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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Availability of Final Policy Document

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Health Center Program Compliance Manual (Compliance Manual) has been developed as a comprehensive, significantly streamlined, and web-based guidance document to assist health centers in understanding and demonstrating compliance with Health Center Program requirements. As such, this guidance document will reduce burden for current and prospective health centers and look-alikes and further strengthen HRSA's oversight of the Health Center and Health Center Federal Tort Claims Act (FTCA) Programs. It also responds to recommendations contained within the Government Accountability Office report, *Health Center Program: Improved Oversight Needed to Ensure Grantee Compliance with Requirements*, GAO-12-546, for increased transparency, clarity, and consistency in Health Center Program oversight.

The Bureau of Primary Health Care (BPHC) released a draft Compliance Manual on August 23, 2016, for a 90-day public comment period. Individuals and groups submitted over 700 comments regarding the draft Compliance Manual. After thorough review and consideration of all comments received, HRSA made a substantial number of updates to the Compliance Manual to incorporate suggestions and requests for further clarification. HRSA has also posted a summary of comments for each corresponding section and chapter of the Compliance Manual and HRSA's responses to these comments. HRSA's "Summary of Comments and HRSA

Responses on the Draft Health Center Program Compliance Manual” is available online at <https://bphc.hrsa.gov/programrequirements/pdf/healthcentercompliancemanual-comments.pdf>.

The Compliance Manual, which was effective August 28, 2017, is available online at <https://bphc.hrsa.gov/programrequirements/pdf/healthcentercompliancemanual.pdf>. All Health Center Program non-regulatory policy issuances that remain in effect after release of the Compliance Manual are listed in Appendix A of the Compliance Manual. With the exception of these policies, the Compliance Manual supersedes other previous Health Center Program non-regulatory policy issuances related to Health Center Program compliance or eligibility requirements.

FOR FURTHER INFORMATION CONTACT: For questions regarding this notice, contact HRSA/BPHC at <https://www.hrsa.gov/about/contact/bphc.aspx>.

SUPPLEMENTARY INFORMATION:

Executive Orders 12866, 13563 and 13771

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866, emphasizing the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities (also

referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year), and a “significant” regulatory action is subject to review by the Office of Management and Budget (OMB).

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment or otherwise promulgates a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. OMB’s interim guidance issued on February 2, 2017, explains that for fiscal year 2017 the above requirements only apply to each new “significant regulatory action that imposes costs.” It has been determined that the Compliance Manual is not a “significant regulatory action that imposes costs” and thus does not trigger the above requirements of Executive Order 12866 or of Executive Order 13771.

Background

HRSA provides grants to eligible applicants under section 330(e), (g), (h), and/or (i) of the Public Health Service (PHS) Act, as amended (42 U.S.C. 254b), to support the delivery of preventive and primary care services to medically underserved communities and vulnerable populations. Nearly 1,400 Health Center Program-funded health centers operate approximately 10,400 service delivery sites that provide care to nearly 26 million patients in every U.S. state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin. Note that for the purposes of the Compliance Manual, the term “health center” refers to entities that receive a federal award under section 330 of the PHS Act, as amended, grant subrecipients, and organizations designated as look-alikes, unless otherwise stated within the Compliance Manual. Look-alikes, as described in Sections 1861(aa)(4)(B) and 1905(l)(2)(B) of the Social Security Act (42 U.S.C. 1395x(aa)(4)(B) and 42 U.S.C. 1396d(l)(2)(B)(iii)), do not receive a Health Center Program award but must meet the Health Center Program statutory and regulatory requirements. Organizations designated as look-alikes are eligible for payment as a Federally Qualified Health Center under Medicare, Medicaid, and the State Children’s Health Insurance Program (CHIP), as well as participation in the 340B Drug Pricing Program and the National Health Service Corps Program.

HRSA also makes determinations of deemed PHS employment status for health centers funded under section 330 (including subrecipients), which also extends to certain statutorily eligible “covered individuals,” for purposes of providing liability protections under the Health Center Federal Tort Claims Act (FTCA) Program. A favorable FTCA deeming determination requires approval by HRSA of an application submitted by the Health Center Program awardee in the form and manner specified by HRSA. Health centers may also sponsor individual health professional volunteers for such protections. Sections 224(g) – (n) and (q) of the PHS Act (42

U.S.C. 233(g) – (n), and (q)) authorize the Health Center FTCA Program and afford eligibility for FTCA coverage as the exclusive civil remedy for acts or omissions arising within the scope of deemed federal employment in the performance of medical, surgical, dental, or related functions.

The Compliance Manual restates the Health Center Program’s statutory and regulatory requirements and provides guidance on how health centers would demonstrate compliance with such requirements to HRSA. However, the Compliance Manual also allows health centers to submit alternative means of demonstrating compliance with the specified Health Center Program requirements. All means of demonstrating compliance are subject to HRSA review and approval.

Organizations receiving Health Center Program federal awards, including subrecipients, continue to be subject to all requirements incorporated within terms and conditions stated in Notices of Funding Opportunity, Notices of Award, and other applicable laws, regulations, and policies, as well as the distinct statutory, regulatory, and policy requirements of other federal programs in which they participate.

Dated: September 13, 2017

George Sigounas,
Administrator.

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