Comment:** The term “basic life support skills” is unclear, particularly for a layperson.

   - **Recommendation:** If possible, replace the term “basic life support skills” with a clinical standard that is broadly understood and for which it is easy to demonstrate compliance (e.g., completed CPR training.)
Demonstrating Compliance

1. Clarify that arrangements for hospital admissions must be in writing, but are not limited to formal contracts; also clarify that only one such arrangement is required.

   • **Wording:**
     - *(First bullet, second sub-bullet)*: “The health center has:... **Formal arrangements** between the health center and non-health center provider(s) or entity(ies) (for example, hospital, hospitalists, obstetrics group practice) that address health center patient admissions;” *(emphasis added)*
     - *(Second bullet)*: “The health center has internal operating procedures and, if applicable, related provisions in its **formal arrangements** with non-health center provider(s)...” *(emphasis added)*

   • **Comment:** The term “formal arrangements” in the first bullet is hyper-linked to Chapter 12: Contracts and Subawards. While this hyperlink was likely meant to be helpful, we are concerned that it may create confusion, as it implies that the only types of permissible arrangements for meeting this requirement are formal written **contracts**; by extension, it appears to eliminate health centers’ ability to utilize a common mechanism to ensure compliance with the hospitalization requirement - formal written referral arrangements. Further, because the use of the hyperlink fails to recognize the flexibility afforded to health centers in maintaining arrangements with hospitals for continuity of care, it could result in the false perception that health centers must maintain admitting privileges or enter into a procurement contract with a hospital, ultimately leading to unjustified/unnecessary findings of noncompliance.

   The current Program Requirements (located on the HRSA website) state that:

   “Health center physicians have admitting privileges at one or more referral hospitals, or other such arrangement to ensure continuity of care. **In cases where hospital arrangements (including admitting privileges and membership) are not possible, health center must firmly establish arrangements for hospitalization, discharge planning, and patient tracking.**” *(emphasis added)*

   The language of the current Program Requirement does not indicate the type of arrangement required, provided that the arrangement used is “firmly established.” Accordingly, health centers should be able to comply with this requirement by demonstrating that they have some form of established **written arrangement** with one or more non-health center provider(s) – whether a contract, referral agreement, or some other written arrangement -- that includes provisions for hospitalization, discharge planning, patient tracking generally, and in particular, the following elements listed in the second bullet under Demonstrating Compliance:

   • Receipt and recording of medical information from non-health center providers/ hospitals, such as discharge follow-up instructions and laboratory, radiology, or other results; and
Follow-up actions by health center staff, when appropriate.

Finally, the use of the plural form of “arrangements” is concerning, as it could be interpreted as requiring a health center to have arrangements with multiple hospitals for patient admissions in order to satisfy the continuity of care requirement. The Requirements section of this Chapter (which is consistent with the language in Section 330 of the Public Health Service Act, 42 U.S.C. 254b(k)(3)(L)) states that a health center may satisfy its continuity of care obligations by maintaining an “ongoing referral relationship with one or more hospitals”. (emphasis added) Not only is such an interpretation inconsistent with Section 330 and the actual Requirement language in this Compliance Manual, it is concerning given that many centers have encountered issues on their OSV reviews regarding the appropriate number of such hospital arrangements. This confusion is sure to continue if the provision lacks the qualifier of “one or more.”

- Recommendations:
  - Revise the first bullet to state that the health center must have “an established written arrangement with one or more hospitals or other non-health center providers/entities” without specifying the type of arrangement, or suggesting that more than one such arrangement is required.
  - In the first bullet, eliminate the hyperlink to Chapter 12 on Contracts and Subawards, to avoid the inaccurate implication that procurement contracts are the only type of arrangement that is acceptable to satisfy this requirement.
  - In the second bullet, replace “formal arrangements” with “established written arrangement(s)” for consistency with the current requirements.

2. Encourage - but do not require - health centers to have provisions in their hospital agreements under which the hospital must notify the health center when any of its patients are admitted or visit the emergency department.

- Wording (second bullet): “The health center has internal operating procedures and, if applicable, related provisions in its formal arrangements with non-health center provider(s) or entity(ies) that address the following areas for patients who are hospitalized as inpatients or who visit a hospital’s emergency department:
  - Notification to the health center of a patient’s hospitalization or emergency department visit and of patient discharge;
  - Receipt and recording of medical information from non-health center providers/hospitals, such as discharge follow-up instructions and laboratory, radiology, or other results; and
  - Follow-up actions by health center staff, when appropriate.”

- Comment: While desirable, it may not be possible for the health center to secure such notification from the hospital, particularly for emergency department visits. In fact, it is rare that a health center can obtain written agreement from the hospital to provide notification whenever a health center patient presents to the emergency department even when the health center and hospital have access to each other’s medical records or a shared database. Often, the patient does not identify themselves as a health center patient when presenting to the emergency department. Further, given how “hectic” the emergency department operations can
be, hospitals are often reluctant to formally agree to provide such notification for fear of potential breach. In addition, the hospital may be reluctant to agree to such an arrangement given that the exchange of such protected patient health information to the health center may be unnecessary (and perhaps clinically inappropriate) in some scenarios. For example, some health center patients receive a limited scope of services (e.g., dental, behavioral health, etc.) from the health center, which may not be relevant with the services provided by the hospital. Finally, if the parties have access to a shared database or each other’s records, the hospital often assumes that the health center can secure this information by accessing those shared records.

While health centers should make efforts to receive notification of hospitalizations, emergency department visits and patient discharge, when clinically appropriate and consistent with federal and state patient privacy laws, mandating the receipt of such disclosures is inappropriate and will lead to unnecessary/unjustified findings of noncompliance.

- **Recommendation:**
  - **First sub-bullet:** At the beginning of this sub-bullet, include “To the extent possible (based on the specific arrangement with the hospital and subject to federal state and local law)”.
  - **Second sub-bullet:** As noted above, the health center’s ability to receive and record medical information from non-health center providers/hospitals is subject to the health center’s receipt of such information. Accordingly, we suggest including “As applicable” at the beginning of second the sub-bullet.

3. Clarify, in either the Compliance Manual or the OSV guide that formal written referral agreements between hospitals and health centers for the admission and hospitalization of health center patients are not required to include sliding fee discounts for rounding services provided to health center patients as part of the hospitalization.

- **Wording:** Not applicable.

- **Comment:** We are pleased that this chapter does not include, either under Requirements or Demonstrating Compliance, an expectation that collaborating hospitals must furnish rounding services to referred health center patients in accordance with a schedule of discounts that complies with HRSA requirements. We agree that such an expectation is inappropriate, given that the Section 330 definition of “required primary health services” does not include hospital services. However, in the past, some OSV reviewers have cited health centers for not having requirements around sliding fee discounts for rounding services in their agreements with hospitals.

- **Recommendation:** Clarify, either in the Compliance Manual or the OSV guide, that hospitals that have written agreements with health centers for hospitalization are not required to apply sliding fee discounts, as set forth in 42 CFR §51c.303(f), to rounding services provided to health center patients.
Chapter Nine: Sliding Fee Discount Program

General

1. Retain valuable guidance on the development and implementation of the Sliding Fee Discount Program by not rescinding PIN 2014-02, and using it as a “complementary” guidance to be used in conjunction with the Compliance Manual.

- **Wording:** Not applicable.

- **Comment:** Chapter 9 of the Compliance Manual incorporates many of the key requirements of the Sliding Fee Discount Program as set forth in PIN 2014-02. However, PIN 2014-02 is much more than a recitation of requirements - it provides health centers with clear policy guidance that puts the requirements into operational context by offering useful interpretations and clarifications on developing and implementing the Sliding Fee Discount Program (SFDP) and related billing and collection processes. Given the complexities in establishing a successful SFDP that minimizes barriers to care in every aspect of its structure, the “best practices” included within the PIN are invaluable in assisting health centers in reviewing the various alternatives available and choosing what works best for the particular health center while maintaining compliance with the core requirements that for the framework of the SFDP.

Similar to the Affiliation PINs discussed in the Introduction, PIN 2014-02 is another example of an interpretative policy that should not be rescinded and replaced in toto with the Compliance Manual. When the PIN was issued only 2 years ago, HRSA indicated that it would be “the primary HRSA policy resource on the Health Center Program sliding fee discount and related billing and collections program requirements.” Rather than abandoning what was intended as HRSA’s ultimate guidance on this topic, because of the extent of valuable information included within, the PIN should be retained as an interpretative guidance to complement the requirements included in the Manual.

*Note that this comment is an example of the concerns raised in NACHC's first “Overarching Comment.”*

- **Recommendation:** Rather than rescinding PIN 2014-02, HRSA should retain the PIN as a complement to the requirements included in Chapter 9 of the Compliance Manual, thereby retaining its valuable guidance on developing and implementing the Sliding Fee Discount Program and related billing and collection processes. If HRSA agrees not to rescind PIN 2014-02, we have the following additional recommendations:
  
  o To the extent that the final Compliance Manual differs from the PIN, HRSA should indicate in the appropriate sections of the Manual which parts of the PIN are superseded by such Manual section.
  
  o To avoid confusion regarding which standards should be used to determine compliance, HRSA should issue clear instructions that the requirements in the final Compliance
Manual serve as the authority for purposes of determining a health center’s compliance, while the PIN will serve as guidance only.

**Demonstrating Compliance**

1. **Clarify the status of the requirements from PIN 2014-02 regarding nominal fee, eligibility reassessments, and the number of discount classes between 101-200% FPL.**

The following requirements from PIN 2014-02 are not discussed in the draft Compliance Manual:

- **The nominal fee must be a fixed flat fee.**
  - **Wording (second bullet, fourth sub-bullet):** “The health center has board-approved policies for its sliding fee discount program that apply uniformly to all patients and address the following areas: ..."  
  - **Only applicable to health centers that choose to have a nominal charge for patients at or below 100 percent of the FPG:** The setting of the nominal charge(s) at a level that would be nominal from the perspective of the patient and would not reflect the actual cost of the service being provided.”
  - **Comment:** This language appears to remove the requirement from PIN 2014-02, which is reiterated in the OSV Guide, that the nominal fee must be a fixed flat fee.

- **Patient eligibility for the SFDS must be reassessed at least once a year or upon the patient’s next visit.**
  - **Wording (Fourth bullet):** “The health center has operating procedures for and records of assessing/re-assessing patients for income and family size (unless the patient declines/refuses to be assessed) consistent with board-approved policies.”
  - **Comment:** PIN 2014-02 states that “patient eligibility for the SFDS should be renewed/reviewed at least once a year or upon the patient’s next visit to the health center,” while the OSV Guide simply requires re-assessment without mandating the frequency of such activity. It appears that the draft Compliance Manual is eliminating the PIN’s requirement for annual re-assessment.

- **A SDFS must have at least three discount pay classes between 100 and 200 percent FPG.**
  - **Wording (seventh bullet, second sub-bullet):** “The health center’s SDFS(s) is structured consistent with board-approved policy and provides discounts as follows: ..."  
    - Partial discounts are provided for individuals and families with incomes above 100 percent of the current FPG and at or below 200 percent of the current FPG that adjust in accordance with income (for example, three (3) to five (5) discount pay classes based on gradations in income levels above 100 percent of the FPG and at or below 200 percent of the FPG)”
• **Comment:** Similar to other comments above, this standard appears to be inconsistent with PIN 2014-02 and the OSV Guide, both of which require at least three discount pay classes above 100 percent and at or below 200 percent of the FPG. The draft Compliance Manual appears to provide health centers with additional flexibility by using three to five levels as an example.

• **Recommendation:** If these three current requirements are being removed (either because PIN 2014-02 is being rescinded or -- preferably -- the PIN is not being rescinded but the Manual will supersede these requirements), we would appreciate HRSA proactively and explicitly alerting health centers – and OSV reviewers – about the changes, as this will significantly reduce confusion in the field. Further, in the discussion of discount pay classes, HRSA should emphasize that the statement regarding three to five levels is only an example, and that a minimum of three levels is no longer required. These clarifications can be provided either in the Compliance Manual or in a separate document that accompanies the publication of the final Compliance Manual.

2. **Revise the examples of distinct, permissible SFDSs to clarify that different SFDSs can be based on either broad service types or distinct sub-categories within such service types.**

   • **Wording** *(third bullet)* “For health centers that choose to have more than one SFDS, these SFDSs would be based on services (for example, having separate SFDSs for medical and dental services) or service delivery methods (for example, having separate SFDSs for services provided directly by the health center and for services provided via formal written contract) and no other factors.”

   • **Comment:** While this language regarding multiple SFDSs based on services is consistent with PIN 2014-02, the examples provided are new. In practice, HRSA has allowed health centers to have different SFDSs not just for broad service types (as noted in the examples) but also for distinct sub-categories within those service types (such as different SFDSs for preventive and restorative dental services, as well as different SFDSs for regular gynecological visits and gynecological procedures). The examples included in the draft manual, however, imply that the different SFDSs must be based on broad service types, such as one SFDS for all of dental or for all gynecological services, which would reflect a change in current HRSA policy.

   • **Recommendation:** Revise the examples to clarify that different SFDSs can be based on either broad service types (such as medical, dental, behavioral health) or distinct sub-categories within such service types (such as distinguishing between preventive dental and restorative dental, gynecological visits and procedures, general primary care and specialty care visits).

3. **Clarify that different SDFS are permissible for services provided through established delivery sites versus those provided by mobile outreach teams.**

   • **Wording** *(third bullet)* “For health centers that choose to have more than one SFDS, these SFDSs would be based on services... or service delivery methods (for example, having separate
SFDSs for services provided directly by the health center and for services provided via formal written contract) and no other factors.”

- **Comment:** The parenthetical examples for “service delivery methods” do not make clear that different SFDS are permissible for services provided through an established delivery site versus those provided by a mobile outreach team.

- **Recommendation:** Add the highlighted language to the parenthetical examples of “service delivery methods” for which different SFDS are permissible:
  
  “(for example, having separate SFDSs for services provided directly by the health center and for services provided via formal written contract, or those provided by an established health center service delivery site (either a health center only facility or a contracted facility) versus those provided by a mobile outreach team).

4. Clarify whether there is a standard for how frequently health centers must evaluate the effectiveness of their SFDS, and if so, what it is.

- **Wording** *(sixth bullet):* “The health center evaluates its sliding fee discount program to ensure its effectiveness in reducing financial barriers to care and to identify and implement changes as needed.”

- **Comment:** PIN 2014-02 states that the “SFDS should also be evaluated at least annually for its effectiveness in addressing financial barriers to care and updated, as appropriate” while the Site Visit Guide indicates that the Sliding Fee Discount Program as a whole should be evaluated at least once every 3 years “from the perspective of reducing patient financial barriers to care.” These separate evaluation frequency standards have been a source of confusion in the field. The statement in the draft Compliance manual does not appear to require either but rather provides the health center with flexibility to determine its own frequency.

