1. **What is the purpose of the Compliance Manual?**
   The Health Center Program Compliance Manual (Compliance Manual) serves as a streamlined and consolidated resource to assist health centers in understanding and demonstrating compliance with Health Center Program and Federal Tort Claims Act (FTCA) deeming requirements, and to increase clarity, transparency and consistency throughout the Health Center Program. The Compliance Manual will also serve as the basis for HRSA staff to determine compliance with program requirements.

2. **Is the Compliance Manual applicable to all health centers?**
   The Compliance Manual applies to **ALL** Health Center Program award recipients, sub-recipients, and look-alikes. This includes health centers that are public entities and health centers funded to serve only special populations (i.e., Health Care for the Homeless, Public Housing Primary Care, and/or Migrant Health Center).

3. **How does the Compliance Manual benefit health centers?**
   HRSA expects that the Compliance Manual, in combination with updated compliance oversight tools and resources, will further increase the impact of the Health Center Program by reducing the time and effort necessary for health centers to understand and demonstrate compliance with program requirements.

4. **Does the Compliance Manual provide best or promising practices for health centers?**
   No, the Compliance Manual is not intended to address best or promising practices or performance improvement strategies undertaken by health centers. The Compliance Manual provides a streamlined and consolidated resource to assist health centers in understanding and demonstrating compliance with Health Center Program and FTCA deeming requirements. However, the “related considerations” sections of the Compliance Manual provides examples of areas where health centers have discretion or that may be useful for health centers to consider when implementing a requirement.

5. **What is the effective date of the compliance manual?**
   The Compliance Manual will become effective and the referenced Policy Information Notices (PINs), Program Assistance Letters (PALS), and related guidance listed in the Introduction of the Compliance Manual will be superseded immediately upon its release. HRSA will use the manual for compliance determinations following the release and will assess all active conditions to ensure that any continued progressive action is consistent with the manual. Note, the Scope-
related PINs, PALs, and related resources will remain in effect after the Compliance Manual release.

6. Will the Compliance Manual replace all PINs and PALs?
Appendix A of the Compliance Manual lists the Health Center Program non-regulatory policy issuances that remain in effect after release of the Compliance Manual. With the exception of these policies, the Compliance Manual supersedes other previous Health Center Program non-regulatory policy issuances (PINs, PALs, Regional Office Memoranda, Regional Program Guidance memoranda, and other non-regulatory materials) related to Health Center Program compliance or eligibility requirements.

7. Will the Compliance Manual supersede the FTCA Policy Manual?
No, the Health Center FTCA Policy Manual will not be superseded by the Compliance Manual. In contrast to the Health Center Program Compliance Manual, the FTCA Health Center Policy Manual does not address requirements related to assessment of compliance with deeming requirements, but rather focuses primarily on how FTCA relates to covered entities, individuals and situations.

8. Will HRSA update conditions currently on health centers’ awards?
The Compliance Manual will become effective immediately upon its release. HRSA will use the manual for compliance determinations following its release and will assess all active conditions to ensure that any continued progressive action is consistent with the manual.

9. Were any changes made to the Compliance Manual from comments received during the 90-day public comment period?
In August 2016, HRSA released a draft of the Compliance Manual for public comment. Written comments were accepted until November 22, 2016. HRSA received over 700 comments. After thorough review and consideration of all comments, HRSA made a substantial number of revisions to the Compliance Manual to incorporate suggestions and requests from commenters for further clarification. HRSA has issued a summary document which details the comments received and HRSA’s response.

10. Will HRSA update the Compliance Manual?
HRSA is committed to reviewing the Compliance Manual on a routine basis and, as deemed appropriate, to proposing updates for public comment.

11. Where should a prospective health center or other stakeholder direct general questions about the Compliance Manual?
For general questions about the Compliance Manual, contact the BPHC Helpline at BPHC Helpline or call 1-877-974-BPHC (2742) from 8:30 am to 5:30 pm ET, Monday through Friday (except Federal holidays).

12. Who should current Health Center Program award recipients and look-alikes contact with case-specific questions related to their grant or look-alike designation and the Compliance Manual?
Current Health Center Program award recipients and look-alikes should contact the Project Officer identified on the Notice of Award (NOA) or Notice of Look-Alike Designation (NLD).

13. How will National Cooperative Agreements (NCAs) and Primary Care Associations (PCAs) assist health centers with the Compliance Manual? Where can I find information on the NCA and PCA resources available to assist health centers with program requirements?
NCAs and PCAs will continue to provide training and technical assistance to existing and potential health centers to increase access to care, achieve operational excellence, improve health outcomes, and reduce health disparities. Although NCAs and PCAs do not have a direct role in health center compliance nor implementation of the manual, they will continue supportive efforts to assist health centers with improving quality and performance. NCAs and PCAs are well positioned to identify and disseminate best practices in health center operations that facilitate compliance.