- **Recommendation:** Either clarify that the frequency of such evaluations is at the discretion of the health center, or require a specific frequency of evaluation to ensure that reviewers do not apply inconsistent standards.

5. State in main body of text that health centers may offer discounts to persons with incomes above 200% FPG if it has access to other grants or subsidies that support patient care.

- **Wording**
  
  *(Seventh bullet, third sub-bullet):* “The health center’s SFDS(s) is structured consistent with board-approved policy and provides discounts as follows:... No discounts are provided to individuals and families with annual incomes above 200 percent of the current FPG.”

  *Footnote:* “Please see Billing and Collections, if the health center has access to other grants or subsidies that support patient care.”
• **Comment:** We appreciate the footnote reference to Billing and Collections, indicating that the health center may provide discounts above 200\% FPG if it has access to other funds. However, given that this option is only stipulated in a footnote, health centers could easily miss this important text and incorrectly assume that they cannot use other funding to finance discounts for patients about 200\% FPG (which is contrary to both existing policy and this Compliance Manual).

• **Recommendation:** In addition to the footnote, state in the main text that health centers may offer discounts to patients above 200\% FPG if the health center has access to other grants or subsidies that support patient care.

6. **Delete the required contractual language regarding the application of the sliding fee discount schedule in detail, which could suggest that contractors can bill patients directly.**

• **Wording (Ninth bullet):** “For services provided via contractual agreements (Form 5A: Services Provided, Column II), the health center’s contracts/agreements contain provisions for sliding fee discounts as follows:
  - A full discount is provided for individuals and families with annual incomes at or below 100\% of the current FPG, unless a health center elects to have a nominal charge.
  - Partial discounts are provided for individuals and families with incomes above 100\% of the current FPG and at or below 200\% of the current FPG that adjust in accordance with income (for example, three (3) to five (5) discount pay classes based on gradations in income levels above 100\% of the FPG and at or below 200\% of the FPG).
  - No discounts are provided to individuals and families with annual incomes above 200\% of the current FPG.”

• **Comment:** The current standard, as addressed in the Site Visit Guide, is that the written agreement for contracted services should “describe how contracted services provided to health center patients will be discounted in accordance with an SFDS that meets the SFDS criteria above.” Under a contract, the health center provides payment to the contractor and bills both third party payors and patients for services rendered by the contractor. The contractor does not bill patients; thus, including all of the aforementioned language is unnecessary. A simple statement recognizing the health center as the billing entity and that such billing of and collections from third party payors and patients will be conducted consistent with the health center’s applicable policies and procedures, including its SFDS policies and procedures, should suffice.

At best, requiring contracts to include the specific language indicated above is unnecessary; at worst, it could have a chilling effect on health centers’ abilities to contract with other entities – more than likely, many contractors will balk at inclusion of such language since it could be interpreted to indicate that they will bill and be paid by patients based on such discount schedules.
Finally, we note that this language appears to be based on the required provisions for referral agreements, which blurs the line between contracts and referrals.

- **Recommendation**: Delete the unnecessary language suggesting that contractors can bill health center patients directly and therefore must comply with the health center’s SFDS. Instead, include a statement recognizing the health center as the billing entity, and stating that billing of and collections from third party payors and patients must be conducted consistent with the health center’s applicable policies and procedures (which would include the health center’s SFDP policies and procedures).

7. **Revise the section on applying the SFDS rules to formal referral arrangements to indicate that such rules apply when the only way in which an in-scope service is provided is through such arrangement.**

- **Wording (Tenth bullet)**: “For services provided via formal referral arrangements (Form 5A: Services Provided, Column III), the health center has ensured that the referral provider either offers sliding fee discounts as described above or offers greater discounts to patients such that:
  - Patients at or below 200 percent of the FPG receive a greater discount for these services than if the health center’s SFDS was applied to the referral provider’s fee schedule; and
  - Patients at or below 100 percent of the FPG receive no charge or only a nominal charge for these services.”

- **Comment**: PIN 2014-02 reads as follows:
  “For services the health center provides only via a formal written referral arrangement (i.e., Form 5A: Services Provided, Column III within the federally approved scope of project), the health center is responsible for ensuring that the referral provider’s discounts for health center patients meet the criteria above.”

The use of the word “only” in the PIN indicates that the requirement to apply discounts to formal referral arrangements included in a health center’s scope of project applies only if the specific referral arrangement is the sole mode of delivery for such services. By omitting the word “only,” the draft Compliance Manual appears to broaden this requirement to apply to all in-scope referral arrangements.

Section 330 contemplates that a health center may furnish a required service through one or more delivery modes. The specific statutory requirement, per 42 U.S.C. § 254b(b)(1)(A), requires all health centers to provide “through the staff and supporting resources of the center or through contracts or cooperating arrangements” the primary care services set forth in 42 U.S.C. § 254b(1)(A). In this regard, Section 330 contemplates health centers utilizing multiple modes of service delivery. Further, 42 U.S.C. § 254b(k)(3)(G) requires health centers to have “a ... schedule of discounts to be applied to the payment of such fees or payments [for services rendered], which discounts are adjusted on the basis of the patient's ability to pay.”
However, neither Section 330 nor the implementing regulations specify that if a health center adopts multiple modes of delivery for a particular service, each mode must offer a sliding fee discount schedule. Rather, as long as the in-scope service that is discounted in accordance with the sliding fee discount requirements, is available and accessible promptly to the residents of the center’s catchment area, per 42 C.F.R. 51c.303(a), the health center has satisfied its statutory and regulatory obligation regardless of whether all referral arrangements also include discounts.

Mandating that a health center ensure that all referral arrangements offer discounts for health center patients that satisfy the sliding fee discount requirements could have a chilling effect on the ability of health center to enter into referral arrangements with other providers. Often health centers are able to get one (but not all) referral sources for a particular service to offer discounts. Further, a health center may furnish an in-scope service directly, which includes application of a sliding fee discount schedule, and may have sufficient capacity to provide access to its full patient population, but may also maintain referral arrangements with other providers to expand access to such service. As long as the services provided by all sources are equivalent and patients who require discounts can access the service either through the referral source that does offer discounts or through the direct services, for which discounts must be made available, there is no need to require that all referral agreements include SFDS language.

- **Recommendation:** Revise this language as follows: “For services provided *only* via formal referral arrangements...” *(emphasis added)*

**8. State explicitly that health centers are permitted to subsidize the cost of services provided by referral to ensure that patient charges adhere to the SFDS rules.**

- **Wording:** Same as above *(tenth bullet).*

- **Comment:** This provision does not recognize that health centers are permitted to subsidize the cost of the referral service if necessary in order to ensure that an eligible patient is charged no more than a discounted amount.

- **Recommendation:** Make it clear (in either the Demonstrating Compliance or Related Considerations section) that health centers are permitted to subsidize the cost of services provided by referral if appropriate to ensure that patient charges and discounts adhere to the SFDS rules.

**9. State explicitly that discounts offered by formal referral providers are compliant, even if they do not meet the SFDS structural requirements in this Compliance Manual, provided that they offer discounts equivalent to (or greater than) the health center’s discounts.**

- **Wording:** Same as above *(tenth bullet).*
- **Comment:** Often health center referral sources have their own charity care policies which may not meet the structural requirements of the SFDS but do provide sufficient discounts equivalent to (or greater than) those that the health center would have offered if providing the service directly. By stating that the referral provider must offer “sliding fee discounts as described above or offers greater discounts to patients,” the aforementioned requirement does not appear to recognize the use of alternatives such as charity care policies that do not meet the structural requirements of the SFDS but offer discounts equivalent to (or greater than) the health center’s discounts.

- **Recommendation:** State explicitly that discounts offered by formal referral providers are compliant, even if they do not meet the SFDS structural requirements in this Compliance Manual, provided that they offer discounts that are equivalent to (or greater than) the health center’s discounts.

**10. Clarify that privately-insured patients who qualify for the SFDS must pay no more than what they would have paid under their applicable SFDS income level.**

- **Wording:**
  - Thirteenth bullet: “Subject to potential legal and contractual restrictions, health center patients with third-party coverage who are also eligible for sliding fee discounts are provided with any applicable sliding fee discounts.” (emphasis added)
  - Footnote: “For example, an insured patient receives a health center service for which the health center has established a fee of $80, per its fee schedule. Based on the patient’s insurance plan, the co-pay would be $60 for this service. The health center also has determined, through an assessment of income and family size, that the patient’s income is 150 percent of the FPG and thus qualifies for the health center’s SFDS. Under the SFDS, a patient with an income at 150 percent of the FPG would receive a 50 percent discount of the $80 fee, resulting in a charge of $40 for this service. Rather than the $60 co-pay, the health center would charge the patient no more than $40 out-of-pocket, consistent with its SFDS, as long as this is not precluded by the insurance contract.”

- **Comment:** PIN 2014-02 requires that patients with insurance be charged no more than what they would have paid under their applicable payment level, as long as the resulting reduction of out-of-pocket costs is not precluded by the applicable insurance contract. This differs from providing “applicable sliding fee discounts” since reducing the co-payment to the applicable payment level may not be the same as providing the sliding fee discount percentage to the co-payment. For example, if a patient at a 50% discount has a co-payment of $60 but their sliding fee payment level would have resulted in a $50 charge (50% of the regular visit charge of $100), the PIN requires that the co-payment charge be reduced to the $50, NOT that it be reduced by 50% consistent with the applicable sliding fee discount percentage. The example in Footnote #7 appears to confirm that the co-payment would be reduced to the charge under the SFDS and not “slid” in accordance with the SFDS.

- **Recommendation:**
  - Revise the language in the 13th bullet to mirror PIN 2014-02 and be consistent with the example provided in the footnote. For example: “health center patients with third-party
coverage who are also eligible for sliding fee discounts are charged no more than what they would have paid under their applicable SFDS payment level.” (emphasis added)  
  o Clarify the proviso at the end of the Footnote (“as long as this is not precluded by the insurance contract”) to read “as long as the reduction of co-payments is not precluded or prohibited by the applicable insurance contract.”

11. Add language to this chapter indicating that different discounting rules apply to “Supplies and Equipment” than to services. Also note that, as discussed in Chapter 16, prescription drugs should be included under required "pharmaceutical services" rather than improperly classified under “Supplies and Equipment.”

  • **Wording:** Not applicable.
  
  • **Comment:** This Chapter contains no discussion about supplies and equipment; rather, these items are discussed under Chapter 16 (Billing and Collection). While a close reading indicates that the requirements in Chapter 9 apply only to “services” – and not supplies or equipment -- this distinction could easily be missed. In addition, there is often confusion as to what HRSA classifies as a service versus a supply (e.g., dentures, eyeglasses.) Given the current policy (which appears to be continued in Chapter 16) that health centers are not required to apply the SFDS rules to supplies and equipment, but must apply the SFDS rules to the underlying services associated with the supplies and equipment, it is advisable to draw attention to these distinctions in this Chapter.

  • **Recommendations:**
    o Add language to this Chapter indicating that different discounting rules apply to “supplies and equipment” than to services, and that information on these rules can be found in Chapter 16.
    o Indicate where readers can find a definition of supplies and equipment.
    o See separate recommendation in Chapter 16 about removing prescription drugs from the examples of supplies and equipment and applying the SFDS rules to them, as they are appropriately part of required "pharmaceutical services."

12. Add language about optional payment incentives from PIN 2014-02 in this Chapter.

  • **Wording:** *not applicable*

  • **Comment:** The draft Compliance Manual does not address the application of prompt pay or cash payment discount incentives in Chapter 9. Rather, there is a brief reference to prompt pay discounts in Chapter 16: Billing and Collections, under Demonstrating Compliance. We are concerned that neglecting to reference prompt pay discounts in Chapter 9 may result in confusion as to whether HRSA has rescinded its policy, per PIN 2014-02, that allows for such collections systems. Prior to PIN 2014-02, there was a long standing ambiguity as to whether such incentives are permissible.

PIN 2014-02 specifically includes the following:
“Health centers may elect to offer incentives through board-approved billing and collections policies. Such incentives are often referred to as ‘prompt payment/cash payment incentives,’ to patients who pay with cash and/or who pay their bills within a specific, expedited timeframe as a method of increasing collections and reducing billing costs. Health centers should thoroughly research the potential consequences of implementing prompt payment/cash payment incentives for patients and conduct cost-benefit analyses in determining the amount of the payment incentive. The operating procedures that support such a policy must ensure that these incentives are accessible to all patients, regardless of income level or sliding fee discount pay class, and consistently applied without preferential treatment of any kind. In addition, health centers must have a mechanism for communicating the availability of these incentives to all of their patients.”

Such payment incentive options, while not required, are consistent with the statutory requirements that health centers maximize reimbursement from payors and patients. Specifically, health centers are required to: (1) “make ... every reasonable effort to collect appropriate reimbursement for its costs in providing health services to persons who are entitled to insurance benefits under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.], to medical assistance under a State plan approved under title XIX of such Act [42 U.S.C. 1396 et seq.], or to assistance for medical expenses under any other public assistance program or private health insurance program” (42 U.S.C. 254b(k)(3)(F); and (2) “make every reasonable effort to secure from patients payment for services in accordance with [the SFDS] schedules” (42 U.S.C. 254b(k)(3)(G)(ii)). In addition, Section 330 contemplates that additional “non-SFDS” discounts may be necessary to assure that no patient will be denied health care services due to the individual’s inability to pay, requiring health centers to “assure that any fees or payments required by the center for [health care] services will be reduced or waived to enable the center” (42 U.S.C. 254b(k)(3)(G)(iii)).

Confusion over whether HRSA has removed the option of adopting payment incentives, such as prompt payment and cash payment discounts, could result in negative financial consequences for health centers that utilize payment incentives to support their collection efforts by securing some payment from patients and thus, maximizing revenue. Further, given the prior ambiguity as to whether such incentives are even allowed, any confusion at this time could result in a step backwards, once again subjecting health centers to inappropriate (and inconsistently applied) noncompliance findings.

- **Recommendation:** Add language in Chapter 9 under Related Considerations noting that health centers may elect to offer incentives through board-approved billing and collections policies, consistent with Chapter 16. In the body of the Chapter or in a footnote, include the additional guidance from PIN 2014-02 set forth above. (Please also see our related recommendation on the fourth bullet, fourth sub-bullet under Demonstrating Compliance in Chapter 16.)
Chapter Ten: Quality Improvement/Assurance

Requirements

1. Clarify that the management issues to be addressed in QI/QAs plan are limited to clinical management issues.

- **Wording (first bullet):** “The health center must have an ongoing quality improvement/assurance (QI/QA) system that includes clinical services and management and maintains the confidentiality of patient records.” (emphasis added)

- **Comment:** It is unclear whether the term “management” above refers only to “clinical management,” or to management more broadly (e.g., financial, administrative.) The current OSV Guide states that “clinical services and management” is describing both “clinical services” and “clinical management”, thereby indicating that the QI/QA plan or program does NOT have to address administrative management or financial management. While we assume that HRSA is not intending to extend the QI/QA plan to these areas, clarification would be helpful.