HRSA utilizes its BPHC Primary Health Care Digest and its website to provide various technical assistance resources and to describe how health centers can access opportunities for technical assistance, including those available through NCAs and PCAs. The Primary Health Care Digest is a weekly electronic newsletter containing updates and information of interest to the health center community. Sign up to receive it here: https://public.govdelivery.com/accounts/USHHSHRSA/subscriber/new?topic_id=USHHSHRSA_18.

14. If a health center has already submitted the calendar year (CY) 2018 FTCA redeeming application, will it be required to resubmit the application now that the Compliance Manual is published?
No, the deadline to submit CY 2018 deeming and redeeming FTCA applications was July 24, 2017. All CY 2018 FTCA applications submitted by the deadline will be reviewed and processed per the guidance provided in PAL 2017-03 and Notice of Deeming Actions will be issued accordingly.

15. Will HRSA update all compliance assessment-related tools, resources and processes to align with the Compliance Manual?
Yes, HRSA is in the process of revising Health Center Program oversight tools, resources, and associated processes, such as the Site Visit Guide, to align with the Compliance Manual.

16. When will HRSA begin using the manual for Operational Site Visits (OSVs)?
HRSA has developed and has piloted a new site visit protocol. Until the new site visit protocol is finalized, HRSA will conduct all OSVs using the current site visit guide; however, HRSA will make all OSV compliance determinations consistent with the Compliance Manual based on data collected and materials assessed on-site. HRSA anticipates releasing the site visit protocol publically in late 2017 and expects to begin using it with OSVs in early 2018.

17. When will HRSA begin using the manual for Service Area Competition (SAC) or Renewal of Designation (RD) application reviews?
HRSA will complete all FY 2018 SAC/RD application reviews and make associated compliance determinations consistent with applicable demonstrating compliance elements in the Compliance Manual. HRSA is updating conditions used on NoAs or NLDs to communicate findings of non-compliance to align with the demonstrating compliance elements for each requirement in the Compliance Manual. HRSA expects to begin using the new conditions for all FY 2019 SAC application reviews.

18. **NEW:** When the Compliance Manual uses the term “would” what does this mean?
The Compliance Manual uses the term “would” in the context of answering the question, “What is HRSA looking for to demonstrate compliance?” If a health center provides what is described in the Compliance Manual for a given “demonstrating compliance” element, then the health center would have demonstrated compliance with that element. For example, as described in Chapter 7: Coverage for Medical Emergencies During and After Hours, if the health center: a) has at least one staff member trained and certified in basic life support at each HRSA-approved service site; b) has and follows its applicable operating procedures when responding to patient medical emergencies during regularly scheduled hours of operation; c) has after-hours coverage operating procedures that ensure coverage and access as described in the Compliance Manual; and d) has documentation of after-hours call and any necessary follow-up, then the health center will have demonstrated compliance with every element and thus all the requirements described in the chapter.

19. **NEW:** Are there specific timeframes associated with reviewing and updating health center policies or procedures? For example, how often are health centers expected to update and review their financial management and accounting systems or bylaws to meet requirements?
The Compliance Manual contains several specific timeframes for either updating or evaluating documents such as policies and/or for conducting other activities. These are the only cases where an assessment of compliance would be based on whether the health center met a specified timeframe and/or had updated documents. If the Compliance Manual does not specify a timeline, then the health center determines the interval, as appropriate for reviewing and updating the given document or activity.

20. **NEW:** Does the Compliance Manual specify which policies or procedures require board approval?
Yes, Chapter 19: Board Authority within the Compliance Manual specifies which policy areas require board approval in order to demonstrate compliance with Health Center Program requirements. Specifically, the health center board adopts, evaluates at least once every three years, and, as needed, approves updates to policies in or that support the following areas:

- Sliding Fee Discount Program
- Quality Improvement/Assurance
- Billing and Collections (those that address the waiving or reducing of amounts owed by patients due to inability to pay, and if applicable those that limit or deny services due to refusal to pay).
- Financial management and accounting systems and personnel.
Note that the governing board of a health center is generally responsible for establishing and/or approving policies that govern health center operations, while the health center’s staff is generally responsible for implementing and ensuring adherence to these policies (including through operating procedures). Procedures do not require approval by the governing board in order to demonstrate compliance with Health Center Program requirements.

21. **NEW: When will the new Site Visit Protocol (SVP) be available?**

BPHC is in the process of finalizing the SVP based on survey and focus group feedback provided by those project officers, health centers, and consultants that participated in four SVP pilot OSVs. The goal is to release the final SVP document to the public in late 2017, which will allow internal and external stakeholders to familiarize themselves with the SVP and to be fully prepared for when OSV reviewers will use the SVP to conduct OSVs beginning in early 2018.