- **Recommendation:** Clarify that the management issues to be addressed in QI/QAs plan are limited to clinical management issues by replacing the term “clinical services and management” with “clinical services and clinical management.”
Chapter 11: Key Management Staff

Demonstrating Compliance

1. Make clear that health center CEOs must work full-time for the health center, unless HRSA explicitly approves otherwise.

   - **Wording:**
     - *First bullet:* “The health center has determined the makeup of its key management staff* and the percentage of time dedicated to the health center project for each position, as necessary to carry out the HRSA-approved scope of project.”
     - *Footnote:* “Examples of key management staff may include Project Director/CEO, Clinical Director/Chief Medical Officer, Chief Financial Officer, Chief Operating Officer, Nursing/Health Services Director, or Chief Information Officer.”

   - **Comment:** The first bullet suggests that key management staff does not have to be full-time. Rather, the health center retains the discretion to determine the “percentage of time” that each individual member of the key management staff spends on the health center project. Further, the footnote defines key management staff to include the Chief Executive Officer (CEO).

   It is not unusual for some members of a health center’s key management staff (such as the Chief Medical Officer (CMO), Chief Financial Officer (CFO), Chief Information Officer, etc.) to work for the health center on a part-time basis. However, in the past, this list has not extended to the CEO except under unusual or special circumstances that have been approved by HRSA on a case-by-case basis, such as an immediate need resulting from the CEO’s sudden departure or the “lease” of some of the time of the health center employed CEO to an affiliation partner for purposes of continuity of care. Generally, absent such unusual circumstances, HRSA has allowed part-time CEOs only to the extent that the individual holds another position within the health center for the remainder of their time; thus, he/she would not be “part-time” for the health center organization – just in the CEO position. For example, HRSA has allowed individuals to serve as both the CEO and CMO, dedicating a certain portion of their time to each so that each position is “part-time” but together, the individual is “full-time.”

   A policy under which a CEO is allowed to work part-time for the health center organization in the regular course of business (as opposed to on a case-by-case basis) could have significant consequences, potentially impacting both health center operations and the autonomy of the organization. From the operational standpoint, given the increasingly complex health care system and environment in which health centers operate, serving as the chief administrator of a health center should be a full-time job to ensure full dedication of the appropriate amount of time. Allowing part-time CEOs as a matter of policy and in the regular course of business does a disservice to the health center and could result in shoddy operations and the failure of certain health centers. Further, having a part-time CEO (especially if he/she is under contract from another organization) could place a huge burden on the Board of Directors, which oversees the CEO’s performance, potentially forcing the board to overstep into management.
Of great importance, allowing CEOs who work part-time for the health center organization opens the door for health centers to contract with other entities, such as hospitals, to fill this position (see below for additional comments on contracting for the CEO); ultimately, such relationships could significantly harm the autonomy and independence of the health center as well as the integrity of the health center program as a whole by potentially opening a “back door” for entities that are not compliant with health center program requirements (such as hospitals) to gain a foothold into the program.

The health center implementing regulations require that the health center’s governing Board of Directors maintains “specific responsibility for: ... (i) Approval for the selection and dismissal of a project director or chief executive officer for the center.” (See 42 C.F.R. 51c.304(d)(3)(i)). Under this model, the CEO reports directly to the Board, which oversees the CEO’s performance. The Compliance Manual recognizes this relationship in Chapter 20, by including under “Demonstrating Compliance” the requirement that the Board exercise, without restriction, approval, evaluation and dismissal of the CEO. Allowing an individual who does not work for the health center on a full-time basis to serve as the CEO could significantly impact the Board’s ability to fulfill this important responsibility, especially if he/she works for another provider organization and/or is contracted from another provider entity, both of which could result in an unmanageable conflict of interest.

As noted in the discussion of the Affiliation PINs (PIN 97-27 and PIN 98-24) in our comments on the Compliance Manual Introduction, it has been HRSA’s long-standing policy and practice to require CEOs to be direct employees of the health center who work full-time for the organization. The Affiliation PINs are intended to protect the autonomy and independence of the health center and the integrity of the health center program as a whole, in particular from third party involvement in the health center that might compromise the center’s compliance with legal and policy requirements. One of the elements addressed in PIN 97-27 is the way in which employment and selection of key management staff could impact autonomy. In that regard, PIN 97-27 explicitly states: “Executive Director ... In some health centers, this position may be combined with that of Finance Director or Medical Director ... The individual who fills the Executive Director position is expected to work full-time for the health center.”

Although PIN 97-27 is almost 20 years old, the reasons for this prohibition are as true today as they were in 1997 - allowing part-time (and for that matter contracted) CEOs could significantly impact the autonomy of the health center, as it may raise questions regarding whether the CEO has potential “allegiances” outside of the health center, as well as dilute the Board’s authority over the CEO.

Finally, we note that this provision is an example of why -- as discussed at length in NACHC’s comments on the Introduction -- the Affiliation PINs (1997-27 and 1998-24) should remain in effect and be referenced throughout the Compliance Manual. Those PINs contain a thorough explanation of the overarching principle that health centers must be independent organizations that maintain autonomy and independence in order to protect the integrity of the health center program. That principle is highly relevant to this discussion, as it illuminates some of the issues that can arise with a CEO who works only part-time for the health center. Therefore, a reference to these PINs would provide valuable context for this issue.
• **Recommendation:** It is unclear from this provision whether HRSA intends to maintain the current standard under which -- absent unusual or special circumstances and approved by HRSA on a case-by-case basis - the CEO should work for the health center organization on a full-time basis, although he/she may hold multiple positions within the organization. If so, HRSA should clarify this requirement and distinguish between the CEO and other key management, who could work for the health center on a full or part time basis.

If HRSA does intend to allow CEOs to work for the health center organization on a part-time basis, NACHC urges HRSA to reconsider. HRSA’s long-standing policy and practice has been to require CEOs to be direct employees of the health center who work full-time for the organization. As discussed above, to “roll back” this policy could have significant consequences on the health center’s operations and its autonomy and independence, as well as the ability of the health center’s Board to fulfill its responsibilities *without restrictions* to select, oversee and evaluate, and dismiss the CEO.

At a minimum, since this would represent a significant policy change, it should be handled through a separate policy-making process, in which the public is explicitly notified of this specific proposal and encouraged to submit comments directly related to it.

**Related Considerations**

1. **Do not permit health centers to enter into HRSA-approved contracts for their CEOs as part of the regular course of business, except under unusual circumstances requiring case-by-case approval, as doing so could create a “back door” for hospitals and other entities to gain a foothold into the program, undermining health centers’ core identity as community-based and patient-based organizations.**

   • **Wording:**
     - “The health center determines whether to directly employ or contract for the Project Director/CEO or other key management staff positions.”
     - *Footnote #4:* “Contracting for the CEO and/or the entire key management team inclusive of the CEO requires prior approval from HRSA. For more information please see Contracts and Subawards.”

   • **Comment:** This language indicates that HRSA would allow health centers to contract for the CEO as well as for the entire management team, including the CEO, as part of the regular course of business. As noted above, *allowing health centers to contract for the CEO, whether individually or as part of an entire management team, opens the door for health centers to contract with other entities, such as hospitals, to fill this position, which ultimately could adversely impact the autonomy and independence of the health center as well as the integrity of the health center program as a whole by potentially allowing a “back door” for entities that are not compliant with health center program requirements (such as hospitals) to gain a foothold into the program.*
As noted above, the health center implementing regulations require that the health center’s governing Board of Directors maintains “specific responsibility for: ... (i) Approval for the selection and dismissal of a project director or chief executive officer for the center.” (See 42 C.F.R. 51c.304(d)(3)(i)). Under this model, the CEO reports directly to the Board, which oversees the CEO’s performance. The Compliance Manual recognizes this relationship in Chapter 20, by including under “Demonstrating Compliance” the requirement that the Board exercise, without restriction, approval, evaluation and dismissal of the CEO.

This direct employment relationship is one of the hallmarks of the health center program. The requirement that the CEO report and be beholden only to the health center board (with exceptions for public entities), without any conflicts that could arise from the CEO’s allegiances to other organizations, ensures the autonomy and independence of the health center. Insofar as other organizations are not indirectly controlling the health center through placement of their personnel in the top management position, a direct employment relationship also preserves and advances community-based governance and helps to ensure that health center Boards of Directors can fulfill their responsibilities without restrictions to select, oversee and evaluate, and dismiss the CEO. Allowing contracted CEOs as part of the regular course of business is antithetical to the overriding principles of autonomy and independence and could severely “handcuff” or limit the Board’s ability to fulfill its responsibilities.

Contracting for the entire management team, including the CEO, could have similar grave consequences. Under this option, no key management would be directly employed by the health center, allowing an even bigger opening for another organization to step in and control the health center.

As noted in the discussion of the Affiliation PINs (PIN 97-27 and PIN 98-24) in our comments on the Compliance Manual Introduction, these PINs are intended to protect health centers from the potential consequences discussed above - the weakening or dilution of the autonomy and independence of the health center and the integrity of the health center program as a whole resulting from third party involvement in the health center that compromises the center’s compliance with legal and policy requirements. To advance autonomy and independence, HRSA’s long-standing policy and practice, as codified in PIN 97-27, requires CEOs to be direct employees of the health center. In that regard, PIN 97-27 explicitly states:

“Executive Director: By law, the health center must select and directly employ an Executive Director (i.e., Chief Executive Officer). In some health centers, this position may be combined with that of Finance Director or Medical Director ... The individual who fills the Executive Director position is expected to work full-time for the health center.”

Although PIN 97-27 is almost 20 years old, the reasons for this prohibition are as true today as they were in 1997 - allowing contracted CEOs could significantly impact the autonomy of the health center, as it may raise questions regarding whether the CEO has potential “allegiances” outside of the health center, as well as dilute the Board’s authority over the CEO.

HRSA indicates that the options to contract for the CEO and/or the full management team including the CEO would require prior approval from HRSA. However, to allow contracting options within the regular course of business, as currently allowed for other key management (rather than the current practice of allowing contracted CEOs only as special exceptions due to unusual circumstances) is a slippery slope – how will HRSA evaluate the requests? What criteria
Chapter 11: Key Management Staff

can be put in place to protect against the aforementioned consequences, especially if the request is being made with the help of the very persons who may desire to control the health center?

In addition, as noted above, presently health centers must receive prior approval to contract for key management (other than the CEO, which is not allowed). However, the current process to request such approval is not applied uniformly; in addition, the criteria used in reviewing requests is unclear and the process itself is often disregarded until the contract comes up in a grant application. Further, approval can be a lengthy process, often taking months to secure (ultimately resulting in “gaps” in management while the health center awaits approval). In addition to the other consequences discussed above, applying this same process to approval of a contracted CEO and/or full management staff could have grave consequences for the continued operation of the health center.

Since NACHC announced to PCA leaders that the draft Compliance Manual would permit contracted CEOs, we have heard from multiple PCA directors about specific examples of health centers contracting for CEOs with distressing results.

We also note that this provision is an example of why — as discussed at length in NACHC’s comments on the Introduction — the Affiliation Agreement PINs (1997-27 and 1998-24) should remain in effect and be referenced throughout the Compliance Manual. Those PINs contain a thorough explanation of the overarching principle that health centers must be independent organizations that maintain autonomy and independence in order to protect the integrity of the health center program. That principle is highly relevant to this discussion, as it illuminates some of the issues that can arise with a contracted CEO, so a reference to these PINs would provide valuable context for discussions around contracting for key leadership positions.

- **Recommendation:** We strongly urge HRSA to not allow health centers to contract for their CEO as a matter of policy and within the regular course of business (even with a standard prior approval process). Rather, such option should be used sparingly and approved solely on a case-by-case basis under unusual circumstances that either require quick short-term solutions for unanticipated “gaps” that cannot be filled otherwise or involve other urgent situations. HRSA’s long-standing policy and practice has been to require CEOs to be direct employees of the health center who work full-time for the organization. As discussed above, to “roll back” this policy, even if prior approval is required, could have significant consequences on the health center’s operations and its autonomy and independence, as well as the integrity of the health center program, by allowing a “back door” for entities that are not compliant with health center program requirements (such as hospitals) to gain a foothold into the program, undermining health centers’ core identity as community-based organizations. Further, allowing the options to contract for the CEO and/or the full management team including the CEO as part of the regular course of business could significantly weaken the ability of the health center’s Board to fulfill its responsibilities *without restrictions* to select, oversee and evaluate, and dismiss the CEO.

Finally, if HRSA were to pursue permitting health centers to contract for the CEO position, this would represent a significant policy change. This type of change should be handled through a separate policy-making process, in which the public is explicitly notified of this specific proposal and encouraged to submit comments directly related to it.
2. Clarify that prior HRSA approval is still required for contracts involving individual members of the key management team (other than the CEO, which is addressed above).

- **Wording:** Footnote #4: “Contracting for the CEO and/or the entire key management team inclusive of the CEO requires prior approval from HRSA.”

- **Comment:** By stating that prior approval is required for contracts involving “the CEO and/or the entire key management team inclusive of the CEO,” this footnote suggests that prior approval may no longer be needed for contracts for other individual key management staff such as the CFO and the CMO (as currently required under PIN 97-27). For many of the reasons discussed above, NACHC thinks it would be inadvisable for HRSA to eliminate its current prior approval process for the CFO and CMO.

- **Recommendation:** Revise the footnote to be clear that prior HRSA approval will still be required for contracts involving individual members of “C” suite, in particular the CFO and CMO.
Chapter 12: Contracts and Subawards

Requirements and Demonstrating Compliance

1. Make clear that Part 75 Uniform Administrative Requirements (including, but not limited to, procurement requirements) do not apply to contracts for which payment is made only with nongrant funds (i.e., program income and other operational funding).

- **Wording:** Chapter 12 includes several bullets under “Requirements” and “Demonstrating Compliance” that reflect the procurement requirements set forth in the *Uniform Administrative Requirements, Cost Principles, and Audit Requirements For HHS Awards*, 45 C.F.R. Part 75 (Part 75). Examples include, but are not limited to the following:
  - *Under Requirement: General:* “The health center must perform a cost or price analysis in connection with every procurement action in excess of the Simplified Acquisition Threshold.” (emphasis added)
  - *Under Requirements – Contracts: Procurement and Monitoring:* “The health center must conduct all procurement transactions in a manner that provides full and open competition consistent with the standards of 45 CFR 75.328.” (emphasis added)

- **Comment:** These bullets suggest that, for purposes of the health center program, the HHS Administrative Requirements in Part 75 (including, but not limited to, procurement requirements) apply not only to contracts paid for in whole or in part with HHS grant funds (i.e., the Section 330 grant) but also to contracts for which payment is made only with nongrant funds (i.e., program income and other operational funding).

The application of Part 75 requirements to nongrant funds would be a new - and highly significant - policy development, which would be contrary to the Section 330 statute, extensive legislative history, and HRSA’s own policy documents.

The question of whether the HHS Administrative Requirements apply to a health center’s nongrant funds has been clarified by Congress in legislative history that spans nearly 30 years, including the following:

- **The Community and Migrant Health Centers Amendment of 1988:**
  The report language from the Senate Committee on Labor and Human Resources Committee (whose version of the bill was enacted into law) indicated that the Administrative Requirements should not apply to “State, local or other operational funding.” Specifically, the report stated that:
  “It is not the Committee’s intent . . . to require that State, local, or other operational funding be subject both to the requirements of the funding source and also to HHS’ rules and policies governing the expenditure of federal funds or income derived therefrom. *The burden placed on health centers by having them comply with two sets of requirements would be unfair and would place them in an*

- **The Health Centers Consolidation Act of 1996 - Statutory Language**
  When Congress enacted the Health Centers Consolidation Act of 1996, Section 330 was amended to explicitly provide statutory flexibility to grantees in their use of nongrant funds. Specifically, Section 330(e)(5)(D) [42 USC 254b(e)(5)(D)] was added, which states:
  “Nongrant funds . . . including any such funds in excess of those originally expected, shall be used as permitted under this section, and may be used for such other purposes as are not specifically prohibited under this section if such use furthers the objectives of the project.”

As noted below in the report language for this section, by including only two criteria for the use of nongrant funds (“as permitted under this section” and “for such other purposes as are not specifically prohibited under this section if such use furthers the objectives of the project”), Congress intended that the restrictions imposed by the Administrative Requirements would not apply.

- **The Health Centers Consolidation Act of 1996 - Report Language**
  The report of the Senate Labor and Human Resources Committee, whose version of the bill became law, indicated that Section 330(e)(5)(D) was intended to ease the regulatory burden associated with the use of all nongrant funds. Specifically, the report stated:
  “Under current policy, most of the restrictions and requirements which apply to the health centers’ use of Federal funding, including Federal cost principles, also apply to the centers’ use of their nongrant funding. The committee understands that some of these restrictions and requirements impede health centers’ ability to respond to changes in the needs and size of the population its serves [sic] and to compete on an equal footing in an increasingly competitive and rapidly changing health care marketplace. . . . Relieving centers from the requirements for prior Federal approval for things like equipment purchases and procurement and property standards will allow health centers to respond quickly to critical business opportunities in the competitive marketplace. The committee has therefore included in the bill provisions to clarify that, although the level of nongrant funding available to a health center for an approved project would continue to be considered by the Secretary in computing the amount of the Federal grant, the restrictions that apply to a center’s use of Federal grant funds under the Federal cost principles and the procurement and property standards would no longer apply to the center’s use of nongrant funds. . . .” See S. Rep. No. 104-186 at 9-10, 1996 U.S.C.C.A.N. 4137-4138 (Dec. 15, 1995) (emphasis added).

In short, this report language prohibits HRSA from restricting a health center’s use of its nongrant funds through the application of either the federal cost principles or the federal grant administration requirements, including, but not limited to procurement requirements.
HRSA reinforced Congress’ position that HHS Administrative Requirements do not apply to a health center’s nongrant funds in Policy Information Notice (PIN) 2013-01: *Health Center Budgeting and Accounting* (which HRSA has indicated will *not* be superseded by the Compliance Manual.) In this PIN, HRSA appears to further acknowledge that the HHS Administrative Requirements apply solely to federal funds by stating that “*expenditures of section 330 federal grant funds* must follow all applicable requirements described in 45 CFR 74 and 45 CFR 92 (including Federal cost principles incorporated by reference)” (*emphasis added*); PIN 2013-01 also notes that “because LALs do not receive federal grant funding under section 330 of the PHS Act, the specific sections of this PIN that apply to only section 330 grant funding are not applicable; all other sections of this PIN apply to the extent they describe the appropriate uses of non-grant funds.”

*If not clarified, Chapter 12, as presently drafted, could set a disastrous precedent, resulting in the interpretation that the HHS Administrative Requirements in Part 75, including, but not limited to, the procurement requirements, apply to all health centers funds including nongrant funds, as well as to LALs.* This would set back years of advocacy for the flexibility currently afforded health centers and could have a ripple effect significantly impacting health center financial management systems and budgeting, as well as general operations.

- **Recommendation:** NACHC strongly urges HRSA to revise all language in Chapter 12 to avoid any suggestion that Administrative Requirements in Part 75 (including, but not limited to, the procurement standards) apply to nongrant funds, thereby making the Compliance Manual consistent with Section 330, related legislative history, and PIN 2013-01. For example, HRSA could add the following qualifier to provisions that address the procurements: “paid for in whole or in part by federal grant funds.” Further, HRSA should include a specific statement in this Chapter indicating that the HHS Administrative Requirements apply solely to federal grant funds, similar to current policy set forth in PIN 2013-01.

2. **Remove the “General” sections under Requirements and Demonstrating Compliance in order to avoid suggesting that certain requirements applicable to one category also apply to the other. Instead, place all relevant provisions in the appropriate subsections on either Contracts or Subawards (or both) as applicable.**

- **Wording:** Under both Requirements and Demonstrating Compliance, Chapter 12 contains separate sections applicable to Contracts and to Subawards, as well as a general section applicable to both categories.

- **Comment:** While we appreciate HRSA’s efforts to consolidate requirements applicable to both contracts and subawards into a “General” section, we are concerned that this consolidation may lead to confusion and/or incorrect interpretations. For example, this structure may suggest that certain requirements specific to contractors extend to subawards, and vice versa; it also specifies that a subaward is a form of procurement, which is inaccurate. Given that contractors and subawards are substantively and legally different, NACHC recommends that contracts and subawards be addressed separately throughout Chapter 12.
We offer the following examples of the confusion or misinterpretation that could result from the “General” section under “Demonstrating Compliance.”

- The first bullet of that section states: “The health center’s contracts and subawards that support the HRSA-approved scope of project include provisions that address the following: ... The integration of applicable requirements of the Health Center Program (for example, sliding fee discounts, credentialing and privileging);”

While integrating the Health Center Program sliding fee discount schedule (SFDS) requirements is applicable to a subaward, it is not relevant to a contract, as defined for purposes of Column II of Form 5A. Under these contracts, the contractor is paid by the health center, which in turn bills and collects payments from patients and payors for services provided by the contractor. The contractor does not bill patients directly for services and thus the SFDS requirements would not apply to the contractor. While the health center would bill patients based on the SFDS, it is not necessary to include that in the contract and could in fact have a chilling effect on a health center’s ability to contract. Further, although the inclusion of the term “applicable requirements” could be interpreted to mean that the example that follows (SFDS requirements) does not have to be included in contracts, it would reduce confusion to address contracts separately and not reference the SFDS requirements.

- The second sub-bullet of the same section indicates that the contract or subaward should include provisions addressing, among other things, “property management.” Similar to the aforementioned, while such provision may be appropriate for a subaward, more than likely it is not appropriate for a contract since the contractor is not purchasing property paid for in whole in part with federal funds. Rather, the contractor is being paid by the health center to provide services to or on behalf of the center.

- Similarly, the fourth sub-bullet implies that contracts would have to include provisions requiring all costs under the contract to be allowable in accordance with the Federal Cost Principles. Such provisions are not required for most contracts under grants, and would create substantial hardship in commercial contracting.

Requiring health centers to address extraneous requirements in their contracts is not only legally incorrect, but could also make it more difficult for health centers to enter into these necessary arrangements – whether due to the reluctance of the contracting partner to execute an agreement including unnecessary provisions or the health center’s confusion as to what should or should not be included in the agreement.

- **Recommendation:** To reduce confusion and potential misinterpretation, we recommend that Chapter 12 be restructured to separate the contract and subaward sections in their entirety, rather than co-mingling certain “general” requirements and compliance suggestions.

**Requirements - General**
1. Clarify that the requirement for prior HRSA approval of contracts for the delivery of health care services under the Federal award applies only to those contracts for “substantive programmatic work.”
   - Wording:
     o Under Requirements: “The health center must request and receive approval from HRSA to subaward or to contract for work* under the Federal award.”
     o Footnote: This does not apply to the acquisition of supplies, material, equipment or general support services. **However, it does apply to the delivery of health care services under the Federal award.** (emphasis added)
     o Under Demonstrating Compliance: General: “If the health center has arrangements with a contractor or subrecipient to perform **substantive programmatic work**...” (emphasis added)
   - Comment: The requirement that the health center request prior approval for certain contracts is based on provisions of the HHS Grants Policy Statement, which requires HHS grantees to obtain prior approval for contracts for **substantive programmatic work**. Nevertheless, the wording in the Requirements section does not qualify “contract for work” by including the phrase “substantive programmatic work”; rather, when combined with the related footnote #3, it appears to require prior approval for all contracts for the delivery of health care services, regardless of whether those contracts involve substantive programmatic work. By omitting that phrase, effectively HRSA is requiring prior approval of all contracts for services provided within a health center’s approved scope of project, including agreements for individual services (rather than a majority of services) as well as contracts for ancillary services such as diagnostic lab.

   We believe that the omission of “substantive programmatic work” in the Requirements section was an oversight, given that this language is included in the “Demonstrating Compliance” section. If, however, this terminology was intentionally removed from the Requirement language, it would be a significant change from current policy, reflecting a substantial overreach on the part of HRSA. Further, this would be overly burdensome on health centers, potentially resulting in serious consequences impacting their ability to enter into contracts with other providers within the community.

   - Recommendation: Revise this requirement to clarify that the prior approval requirement applies only to contracts that involve “substantive programmatic work,” consistent the requirement from the HHS Grants Policy Statement, and the language in the Demonstrating Compliance section.

**Requirements - Subawards: Monitoring and Management**

1. Delete requirement for health centers to ensure subrecipients’ compliance with FTCA requirements at the time the subaward is made.
   - Wording: “The health center must ensure that, at the time of making a subaward, each subrecipient which is a subawardee of Federal funds complies with all applicable requirements
specifying the Federal award (including those found in section 330 of the PHS Act, implementing program regulations, Health Center Federal Tort Claims Act (FTCA) Program requirements (where applicable), and grants regulations in 45 CFR Part 75).” (emphasis added)

- **Comment:** A subrecipient is eligible to apply for FTCA deeming after HRSA has approved the subaward. Accordingly, it is inaccurate to suggest in the first bullet that demonstrating compliance with the FTCA Program is a prerequisite to making a subaward.

- **Recommendation:** Strike the reference to FTCA Program requirements in the language cited above. At a minimum, if HRSA’s reference to the FTCA program requirements was intended to address compliance with the Program Requirements that are included in FTCA deeming (i.e., QI/QA and credentialing and privileging), this section should be clarified as such.

2. Clarify the specific FTCA requirements that a health center must monitor in its subrecipients.

- **Wording:** “The health center must monitor the ongoing activities of the subrecipient which is a subawardee to ensure that the subaward is used for authorized purposes and that the subrecipient maintains compliance with all applicable requirements specified in the Federal award (including those found in section 330 of the PHS Act, implementing program regulations, Health Center FTCA Program requirements (where applicable), and grants regulations in 45 CFR Part 75).”

- **Comment:** While the grantee is responsible for ensuring the subrecipient’s compliance with the Program Requirements, it should not be held responsible for its compliance with all FTCA Program requirements (which include requirements beyond the Program Requirements, such as claims management).

- **Recommendation:** Strike the reference to FTCA Program requirements. At a minimum, clarify the specific FTCA requirements that must be monitored by the grantee rather than using a general catch-all such as “FTCA Program requirements.”

**Demonstrating Compliance- General**

1. Clarify whether prior approval is needed for contracts for non-CEO key management positions, and for contracts involving the majority of primary care providers or the majority of core primary care services.

- **Wording:**
  - “If the health center has arrangements with a contractor or subrecipient to perform substantive programmatic work, the health center requested and received prior approval from HRSA…”
  - *Footnote:* “This includes, but is not limited to, all subrecipient arrangements and contracting for the majority of core primary care services, or CEO/Project Director, or both.” (emphasis added)
- **Comment:** The Affiliation Policies set forth in PIN 97-27 indicate that HRSA prior approval is required if the health center seeks to contract for its CFO, CMO, or a majority of its primary care providers. Accordingly, the above bullet is inconsistent with current HRSA guidance and, to the extent that it mentions contracting for the CEO, appears to reflect new policy. Specifically:
  - Based on the footnote, it appears that HRSA is no longer requiring prior approval for other non-CEO key management, which is inconsistent with current policy.
  - The footnote also refers to contracting for the majority of core primary care services, rather than the majority of core primary care providers.

*NOTE: Our serious concerns regarding the rescission of the Affiliation PINs are addressed in detail as part of our comments on the Compliance Manual Introduction. Further, we have addressed our serious concerns regarding contracting for the CEO in our comments on Chapter 11. Those concerns are mirrored here to the extent that this footnote includes contracting for the CEO under the definition of “substantive programmatic work”.*

- **Recommendations:**
  - Revise Chapter 12 to align the concept of contracting for a substantial portion of the health center project with the requirements set forth in PINs 97-27 and 98-24. HRSA should explain, in detail, what would qualify as a contract for “substantive programmatic work” necessitating HRSA approval. The “includes, but is not limited to” language is too vague.
  - Revise the footnote to refer to the majority of primary care providers, rather than the majority of core primary care services, for consistency with existing policy. If HRSA intended to replace “providers” with “service,” clarify how the health center would measure the services for purposes of determining whether they reflect a “majority” (e.g., proportion of visits to the total visits, proportion of budget to the budget for all services, etc.).

**Related Considerations**

1. **Similar to the earlier recommendation, create separate sub-sections under “Related Considerations” to address Contracts and Subawards.**

   - **Wording:** “The health center determines the methods it will utilize to settle any contractual or administrative issues arising out of procurements, with respect to contracts or subawards. These issues include, but are not limited to, source evaluation, protests, disputes, and claims.”

   - **Comment:** The above bullet is intended to reflect the procurement requirements set forth in 45 CFR 75.327(k). It incorrectly states that such requirements extend to subawards. Subawards are not a form of procurement.

   - **Recommendation:** As with the sections on Requirements and Demonstrating Compliance, we suggest that separate sub-sections be created under “Related Considerations” to clarify the different issues that apply to contracts versus subawards. If this is not possible, we recommend
striking the above reference to “subawards” and clarifying that the requirement is applicable to contracts paid for using federal grant funds.
Chapter 13: Conflict of Interest

Overarching Comments

1. NACHC supports HRSA’s plan to separate the Conflict of Interest requirements from the Governance section, as these issues apply throughout a health center.

2. Add the term “board member” to provisions under both the “Requirements” and the “Demonstrating Compliance” sections that address requirements for “officers,” in order to encompass the full Board of Directors.

   • Wording: All references to the word “officer”
     o Second bullet under Requirements: “No employee, officer, or agent of the health center may participate in the selection, award, or administration of a contract…”
     o Third bullet under Requirements: “Officers, employees, and agents … may neither solicit nor accept gratuities, favors, or anything of monetary values …”
     o Fourth bullet under Requirements: “The health center’s standards of conduct must provide disciplinary actions to be applied for violations of such standards by officers, employees, or agents…”
     o First bullet under Demonstrating Compliance: “The health center has and implements written standards of conduct applicable to all health center employees, officers, and agents…”
     o Third bullet under Demonstrating Compliance: “The health center has mechanisms or procedures for informing employees, officers, and agents of the health center’s standards of conduct…”

   • Comment: While the procurement regulations cited as “Authority” for these provisions address only “officers,” these provisions apply to all health center board members given the full board’s role in decision-making and their positions as fiduciaries of the organization.

   • Recommendation: Since the word “officer” refers solely to a subset of the entire governing Board of Directors, NACHC recommends adding the term “board member” to encompass the full board.

Requirements

1. Expand the requirement to maintain standards of conduct to include officers, board members and agents.

   • Wording (first bullet): “The health center must maintain written standards of conduct covering conflicts of interest and governing the actions of its employees engaged in the selection, award,
Chapter 13: Conflict of Interest

or administration of contracts that comply with all applicable federal requirements.” (emphasis added.)

- **Comment**: The first bullet under the Requirements section reflects the first sentence of the applicable provision in 45 CFR Part 75.327(c)(1), which references only “employees”. However, while the rest of the regulatory provision broadens the language to include employees, officers and agents, this broader applicability is not noted in the first bullet of this section of the Manual. Thus, by splitting the requirements into multiple bullets, the Requirements section of this Manual *in toto* reflects an internal inconsistency that should be rectified by including “officers and agents” in the first bullet. Further, consistent with the overarching concern noted above, “board members” should be added.

- **Recommendation**: To be consistent with the other requirements in this section and with the full language in 45 CFR Part 75.327(c)(1), and also to recognize the potential role of board members and agents in approving and overseeing contracts and contract administration, this first bullet should be expanded to read “‘governing the actions of its employees, officers, board members, and agents engaged in the selection...”

2. **Remove the word “contractor” from the definition of “agent” in second footnote.**

- **Wording** (second footnote): “An agent of the health center includes, but is not limited to, an employee, officer, governing board member, or contractor acting on behalf of the health center.”

- **Comment**: A contractor is not an agent of the health center. As noted in the footnote, agents are empowered to act on behalf of the health center. Contractors provide services to the health center. In doing so, the contractor may provide the service directly to a health center patient; however, the contractor is furnishing such service under the oversight and control of the health center. Such provision of services is not the same as acting on behalf of the health center, which indicates a higher level of autonomy and ability to make decisions for the health center than what is typically granted to contractors. Further, most (if not all) contracts include provisions specifically precluding contractors from acting as agents of the health center.

- **Recommendation**: Remove the term “contractor” from the list of individuals who can act on behalf of the health center.

3. **Remove the word contractors from the footnote addressing organizational conflicts of interest.**

- **Wording** (footnote to fifth bullet): “If a health center has a parent, affiliate, or subsidiary organization* that is not a State local government, or Indian tribe, the health center also must maintain written standards of conduct covering organizational conflicts of interest.”
  - *Footnote #3: “This would include a subrecipient or contractor.”

- **Comment**: Contractors are not subsidiary or affiliate organizations that could result in organizational conflicts. The organizations included in this prohibition are ones in which there is a level of corporate integration with the health center or, in the case of an “affiliate,” a legal
Chapter 13: Conflict of Interest

affiliate that is corporately related to the health center. Contractors do not fit within those categories. Further, as noted in footnote #5, 45 CFR 75.327(c)(2) states that:

“[O]rganizational conflicts of interest mean that because of relationships with a parent company, affiliate, or subsidiary organization, the [health center] is unable or appears to be unable to be impartial in conducting a procurement action involving a related organization.” (emphasis added).

This provision is intended to ensure that the health center will be impartial in contracting with related entities regardless of its corporate relationships with such entities. Contractors are not related organizations; thus, procurements with contractors would be covered under general standards of conduct and procurement policies.

- **Recommendation:** Remove the word “contractors” from the footnote.

**Demonstrating Compliance**

1. **Require written disclosure of both actual and apparent conflicts of interest.**

   - **Wording:**
     - **First bullet:** “The health center has and implements written standards of conduct ... that ... [R]equire written disclosure of any conflicts of interest related to procurements.”
     - **Second bullet:** “If the health center has a parent, affiliate, subsidiary, or subrecipient organization ... These standards of conduct require ... written disclosure of any conflict of interest related to procurement.”

   - **Comment:** The requirement prohibiting individuals with conflicts of interest from participating in the procurement process applies to individuals with actual as well as apparent/potential conflicts of interest. To ensure consistency with the provisions addressing the avoidance or mitigation of conflicts of interest, disclosure should apply equally to actual and apparent/potential conflicts of interest.

   - **Recommendation:** Broaden this language to require written disclosure of any “actual or apparent” conflicts of interest, to be consistent with other sections in this Chapter as well as good management practices.

2. **Clarify that written standards of conduct must apply to the selection, award, or administration of contracts paid for in whole or in part with HHS grant funds.**

   - **Wording (first bullet):** “The health center has and implements written standards of conduct applicable to all health center employees, officers, and agents regarding the selection, award, or administration of contracts that...”

   - **Comment:** This bullet suggests that the requirements apply to the selection, award and administration of all contracts executed by the health center, including contracts paid for in whole or in part with HHS grant funds (i.e., the Section 330 grant), as well as contracts for which payment is made only with non-grant funds (i.e., program income and other operational.
funding). This is inconsistent with the application of the *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards*, 45 C.F.R. Part 75, to health center grants, as noted in Chapter 12: Contracts and Subawards.

- **Recommendation:** “Contracts” should be clarified to note “contracts supported, in whole or in part, by federal grant funds.”

**Related Considerations**

1. **Add a bullet stating that “A health center’s standards of conduct should include a statement referencing the health center’s procurement policies.”**

- **Wording:** None. *(This is a suggestion to add a new bullet.)*

- **Recommendation:** Given the importance of avoiding conflicts of interest in procurements, NACHC recommends encouraging health centers to include a reference to their procurement policies in their standards of conduct. This can be done by adding a new bullet under “Related Considerations.”

2. **Clarify that health center officers, employees, or agents may accept unsolicited gifts from contractors if they are of “nominal value.”**

- **Wording:**
  - Under Requirements: “Officers, employees, or agents of the health center may neither solicit nor accept gratuities, favors or anything of monetary value from contractors or parties to subcontracts.”
  - Under Demonstrating Compliance: “Restrict health center employees, officers, and agents from soliciting or accepting gratuities, favors, or anything of monetary value from contractors or parties to sub-agreements….”
  - Under Related Considerations: “The health center sets standards for when… a gift is an unsolicited item of nominal value.”

- **Comments:** The Requirements and Demonstrating Compliance sections appear to prohibit individuals associated with the health center from accepting *anything* of monetary value from contractors, regardless of amount. However, the Related Considerations section states the health center may set standards for when an unsolicited gift is of “nominal value,” suggesting that such gifts may be permissible if they meet the “nominal value” standard.

The Uniform Guidance, 45 C.F.R. 75.327(c)(1), in relevant part, specifies that: “The officers, employees, and agents of the non-Federal entity may neither solicit nor accept gratuities, favors, or anything of monetary value from contractors or parties to subcontracts. However, non-Federal entities may set standards for situations in which the financial interest is not substantial or the gift is an unsolicited item of nominal value. The standards of conduct must provide for disciplinary actions to be applied for
violations of such standards by officers, employees, or agents of the non-Federal entity.” (emphasis added.)

Failing to include the option to set standards for situations in which the financial interest is not substantial or the gift is an unsolicited item of nominal value misconstrues the Uniform Guidance requirements.

- **Recommendation:** Clarify that officers, Board member, employees or agents of the health center may accept unsolicited gifts from contractors if they meet the “nominal value” standard, consistent with a Board-approved policy on gifts and gratuities (or, at a minimum, a provision included in the Board-approved Standards of Conduct).
Demonstrating Compliance

1. Clarify any specific expectations as to how a health center must “document its efforts” to collaborate with nearby providers and program.

   - **Wording:**
     - “The health center documents its efforts to coordinate and integrate activities with other providers or programs in the service area (for example, social service organizations, specialty practices, hospitals) in order to support patient:
       - Continuity of care across community providers; and
       - Access to services that are beyond the scope or capacity of the health center.” *(emphasis added)*
     - “The health center documents its efforts to collaborate with other primary care providers serving similar patient populations in the service area (at a minimum, this would include establishing and maintaining relationships with other health centers in the service area).” *(emphasis added)*

   - **Comment:** The term “documents its efforts” is unclear. Would letters of support suffice as documentation? What about emails, records of other correspondence and/or evidence of meetings with such other providers/programs? Does the health center need a procedure for these activities? This lack of clarity may result in findings of noncompliance if a health center does not have the requisite documentation required by HRSA.

   (We also note that this requirement is inconsistent with the Health Center Site Visit Guide, in its current form, which simply inquires whether the health center “work(s) to establish and maintain collaborative relationships (formal and/or informal) with other health care providers in its service area, in particular other health centers.” However, we recognize that HRSA intends to update the Site Visit Guide to reflect the Compliance Manual, once the latter is finalized.)

   - **Recommendation:** If HRSA – or OSV reviewers – will have specific expectations around what types of documentation are necessary to document the health center’s efforts to collaborate, please clarify as such in the Compliance Manual. If there are no specific expectations in regard to documentation, we recommend that this is stated explicitly or that the reference to “documentation” be deleted.

2. Remove or qualify the expectation that letters of support from providers serving similar patient populations in the service area must address areas of coordination or collaboration.

   - **Wording:** ”If the health center expands its HRSA-approved scope of project:
The health center obtains letters or other appropriate documents specific to the request or application that _describe areas of coordination or collaboration_ with providers serving similar patient populations in the service area (for example, health centers, rural health clinics, critical access hospitals, health departments, other providers); or

- If such letters or documents cannot be obtained from such providers, the health center documents the process it utilized to attempt to obtain support for the specific request or application proposal.” (emphasis added)

**Comment:** HRSA has not previously included an expectation that letters of support (or other appropriate documentation) specifically describe areas of coordination or collaboration. An organization may support the health center’s proposed scope change expansion without including areas of coordination or collaboration between the two parties. For example, a center may expand its scope to open a HCH program in a shelter that is near another full service health center that does not provide HCH services. While it would be ideal for the two centers to collaborate with respect to the non-homeless populations who may present at the HCH site, realistically such populations would not present to that site because of the shelter location, as well as because they probably already receive services from the other health center. Having a letter of support that addresses collaboration would not be pertinent in this case.

**Recommendation:** Remove the expectation that letters of support from providers serving similar patient populations in the service area address areas of coordination or collaboration. If this is not possible, include a qualifier that descriptions of areas of coordination or collaboration must only be addressed “as applicable.”
Chapter 15: Financial Management and Accounting Systems

General

1. Explain what elements of PIN 2013-01 are not addressed in this Compliance Manual but will remain in effect once the Compliance Manual is finalized.

   • **Wording:** Not applicable.

   • **Comment:** In Appendix A, HRSA notes that PIN 2013-01, Health Center Program Budgeting and Accounting Requirements, will remain in effect once this Compliance Manual is finalized. Given that much of the content of PIN 2013-01 has been incorporated into this draft Compliance Manual, we are unclear what remaining elements of the PIN will still be in effect. Based on a detailed comparison of the two documents, the only statement we found in the PIN that is not included in the Compliance Manual is the following: “The proposed amount of 330 funding to support the scope of project may not exceed the amount by which the projected cost of operations exceeds the projected non-grant revenue sources.”

   • **Recommendation:** Explain what elements of PIN 2013-01 are not addressed in this Compliance Manual but will remain in effect once the Compliance Manual is finalized. If there are no elements in this category, please explain why this PIN remains in effect while others are being superseded.

Requirements

1. Include citations to 45 CFR 75.302, the key regulatory requirement for financial management systems under the grant management regulations, in the discussion of requirements for health centers’ financial management systems.

   • **Wording** (third bullet, first and second sub-bullets): “The health center’s financial management system must... provide for all of the following:
   o “Accurate, current, and complete disclosure of the financial results of each Federal award or program in accordance with the reporting requirements. (see 45 CFR 75.341 and 75.342);
   o “Records that identify the source (receipt) and application (expenditure) of funds for federally-funded activities. These records must contain information pertaining to awards, authorizations, obligations, unobligated balances, assets, expenditures, income, and interest, and be supported by source documentation;”

   • **Comment:** 45 CFR 75.302 is the key regulatory requirement for financial management systems under the grant management regulations. While 75.341 and 75.342 are relevant with respect to reporting, the core obligation for systems and records that support the reporting is at 75.302. Citation to 45 CFR 75.302 will help recipients to identify critical requirements, and will assist reviewers (such as OSV reviewers) that use the handbook to identify the proper requirements.
Chapter 15: Financial Management and Accounting Systems

- **Recommendation:** In both the first and second sub-bullet under the third “Requirements” bullet, add a citation to 45 CFR 75.302, which is the key regulatory requirement for financial management systems under the grant management regulations.

2. **Clarify the intent of the reference to 45 CFR 75.305.**

- **Wording:** (third bullet, third sub-bullet): “The health center’s financial management system must... provide for... Written procedures to implement Federal Payment Management System requirements; and (see 45 CFR 75.305.)”

- **Comment:** The reference to “Federal Payment Management System requirements” is ambiguous and has potential to cause confusion on the part of recipients and reviewers (such as OSV reviewers). 45 CFR 75.305 sets forth a number of requirements specific to requests for, and management of, advance payments, including a requirement at 75.305(b)(1) that recipients must have in place written procedures to ensure drawdowns are made near in time to disbursement/expenditure of the drawn funds. The Payment Management System (“PMS”) is HHS’ system for making payment and is configured to accommodate the requirements of 75.305, but the actual regulatory requirements are not “Federal Payment Management System requirements.” Referring to the requirements as “Federal Payment Management System” therefore has the potential to create confusion, misdirect focus from important regulatory requirements, and potentially have other unintended consequences. Instead referring specifically to the 75.305(b)(1) requirement for written procedures for drawdown near in time to disbursements, or perhaps referring more generally to “advance payment” requirements, would eliminate such confusion. If there are specific additional requirements related to PMS that HRSA intended to highlight here, we alternatively recommend a citation to those requirements be provided.

- **Recommendation:** Change the wording in this sub-bullet to reflect the requirement at 75.305(b)(1) by stating either: (a) “Written procedures to minimize the time elapsing between the transfer of funds from the Department of Health and Humans services and disbursement by the non-Federal entity” or (b) “Policies and, as necessary, procedures to facilitate compliance with advance payment requirements set forth in 45 CFR 75.305.” Alternatively, if a broader reference to specific PMS requirements is intended, provide a specific citation to such requirements.

4. **State clearly that expenditures of program income funds (“non-Grant funds”) by federally-funded health centers are not subject to the Federal Cost Principles.**

- **Wording:** *Third bullet, fourth sub-bullet:* “The health center’s financial management system must... provide for... Written procedures for assuring that costs under the award are allowable in accordance with the terms and conditions of the Federal award and with the Federal Cost Principles. (see 45 CFR Part 75 Subpart E).” *(emphasis added)*

- **Comment:** The use of the phrase “costs under the award” implies that the Federal Cost Principles apply to non-Grant funds. As discussed at length in our comments on Chapter 12 -
Chapter 15: Financial Management and Accounting Systems

Requirements, established by statute at 42 U.S.C. § 254b(e)(5)(D), and confirmed by PIN 2013-01, expenditures of program income funds (“non-Grant funds”) by federally-funded health centers are not subject to the Federal Cost Principles.

- **Recommendation**: Revise this bullet to make clear that expenditures of program income funds (“non-Grant funds”) by federally-funded health centers are not subject to the Federal Cost Principles, as follows:

  “The health center’s financial management system must... provide for... Written procedures for assuring that expenditures of federal funds are allowable in accordance with the terms and conditions of the Federal award and with the Federal Cost Principles.”

  *Please also see our comment regarding third bullet, second sub-bullet under Demonstrating Compliance, which addresses a similar concern.*

5. For health centers that expend less than $750,000 of Federal award funding in a fiscal year, verify whether the Single Audit Act overrides the Section 330(q) audit requirement; if 330(q) is not overridden, expressly state the authority for applying this requirement to these health centers.

- **Wording** *(fourth bullet)*: “The health center must provide for and submit an independent annual financial audit that is conducted in accordance with Generally Accepted Accounting Principles (GAAP) and the applicable requirements prescribed in 45 CFR Part 75 Subpart F.”

- **Comment**: This language suggests that the requirement for an “independent annual financial audit” applies to all health centers, regardless of the amount of their Federal award. However, for health centers receiving less than $750,000 in total Federal awards, this requirement appears to be inconsistent with the Single Audit Act (SAA.) This Act reads at 31 U.S.C. § 7502(a)(2):

  “Each non-Federal entity that expends a total amount of Federal awards of less than [$750,000] in any fiscal year of such entity, shall be exempt for such fiscal year from compliance with—

  (i) the audit requirements of [the SAA]; and

  (ii) any applicable requirements concerning financial audits contained in Federal statutes and regulations governing programs under which such Federal awards are provided to that [NFE].” *(emphasis added)*

(Note that the SAA as amended in 1996 originally set the threshold at $300,000, but gave the OMB Director the authority to raise this amount as appropriate. The $750,000 threshold has been in effect for all SAA audits for fiscal years beginning on or after December 26, 2014. See 45 C.F.R. §§ 75.110(b) and 75.501.)

While we support the transparency and oversight facilitated by such audits, we recognize that they can be expensive and burdensome. It is therefore appropriate to ask whether requiring these audits is the best use of federal funds provided for programmatic purposes.

- **Recommendation**: HHS is required by the SAA to have a designated internal division, likely the Office of Inspector General (OIG), tasked with reviewing audit requirements beyond the SAA for consistency with the SAA. 31 U.S.C. §§ 7503(e) and 7504(b). We recommend HRSA consult such entity before imposing the audit requirement on health centers that expend less than $750,000
of Federal award funding in a fiscal year. If this audit requirement continues to be asserted for these grantees, we recommend that HRSA avoid future uncertainty by including in the Compliance Manual:

- an express statement of authority for this financial audit requirement, and
- express confirmation that the cost of such an audit is an allowable cost.

*Also see our comment on the fourth bullet under Demonstrating Compliance, which addresses the same issue.*

**Demonstrating Compliance**

1. **State clearly that expenditures of program income funds (“non-Grant funds”) by federally-funded health centers are not subject to the Federal Cost Principles.**

   - **Wording:** *(Third bullet, second sub-bullet):* “The health center has written procedures for... Assuring that *costs expended under the award* are allowable in accordance with the terms and conditions of the Federal award and with the Federal Cost Principles in 45 CFR Part 75 Subpart E.” *(emphasis added)*

   - **Comment:** As stated in our comment on the third bullet, fourth sub-bullet under Requirements, the use of the phrase “costs expended under the award” implies that the Federal Cost Principles apply to non-Grant funds. As discussed at length in our comments on Chapter 12 - Requirements, established by statute at 42 U.S.C. § 254b(e)(5)(D), and confirmed by PIN 2013-01, expenditures of program income funds (“non-Grant funds”) by federally-funded health center are not subject to the Federal Cost Principles.

   - **Recommendation:** Revise this bullet to make clear that expenditures of program income funds (“non-Grant funds”) by federally-funded health centers are not subject to the Federal Cost Principles, as follows:

     “The health center has written procedures for.... Assuring that *expenditures of federal funds* under the award are allowable in accordance with the terms and conditions of the Federal award and with the Federal Cost Principles in 45 CFR Part 75 Subpart E.” *(emphasis added)*

     *Please also see our comment regarding the third bullet, fourth sub-bullet under Requirements, which addresses a similar, critical concern.*

2. **For health centers that expend less than $750,000 of Federal award funding in a fiscal year, verify whether the Single Audit Act overrides the Section 330(q) audit requirement; if 330(q) is not overridden, expressly state the authority for applying this requirement to these health centers.**

   - **Wording** *(fourth bullet):* “If a health center expends less than $750,000 in award funds from all federal sources during its fiscal year, the health center ensures that an annual independent financial audit is conducted and submitted in accordance with generally accepted accounting
principles and ensures that subsequent audits demonstrate corrective actions have been taken to address all findings, questioned costs, reportable conditions, and material weaknesses cited in the previous audit report, if applicable."

- **Comment:** As discussed in our comment on the fourth bullet under Requirements, the requirement for health centers that expend less than $750,000 in Federal funds in a fiscal year to have an “annual independent financial audit” may be inconsistent with the Single Audit Act. While we support the transparency and oversight facilitated by such audits, we ask whether requiring these audits is the best use of federal funds, and request that these two statutes be reconciled.

- **Recommendation:** As discussed in our previous comment, we recommend that HRSA determine whether the SAA rules override Section 330(q) requirements for health centers that expend less than $750,000 of Federal award funding in a fiscal year. If this audit requirement continues to be asserted for these grantees, we recommend that HRSA avoid future uncertainty by including in the Compliance Manual:
  - an express statement of authority for this financial audit requirement, and
  - express confirmation that the cost of such an audit is an allowable cost.

*Also see our comment on the fourth bullet under Requirements, which addresses the same issue.*
Chapter 16: Billing and Collections

Demonstrating Compliance

1. Add language about payment incentives from PIN 2014-02, in order to explicitly mention cash incentive plans and to provide guidance around factors to consider and requirements for implementing such incentives.

- **Wording (fourth bullet, fourth sub-bullet):** “The health center has systems, which may include operating procedures, for billing and collections that address... If applicable, incorporating additional elements such as payment plans, grace periods, and prompt payment incentives.”

- **Comment:** As stated in our comment on Chapter 9, the inclusion in PIN 2014-02 of discussion about payment incentives resolved a long-standing ambiguity as to whether such incentives are allowed. Notwithstanding, there continues to be confusion. For example, some health centers are unclear as to whether a payment must be at the time of service to qualify as a “prompt” pay discount.

   In addition, the above text from the draft Compliance Manual does not reference cash payment incentives, which are referenced in PIN 2014-02. We are unclear as to whether this was an intentional omission.

- **Recommendations:**
  - Include a reference to cash payment incentives in the above bullet, such as “and incentives for prompt payment/cash payment.”
  - Provide guidance to health centers contemplating prompt payment/cash payment incentives, around both factors to consider and requirements for implementing such incentives. This can be achieved by adding the following language from PIN 2014-02 in this Chapter under “Related Considerations.”

   “Health centers may elect to offer incentives through board-approved billing and collections policies. Such incentives are often referred to as ‘prompt payment/cash payment incentives,’ to patients who pay with cash and/or who pay their bills within a specific, expedited timeframe as a method of increasing collections and reducing billing costs. Health centers should thoroughly research the potential consequences of implementing prompt payment/cash payment incentives for patients and conduct cost-benefit analyses in determining the amount of the payment incentive. The operating procedures that support such a policy must ensure that these incentives are accessible to all patients, regardless of income level or sliding fee discount pay class, and consistently applied without preferential treatment of any kind. In addition, health centers must have a mechanism for communicating the availability of these incentives to all of their patients.”

85
Demonstrating Compliance & Related Considerations

1. Delete prescription drugs dispensed to patients from “Supplies and Equipment” and include them under required pharmaceutical services, which are subject to the health center’s sliding fee discount schedule.

- **Wording:**
  - *Demonstrating Compliance, eighth bullet:* If a health center provides supplies or equipment that are related to, but not included in the service itself as part of the prevailing standards of care (for example, eyeglasses, prescription drugs, including those purchased under discount programs, dentures) ...
  - *Related Considerations (fourth bullet):* “If a health center elects to provide its patients access to supplies or equipment (for example, eyeglasses, prescription drugs, dentures) ...

- **Comment:** The provisions above inappropriately and incorrectly classify prescription drugs as “supplies and equipment.” Unlike eyeglasses, dentures, and other dental implants, prescription drugs are not simply “related to, but not included in the service itself as part of the prevailing standards of care.” Rather, prescription drugs are an integral part of the underlying “pharmaceutical services.” The HRSA Service Descriptor Guide defines pharmaceutical services as follows:

  “[P]harmaceutical services provide access to prescribed medications. These services may include a broad spectrum of functions ranging from dispensing and tracking of medications to pharmacist-delivered patient care services (disease state management, medication reconciliation, therapeutic monitoring, wellness promotion, and disease prevention).”

Given this definition, detaching the drug component from “pharmaceutical services” is illogical. While vision care services may / may not include the provision of eyeglasses and restorative dental services may / may not include dentures, crowns and other dental implants, it is difficult to conceive of a “pharmaceutical service” that does not involve the prescription drug. The first sentence of the definition implies as much - pharmaceutical services provide access to prescribed medication. Further, in order to provide “dispensing and tracking of medications,” the health center must be in possession of, acquire, or provide access to prescription drugs - the drugs are an essential part of service. (In other words, there is no “dispensing and tracking” without the prescription medication). While certain “pharmacist-delivered patient care services” may not relate directly to the prescription drug, the initial dispensing of the drug is the key element that drives the need for the underlying patient care services provided by a pharmacist (rather than another provider).

We also note that unlike the underlying services for the other examples of “supplies and equipment” (vision care services for eyeglasses and restorative dental services for dentures), pharmaceutical services are required under Section 330. Insofar as prescription drugs cannot be detached or separated from required pharmaceutical services, the drugs should be removed
from “supplies and equipment” and -- similar to other required services -- made subject to the sliding fee discount schedule.

- **Recommendation:** HRSA should delete prescription drugs from the examples of “supplies and equipment” and include them under required pharmaceutical services, subject to the health center’s sliding fee discount schedule.
Chapter 17: Budget

No comments
No comments
Chapter 19: Board Authority

General

1. Maintain valuable guidance on the public entity model by either incorporating Section IV of PIN 2014-01 in its entirety into the Governance chapters, or else not rescinding the PIN.

- **Wording:**
  - *Requirements, first bullet and footnote:* "The health center must establish a governing board* that has specific responsibility for oversight of the Health Center Program project.... *Footnote: [F]or public agencies that elect to have a co-applicant, these authorities and functions apply to the co-applicant board."
  - *Demonstrating Compliance, first bullet, third sub-bullet:* “For public agencies with a co-applicant board, the health center has a co-applicant agreement that delegates the required authorities and functions to the co-applicant board and delineates the roles and responsibilities of the public agency and the co-applicant in carrying out the health center project.”
  - *Demonstrating Compliance, fifth bullet:* “In cases where a public agency is the recipient of the Health Center Program Federal award or designation, the public agency may establish and retain the authority to adopt and approve financial management and personnel policies.”
  - *Related Considerations, third bullet:* “For public agencies with co-applicant boards, the co-applicant board and the public agency determine how to collaborate in carrying out the health center project (for example, shared project assessment, public agency participation on board committees, and joint preparation of grant applications).”

- **Comment:** While many of the interpretive policies in PIN 2014-01 have been incorporated into the draft Compliance Manual, there is one key area missing – Section IV, which discusses public health centers. At present, this section is the only existing guidance on the public entity/ co-applicant board model, including the general concept of what a public health center is and the way in which the two parties can split authorities.

PIN 2014-01 contains valuable, additional detail on the public entity/ co-applicant board model, far beyond the limited information contained in the draft Compliance Manual. For example, it indicates which policies within the broad categories of “financial management and personnel policies” the public entity can retain outright (versus “share” with the co-applicant board), and provides additional information and detail on the co-applicant agreement.

Given the inherent difficulties with developing and implementing the public health center model, in particular the issues faced by co-applicant boards in retaining and exercising their authorities due to resistance on the part of their public entity partners, eliminating the guidance in Section IV of the PIN could dilute the co-applicant board’s authorities even further, leading to situations where the board is nothing more than a "figurehead."
Chapter 19: Board Authority

Note that this comment is an example of the concerns raised in NACHC’s “Overarching Comment.”

- **Recommendation:** NACHC recommends that HRSA maintain the valuable guidance on the public entity model currently included in Section IV of PIN 2014-01 by either incorporating that guidance in its entirety into this Chapter or not superseding that section of the PIN.

**Requirements**

1. Clarify that the bylaws are written operating rules for the board, not the health center.
   - **Wording** (second bullet): “The health center governing board must develop bylaws which specify the responsibilities of the board with respect to the conduct of the health center” (emphasis added)
   - **Comment:** The highlighted language is confusing, as bylaws are the written operating rules for the board, rather than the health center.
   - **Recommendation:** To increase clarity, reword this bullet to read “bylaws which specify the responsibilities of the board with respect to how the board operates.”

2. Clarify if governing boards will continue to be required to evaluate the performance of the CEO/Project Director, and if so, how frequently.
   - **Wording:**
     - Under Requirements (fifth bullet): “The health center governing board must approve the selection and termination/dismissal of the health center’s Project Director/Chief Executive Officer.”
     - Under Demonstrating Compliance:
       - Second bullet, second sub-bullet: “The health center’s articles of incorporation, bylaws, or other relevant documents outline the following required authorities and responsibilities of the governing board.... Approving the selection (and termination or dismissal, as appropriate) of the health center’s Project Director/CEO.”
       - Third bullet, second sub-bullet: “The health center’s board minutes and other relevant documents confirm that the board exercises, without restriction, the following authorities and functions... Approving the selection of, evaluating and, if necessary, approving the dismissal or termination of the Project Director/CEO from the health center project;”

   - **Comments:** Both the first bullet above (under the Requirements section of the Manual) and second bullet above (under the Demonstrating Compliance section of the Manual) are consistent with Section 51c.304 (d)(3)(i) of the Health Center regulations, which states that the board is responsible for the approval of “the selection and dismissal of a project director or chief executive officer of the center.” The third bullet (also under Demonstrating Compliance),
however, includes an additional requirement that the board evaluate the CEO’s performance. Including “evaluation” in the third bullet above results in an inconsistency between the Requirements and the Demonstrating Compliance sections, as well as between two provisions both of which are included within Demonstrating Compliance section. Given these multiple inconsistencies, it is unclear whether or not the Board is required to evaluate the CEO (as currently required under PIN 2014-01), or whether evaluation is simply a “best practice.” Insofar as many OSV reviewers have cited health centers for failure to annually review the CEO, HRSA should explicitly and consistently state whether such evaluation is required and if so, the required frequency.

- **Recommendation:** Clarify whether governing boards are required to evaluate the performance of the CEO/Project Director, and ensure consistency among the provisions of the Demonstrating Compliance section. If this is a requirement, provide guidance on a minimum required frequency for such evaluations to ensure that health centers and reviewers utilize the same standard.

3. **Clarify if and how governance requirements set forth solely in regulations apply to grantees who receive only 330(h) and/or 330(i) funds.**

- **Wording:** Not applicable.

- **Comment:** In prior guidance, including PIN 2014-01 and the Health Center Program Operational Site Visit Guide, HRSA indicated that the governance requirements found solely in the health center program implementing regulations at 42 C.F.R. 51c.304(d) (but not in the Section 330 statute) do not apply to health centers that receive only Health Care for the Homeless [330(h)] funds and/or Public Housing Primary Care [330(i)] funds. Nevertheless, since those requirements are considered complementary to the statutory requirements in Section 330 (which absent a specific waiver approved by HRSA, apply to all health centers receiving Section 330 funds), HRSA strongly recommends that all health centers comply with the requirements as “best practices that all health centers should follow, regardless of the specific community served.” (See PIN 2014-01 at p. 4). We note that the Compliance Manual neither includes a similar statement nor identifies the specific regulatory requirements that do not apply to centers receiving only 330(h) and/or 330(i) funds.

- **Recommendation:** HRSA should clarify whether its position has changed regarding whether the regulatory-only requirements apply to health centers that receive only Health Care for the Homeless [330(h)] funds and/or Public Housing Primary Care [330(i)] funds.

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**Demonstrating Compliance**

1. **Ensure that Executive Committees can act independently of the full Board in time-sensitive situations, provided that it acts in a manner consistent with the priorities established by the full Board.**
• **Wording** (*first bullet, first sub-bullet*): “The organizational structure and documents do not allow for any other individual, entity or committee (including, but not limited to, an executive committee authorized by the board) to reserve or have approval/veto power over the health center board with regard to the required authorities and functions.”

• **Comment:** It is unclear from this language whether HRSA's intent is to prohibit an executive committee from acting independently of the board under any circumstances. If so, there is concern that health centers’ ability to act quickly will be adversely impacted; it could also encourage management to act without board approval if they need to act quickly. Typically, when the executive committee acts in emergencies or in the interim between board meetings, it does so consistent with the priorities established by and under the direction of the board. As such, it is unclear why HRSA would take a hard line on such actions by the executive committee. Such action will ultimately be detrimental to the center insofar as it could "handcuff" it at times when quick decisions are necessary and cannot wait until a monthly board meeting.

• **Recommendation:** Ensure that an executive committee can act independently of the full Board in time-sensitive situations, provided that it does so it is in a manner consistent with the priorities established by the full board and that the actions taken are presented to and approved by the full board at the next subsequent meeting.

2. **If HRSA will continue to have expectations around required provisions for the Board bylaws above and beyond the regulatory authorities, state these expectations explicitly in Chapter 19 of the Compliance Manual.**

• **Wording** (*second bullet*): “The health center’s articles of incorporation, bylaws, or other relevant documents outline the following required authorities and responsibilities of the governing board ...”

• **Comment:** PIN 2014-01 lists several specific provisions which must be addressed in the bylaws, including, but not limited to, authorities, composition, selection/removal processes, officers, committees, and dissolution. (See Section III, C.) In contrast, Chapter 19 of the Compliance Manual (which will supersede PIN 2014-01) appears to require provisions regarding the required authorities and responsibilities only. While some of the provisions required by PIN 2014-01 are included in Chapter 20 (for example, provisions regarding board composition), several of the PIN requirements appear to be omitted. Further, specification of required bylaws provisions in separate chapters could be confusing and result in inadvertent omission from the health center’s bylaws.

Additionally, PIN 2014-01 also states that “bylaws must be established and approved by the health center’s governing board through a board resolution that is signed and dated by the Secretary of the board or other designated official.” The Compliance Manual contains no language about board approval for the bylaws.
• Recommendation: If HRSA will continue to expect bylaws to address all of the specific provisions listed in PIN 2014-01, it should revise this Chapter to include all of them, including the provisions currently delineated in Chapter 20 of the Compliance Manual, consistent with how they are listed in Section III C in PIN 2014-01. In addition, if HRSA will continue to have specific expectations around how bylaws are to be established and approved, these expectations should be explicitly discussed in the Compliance Manual.

3. Resolve the inconsistency between the Requirements section and the Demonstrating Compliance section regarding approval of the budget.

• Wording:
  o Under Requirements (seventh bullet): "The health center governing board must review and approve the annual Health Center Program project budget."
  o Under Demonstrating Compliance (second bullet, third sub-bullet): "The health center's articles of incorporation, bylaws, or other relevant documents outline the following required authorities and responsibilities of the governing board.... Approving the health center's annual budget" (emphasis added)

• Comment: The first bullet cited above is consistent with Section 51c.304 (d)(3)(iii) of the Health Center regulations, which states that the board is responsible for the approval of the annual "health center program project budget." However, the second bullet, which is included in the Demonstrating Compliance Section, requires board approval of the health center's "annual budget and applications." For many health centers, the “health center program project budget” and the “health center’s budget” will be the same. For some health centers, however, the budget solely for the project (i.e., the health center program project budget) may be one component of the larger organizational budget (i.e., the health center’s budget), resulting in an inconsistency between these two bullets and thus potential confusion for those health centers that have both.

• Recommendation: HRSA should revise the second bullet above to mirror the regulatory language indicating the board is responsible for approving the “annual health center program project budget.” Further, HRSA should include a notation for both bullets (either as a footnote or in the bullets themselves) clarifying that if the health center program project budget is one component of a larger organizational budget, for 330 compliance purposes, the health center is required to provide documentation that the board specifically approved the health center project budget - approval of the broader organizational budget should be consistent with applicable State law.

Regarding the third bullet, second sub-bullet (“The health center’s board minutes and other relevant documents confirm that the board... Approve[es] the selection of, evaluating and, if necessary, approving the dismissal or termination of the Project Director/CEO from the health center project;”) - please see our comment and recommendation under Requirements (fifth bullet) to clarify if governing boards will continue to be required to evaluate the performance of the CEO/Project Director, and if so, how frequently.
4. Clarify that while the board is required to approve the decision to enter into a contract or subaward for a substantial portion of the health center’s services, it is not required to approve the actual agreement.

- **Wording** *(third bullet, fourth sub-bullet):* “The health center’s board minutes and other relevant documents confirm that the board exercises, without restriction, the following authorities and functions... Approving health center project’s sites, hours of operation and services, including subawarding or contracting for a substantial portion of the health center’s services”

- **Comments:** It is unclear from this language whether HRSA is requiring that the board approve the **actual agreements** or simply the **decisions to enter into the agreements** (which would be consistent with the requirement on page 69 – first full bullet). The latter is fine – the former is not. While management should discuss such arrangements with the board given their impact on the center’s operations as well as the potential liabilities that could arise, it is not necessary for the board to approve the actual agreement. Such approval could constitute a board overreach into management’s role.

- **Recommendation:** Clarify that while the board is required to approve the decision to enter into a contract or subaward for a substantial portion of the health center’s services, the board is not required to approve the actual agreement.

5. Acknowledge that not all health centers have capital expenditure plans.

- **Wording** *(third bullet, sixth sub-bullet):* “Conducting long-range planning at least once every three years, which at a minimum results in financial management and capital expenditure plans”

- **Comment:** Not all health centers have capital expenditure plans.

- **Recommendation:** Revise this bullet to state “as applicable.”

6. Explicitly recognize that while boards are responsible to approve financial management and personnel policies, they are not required or expected to approve operating procedures.

- **Wording** *(fourth bullet):* “The health center board has adopted, evaluated at least once every three years, and, as needed, approved updates to Financial Management and Personnel policies.”

- **Comment:** These broad references to “Financial Management” and “Personnel” policies are at best vague, and at worst encourage the present practice of some OSV reviewers requiring boards to approve both the applicable policies and procedures (which is an overreach into
management). In addition, the phrase “Financial Management” links to Chapter 15, which addresses the requirements for financial management and accounting systems. Those requirements, however, include a great number of *procedural* requirements, such as maintaining a system consistent with GAAP standards. By linking to that chapter, this requirement appears to indicate that the board must approve not only financial management policies, but the procedures as well.

**Recommendation:** Clarify this section by:
- removing the link to Chapter 15, and
- indicating that the board approves financial management and personnel policies but not the operating procedures. In addition, it would be useful to give examples of these types of policies, such as those listed in 51c.304 (d)(3)(ii) and (iii).
Chapter 20: Board Composition

Requirements

1. Clarify if and how governance requirements set forth solely in regulations apply to grantees who receive only 330(h) and/or 330(i) funds.

   \textit{Note that this comment is identical to one made regarding the Requirements section of Chapter 19, Board Authority.}

   \begin{itemize}
   \item \textbf{Wording:} Not applicable.
   \item \textbf{Comment:} In prior guidance, including PIN 2014-01 and the Health Center Program Operational Site Visit Guide, HRSA indicated that the governance requirements found solely in the health center program implementing regulations at 42 C.F.R. 51c.304(d) (but not in the Section 330 statute) do not apply to health centers that receive only Health Care for the Homeless [330(h)] funds and/or Public Housing Primary Care [330(i)] funds. Nevertheless, since those requirements are considered complementary to the statutory requirements in Section 330, which absent a specific waiver approved by HRSA, apply to all health centers receiving Section 330 funds, HRSA strongly recommends that all health centers comply with the requirements as “best practices that all health centers should follow, regardless of the specific community served.” (See PIN 2014-01 at p. 4). We note that the Compliance Manual neither includes a similar statement nor identifies the specific regulatory requirements that do not apply to centers receiving only 330(h) and/or 330(i) funds.
   \item \textbf{Recommendation:} HRSA should clarify whether its position has changed regarding whether the regulatory-only requirements apply to health centers that receive only Health Care for the Homeless [330(h)] funds and/or Public Housing Primary Care [330(i)] funds.
   \end{itemize}

Demonstrating Compliance

1. Delete the requirement that, to be eligible to be a patient Board member, an individual must receive an in-scope service at a site approved under the HRSA Scope of Project; replace this with the language from PIN 2014-01 requiring such individuals to receive at least one in-scope service that generated a health center visit.

   \begin{itemize}
   \item \textbf{Wording:} “For the purposes of board composition, a patient is an individual who has received at least one service in the past 24 months that generated a health center visit, \textit{where both the service and the site where the service was received are within the HRSA-approved scope of}
**project.**” (Emphasis added.) Please note that this language appears in two separate bullets in this section.

- **Comment:** This language represents a significant departure from the patient definition (for Board membership purposes) in PIN 2014-01, Health Center Program Governance, which was approved and issued by HRSA only 2½ years ago. This PIN reads:

  “Patient board members must be a current registered patient of the health center and must have accessed the health center in the past 24 months to receive *at least one or more in-scope service(s)* that generated a health center visit.” (Emphasis added.)

As demonstrated by the language above, the current PIN does not require that the site where the qualifying service is received be in-scope – only that the service be included in the approved scope and generate a health center visit. Many health centers have contracted services included within their approved scopes of project. Often these contracted in-scope services are provided at the contractor’s facility rather than the health center site. Under some arrangements, these “contracted sites” comply with the definition of a “site” outlined in PIN 2008-01 (which requires, among other things, that the service be provided on a regularly-scheduled basis) and thus be included on Form 5B.

Other times, however, the contracted site will not fully comply with the “site” definition because the services are provided on an as-needed basis, in which case the health center would document the arrangement on Form 5C. For example, dental services may be provided off-site but the dental facility may not qualify under the site definition if the services are provided to health center patients on an as needed basis. Nevertheless, this is an in-scope service provided to a patient who could qualify as a patient board representative. The same could be said for off-site OB and in-scope specialty services. HRSA’s own policy recognizes the ability of health centers to include in their approved scopes of project in-scope services provided at off-site facilities that do not qualify as “sites” under the HRSA definition – Page 3, footnote 5 of the Column Descriptor Guide states: “For Column I/II, it is possible that the service is provided at a location that does not meet the service site definition but that is listed on Form 5C: Other Activities/Locations.

Therefore, requiring that patients be served at an in-scope (Form 5B) “site” in order to serve as a patient board representative unnecessarily limits the pool of available patient board members by precluding patients who receive services at appropriate and approved contracted locations that do not qualify as a “site.”

- **Recommendation:** HRSA should delete the requirement that the individual receiving an in-scope service must be served at a site that is approved under the HRSA Scope of Project in order to be eligible to be a patient Board member, and instead use the language from PIN 2014-01 requiring such individuals to receive at least one in-scope service that generated a health center visit.

2. **Clarify that the requirement prohibiting “contractors” from serving on the health center board applies solely to “independent contractors” who work primarily for the health center as part of its staff (and not to “individual contractors”.)**
**Wording:**
- *(second bullet, seventh sub-bullet)* “Health center employees, *individual* contractors working for the health center, and immediate family members... of employees may not be health center board members.” *(emphasis added)*
- *(fifth bullet):* “The health center verifies periodically... that the governing board does not include... *individual* contractors currently working for the health center.” *(emphasis added)*

**Comments:** This language extends the regulatory prohibition on employees and their immediate family members from serving on the board to include individual contractors, despite the fact that the extension of this prohibition is not included in the health center program regulation or in the “Requirements” section of the draft Manual. While HRSA, as the grantor agency, has the right to issue interpretative rules, policy statements and other guidance, adding a new classification to the current prohibition appears to go beyond “interpretative guidance.” Therefore, HRSA lacks the legal authority to revise the current requirement in this forum.

Nevertheless, if HRSA insists on including in the prohibition all individuals who comprise the core “staff” of the health center (which often extends beyond employees), it is important to distinguish between “*Individual Contractors*” and “*Independent Contractors.*” As noted in our comments on Chapter 4, the term “*Independent Contractor*” describes the tax classification of the individual providing the services, not necessarily the working relationship of the individual to the health center. Many “*Independent Contractors*” work primarily for the health center and both the individual and the health center consider themselves to be furnishing direct services on behalf of the health center. These persons do not have a separate employer functioning as the contracted entity; typically do not see patients independent of the health center; provide the services at the health center site; are included as and considered part of the health center “staff.”

In contrast, *Individual Contractors* could include anyone who contracts with a health center to provide a distinct service (whether clinical, administrative or otherwise). Many health centers (in particular, those in small towns and rural areas) may allow contracting with board members to provide distinct services to the center (e.g., snow plowing; maintenance). Others may allow a collaborative partner to serve on the board as a means to advance the collaboration. Such arrangements should not be precluded automatically by HRSA; rather the decision to allow board members to contract with the health center should be in the sole discretion of the individual center and its board, provided that the Bylaws / applicable board policy allow (or at a minimum, do not preclude) such arrangements; appropriate conflicts of interest standards are followed (including the contractor’s disclosure of the conflict and recusal from decision-making); and an appropriate procurement process is conducted prior to entering the contract with the board member.

Extension of the prohibition on employees serving on the board to include *Individual Contractors* without any clear reason or legal authority to do so could result in unnecessary harm to health centers, in particular those health centers with few options. Accordingly, HRSA should reverse course and mirror this provision on the actual legal requirements as drafted. Alternatively, given that *Independent Contractors* may comprise part of the core health center “staff” (as described above) and thus could raise the same conflicts of interest raised by
allowing employees to serve, NACHC would support prohibiting *Independent Contractors* (but not *Individual Contractors*) from serving as board members.

- **Recommendation:** HRSA should delete “*Individual Contractors*” from the list of individuals precluded from serving on the health center board. At a minimum, HRSA should clarify that the prohibition extends to *Independent Contractors* who comprise part of the health center’s core “staff,” but not to *Individual Contractors*.

3. **Eliminate the 51 percent quorum requirement from under “Demonstrating Compliance” and move it to “Related Considerations”**.

- **Wording:**
  - *(third bullet):* “The health center has bylaws or other relevant documents requiring a quorum of not less than 51 percent of board members (absent a different quorum requirement in state law)”
  - *(footnote):* “State law may specify whether quorum standards should be outlined in the bylaws or articles of incorporation.”

- **Comment:** The Health Center Requirements, as outlined in this Chapter, do not address quorum requirements. Typically, such requirements are set by State law (which HRSA acknowledges in the footnote) and as a procedural requirement, have traditionally been (and should continue to be) outside the purview of HRSA. Qualifying the requirement by including the parenthetical “(absent a different quorum requirement in state law)” adds additional confusion—is HRSA referring to a different percentage or a definitive number? Would the relevant state law have to preclude the health center’s ability to comply with the 51 percent threshold in order for the health center to have a quorum of less than the threshold? Alternatively, if state law allows a quorum of less than 51 percent, would that be sufficient to satisfy the parenthetical? While a 51 percent quorum requirement may be ideal from a policy perspective (mathematically, it ensures at least one consumer board member is involved in decisions at all times), it is inappropriate for HRSA to require this for purposes of compliance.

- **Recommendation:** Given the lack of legal authority for HRSA to require a 51 percent quorum as well as the potential (and actual) confusion raised by this requirement, HRSA should strike the quorum requirement in its entirety from this section. Nevertheless, given the policy implications of suggesting a 51 percent quorum requirement, HRSA should add it as a “Related Consideration.”

4. **For Health Centers seeking a waiver of the patient majority board requirement, clarify the standard and the documentation required to demonstrate the unsuccessful attempts to recruit a majority of special population board members, and distinguish this from “undue hardship.”**

- **Wording (sixth bullet):** “Health centers requesting a waiver of the patient majority board composition requirements present to HRSA for review and approval:
‘Good cause’ that justifies the need for the waiver by documenting...
- The unique characteristics of the population... or service area that create an undue hardship in recruiting a patient majority; and
- Its attempts to recruit a majority of special population board members and why these attempts have not been successful.”

**Comment:** It is reasonable to expect that health centers seeking composition waivers would first attempt to recruit patient board members prior to the submission of a waiver request, unless they can demonstrate undue hardship. However, the standard by which a health center’s “attempts” will be measured and the documentation required to demonstrate that such actions took place is unclear. This standard is key to determining on an objective basis whether the attempts have been unsuccessful. How would a center satisfy this requirement? What is the level / number of “attempts” required to demonstrate compliance with this standard? Further, it is overly burdensome and unnecessary to require both “undue hardship” and prior attempts to recruit patient-majority board - if the health center can demonstrate “undue hardship” in recruiting such individuals, why would they have to first attempt such recruitment before securing a waiver?

**Recommendation:** HRSA should include a standard by which “attempts” to recruit a patient-majority board can be measured and documented to objectively determine whether the attempts were unsuccessful. Alternatively, if HRSA declines to provide such standard, it should move this requirement to “Related Considerations.”

If HRSA provides the aforementioned standard, it should clarify that health centers must demonstrate either “undue hardship” OR unsuccessful attempts in recruiting the patient-majority board - not both.
Chapter 21: FTCA Deeming Requirements

Cross-Cutting

1. Delete the chapter on FTCA from the Compliance Manual, and include the term “Section 330” in the title of the document.

- **Wording:** This comment applies to the whole chapter, including but not limited to:
  - Under Requirements: “For more information, please review the FTCA Health Center Policy Manual available at...”
  - Demonstrating Compliance, first sentence: “While additional details regarding documentation may be identified in the annual deeming application instructions, a health center would demonstrate compliance with the FTCA requirements by documenting in its annual deeming application, in the form and manner prescribed by HRSA consistent with the descriptions below, the following...” (emphasis added)
  - Introduction Chapter, Additional Health Center Responsibilities, second paragraph: “Health centers (including look-alikes) may be subject to the distinct statutory, regulatory, and policy requirements of other Federal programs such as, but not limited to... The Health Center FTCA Program (with the exception of the deeming requirements included in this Manual).” (emphasis added)

- **Comment:** We greatly appreciate HRSA’s intention to create a consolidated resource for health center compliance. However, we believe that including a chapter on FTCA Deeming Requirements in the Compliance Manual is very problematic, as it contradicts expectations set forth in other FTCA guidance documents published by HRSA, and is likely to increase confusion, rather than reducing it.

As stated in Chapter Two, the Compliance Manual’s purpose is to “provide a consolidated resource to assist health centers in understanding and demonstrating compliance with the Health Center Program Requirements” as well as detailing “requirements for deemed PHS employee status.” However, Chapter 21 discusses (and in some cases summarizes) the FTCA deeming requirements in a way that at times is inconsistent with the FTCA Policy Manual and the annual deeming PALs, and/or deletes important expectations and requirements. For example:

- The FTCA Policy Manual refers to the credentialing and privileging standards set forth in PIN 2001-16 and 2002-22; however, the Compliance Manual explicitly supersedes these PINs and provides conflicting guidance regarding the credentialing and privileging responsibilities of the health center. For example:
  1. The Compliance Manual does not require an appeals process for denial or restriction of privileges as 2002-22 does.
  2. The Compliance Manual does not require confirming immunization and ppd status as 2002-22 does.

- The first sentence under “Demonstrating Compliance” (cited above) suggests that meeting the FTCA “requirements” in the Compliance Manual will be sufficient for a health center’s successful deeming. We recognize that the Compliance Manual states that the annual deeming PAL may contain “additional details regarding documentation” of compliance. However, past experience suggests that the annual deeming PALs will go...
Chapter 21: FTCA Deeming Requirements

beyond “details regarding documentation” and instead establish significant new
expectations. For example, the PALs traditionally include a wide range of policies and
procedures related to risk management that health centers are expected to have in
place, but these requirements do not appear in the Compliance Manual.

As a result, if this Chapter is kept in the Compliance Manual, health centers will need to consult
five separate sources to ensure they understand the full range of FTCA-related requirements in
effect at any one time -- this Compliance Manual, the FTCA Manual, the annual deeming PAL, and
PINs 2001-16 and 2002-22. Given that the Compliance Manual is intended as “one-stop
shopping” for compliance information, including FTCA in this Manual will lead not only to
confusion, but may also lead some health centers to think incorrectly that the Compliance
Manual is the only source they need to consult.

- **Recommendation:** Please limit the Compliance Manual to Section 330 requirements and make
  reference to other health center related program policy documents (FTCA, 340b, NHSC, FQHC)
  where necessary (such as in the section on “Additional Health Center Responsibilities” on page 7
  and 8 of the Compliance Manual). We also recommend including the term “Section 330” in the
  title of the Compliance Manual (in place of or in addition to “Health Center Program”) to
  emphasize to readers that this Manual applies to only to that program.

2. Establish a single, consolidated set of requirements and expectations for
credentialing and privileging, quality improvement/assurance and risk
management that apply to both the health center (§330) and FTCA (§233)
programs. Reference these requirements and expectations in both the Section 330

- **Wording:** Not specific

- **Comment:** As discussed above, there are currently four documents that health centers must
  consult to determine requirements and expectations in the areas of credentialing and
  privileging, quality improvement/assurance and risk management, and this Compliance Manual
  may add a fifth. This leads to confusion and duplicate effort in areas where a single, streamlined
  set of requirements and expectations would be appropriate.

- **Recommendation:** Establish a single consolidated set of requirements and expectations for
credentialing and privileging, quality improvement/assurance and risk management that apply
to both the health center (§330) and FTCA (§233) programs. Reference these standards in both
the Compliance Manual and the FTCA Manual

3. If the Chapter on FTCA is included in the final Compliance Manual, revise the FTCA
Manual and future annual deeming application PALs to indicate that requirements
for deeming are limited to those outlined in the Compliance Manual. In particular,
clarify the status of the credentialing and privileging standards in PIN 2001-16 and
2002-22.
Chapter 21: FTCA Deeming Requirements

- **Wording:**
  - Requirements, Note: “For more information, please review the FTCA Health Center Policy Manual available at:
  - Demonstrating Compliance, first sentence: “While additional details regarding documentation may be identified in the annual deeming application instructions, a health center would demonstrate compliance with the FTCA requirements by documenting in its annual deeming application, in the form and manner prescribed by HRSA consistent with the descriptions below, the following…” (emphasis added)

- **Comment:** As discussed above, this Chapter references the FTCA Manual (which will remain in effect after this Compliance Manual is finalized), which in turn references the credentialing and privileging standards in PINs 2001-16 and 2002-22. However, as indicated in Chapter 2, it is anticipated that both PINs 2001-16 and 2002-22 will be superseded by the Compliance Manual, so the status of these standards is now unclear. If HRSA proceeds as anticipated and rescinds both PINs 2001-16 and 2002-22, HRSA should consider maintaining the Table included in PIN 2002-22 (COMPARATIVE SUMMARY OF REQUIREMENTS FOR CREDENTIALING AND PRIVILEGING “LICENSED OR CERTIFIED HEALTH CARE PRACTITIONERS”), which many health centers incorporate into their credentialing and privileging policies and procedures.

  The Compliance Manual also indicates that future annual deeming PALs will be limited to “details regarding documentation.” Given past history, we are concerned that future PALs may go beyond documentation details and into requirements.

- **Recommendation:** If HRSA maintains a chapter on FTCA in the Compliance Manual, please:
  - ensure that future deeming PALs indicate that requirements for deeming are limited to those outlined in the Compliance Manual.
  - clarify the status of the credentialing and privileging standards in PIN 2001-16 and 2002-22.
  - if PIN 2002-22 is rescinded, maintain the table COMPARATIVE SUMMARY OF REQUIREMENTS FOR CREDENTIALING AND PRIVILEGING “LICENSED OR CERTIFIED HEALTH CARE PRACTITIONERS,” either in the Compliance Manual or on the website.

  Also see related comment in in Chapter Two, under Additional Health Center Responsibilities.

**Demonstrating Compliance**

1. Clarify what is meant by mitigating risk “consistent with the HRSA-approved scope of project”.

- **Wording:** The health center has “operating procedures that address...identifying and mitigating the areas/activities of highest risk for health center patient safety consistent with the health center’s HRSA-approved scope of project.”

- **Comment:** We are unclear what it means to mitigate risk “consistent with... scope of project.”
• **Recommendation:** Please clarify what is meant by this expectation.
Appendix A: Health Center Program Non-Regulatory Policy Issuances That Remain in Effect

1. **Provide a framework for health centers to understand and remember which PINs remain in effect.**

   This is discussed in Chapter Two, under Purpose.

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**Glossary**

1. **See recommendation in Chapter One, first paragraph, about including the statutory definition of “tribal organization” and “Urban Indian organization” in the Glossary.**

2. **Expand the definition of Migratory and Seasonal Agricultural Worker to include aged and disabled agricultural workers and their families, consistent with statute.**

   - **Wording:** *Migratory and Seasonal Agricultural Worker (MSAW):* ...For the purposes of health centers receiving funding or designation under section 330(g) to serve migratory and seasonal agricultural workers and their families, these are individuals principally employed in agriculture on a seasonal basis within the last 24 months who establish temporary housing for the purpose of this work. Seasonal agricultural workers are individuals employed in agriculture on a seasonal basis, who are not also migratory....”

   - **Comment:** This definition is limited to those individuals who are actively or recently engaged in migratory and seasonal agricultural work, and their families. However, it does not include individuals who were previously migratory or agricultural workers but who no longer engage in this work due to age or disability, and their families. This second category – aged and disabled migratory and seasonal agricultural workers and their families – are specifically listed under Section 330(g)(1)(B).

   - **Recommendation:** Expand the definition of Migratory and Seasonal Agricultural Worker to include aged and disabled agricultural workers and their families, consistent with statute.
3. Clarify that the requirement to establish temporary housing for work purposes applies to migratory agricultural workers but not seasonal agricultural workers.

- **Wording:** *Migratory and Seasonal Agricultural Worker (MSAW):* *... migratory and seasonal agricultural workers* and their families... are individuals principally employed in agriculture on a seasonal basis within the last 24 months who *establish temporary housing for the purpose of this work.* *Seasonal agricultural workers* are individuals employed in agriculture on a seasonal basis, who *are not also migratory*...” *(emphasis added)*

- **Comment:** The first sentence highlighted above suggests that both migratory and seasonal agricultural workers must establish temporary housing for the purpose of their work. Per Section 330(g)(3)(A), this requirement applies only to migrant workers, not seasonal ones. While the second sentence might be read as contradicting the first (and therefore being consistent with the statute), clarification is needed.

- **Recommendation:** Clarify that, consistent with the statute, the requirement to establish temporary housing for the purpose of agricultural work applies only to migrant workers, not seasonal ones.