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), HHS. **ACTION:** Final Agency guidance and response to public comments.

SUMMARY: On January 27, 2014, HRSA published Policy Information Notice (PIN) 2014–01 to convey and clarify statutory and regulatory governance requirements for section 330-funded health centers and look-alikes. The PIN, "Health Center Program Governance," and HRSA's "Comments and Response on Draft PIN: Health Center Program Governance" are available on the Internet at http://www.bphc.hrsa.gov/policiesregulations/policies/pin201401.html, and constitutes final agency guidance.

DATES: The effective date of this final agency guidance was January 27, 2014. FOR FURTHER INFORMATION CONTACT: For questions regarding this notice, please contact the Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, at BPHCPolicy@hrsa.gov. SUPPLEMENTARY INFORMATION: HHS Health Resources and Services Administration (HRSA) provides grants to eligible health centers under section 330 of the Public Health Service Act to support the delivery of preventive and primary care services to medically underserved communities and vulnerable populations. In 2012, grants helped fund more than 1,200 health center grantees that provided services at nearly 9,000 health care delivery sites and served more than 21 million people. There are also over 100 organizations known as Federally Qualified Health Center (FQHC) look-alikes (look-alikes). As described in section 1861(aa)(4) and section 1905(l)(2)(B) of the Social Security Act, look-alikes do not receive federal funding under section 330 of the PHS Act; however, to receive the lookalike designation and associated FQHC benefits, look-alikes must meet the statutory, regulatory, and policy requirements for health centers under section 330.

The purpose of this PIN is to: (a) Convey and clarify statutory and regulatory requirements regarding the structure and functioning of governing boards for all Health Center Program grantees (e.g., section 330(e), (g), (h), and/or (i) grantees) and look-alikes; (b) provide clarification regarding board

requirements for public centers under co-applicant arrangements, including public centers funded or designated solely under sections 330(g), 330(h), and/or 330(i) to serve special populations; and (c) outline the eligibility and qualifying requirements for HRSA approval of a governance waiver for the 51 percent patient majority governance requirement for eligible section 330 grantees and lookalikes. This PIN also establishes HRSA policy that eliminates the monthly meeting requirement from waiver consideration.

On August 20, 2009, HRSA made the draft PIN, "Health Center Governance Requirements and Expectations,' available for public comment. HRSA also published a notice in the **Federal** Register of September 18, 2009, requesting comments on this draft PIN. Fifty-one parties, including both individuals and groups, submitted a total of 251 comments regarding the draft PIN. After review and careful consideration of all comments received, HRSA has amended the PIN to incorporate certain recommendations from the public. The final PIN reflects these changes.

In addition to making the final PIN available on HRSA's Web site, HRSA is also posting HRSA's "Comments and Response on Draft PIN: Health Center Program Governance." The purpose of this document is to summarize the major comments received and describe HRSA's response, including any corresponding changes made to the PIN. Where comments did not result in a revision to the PIN, explanations are provided.

Dated: March 28, 2014.

Mary K. Wakefield,

Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Discretionary Advisory Committee on Heritable Disorders in Newborns and Children; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, codified at 5 U.S.C. App.), notice is hereby given of the following meeting:

Name: Discretionary Advisory Committee on Heritable Disorders in Newborns and Children.

Dates and Times: May 29, 2014, 9:30 a.m. to 4:30 p.m. May 30, 2014, 9:30 a.m. to 3:00 p.m.

Place: Webinar and In-Person, U.S. Pharmacopeial Convention (USP) Headquarters, 12601 Twinbrook Parkway, Rockville, Maryland 20852.

Status: The meeting will be open to the public with attendance limited to space availability. Participants also have the option of viewing the meeting via webinar. Whether attending in-person or via webinar, all participants must register for the meeting at https://www.blsmeetings.net/ACHDNCMay2014. The registration deadline is Friday, May 2, 2014, 11:59 p.m. Eastern Time. If there are technical problems gaining access to the Web site, please contact Anthony Rodell, Director of Client Relations,

at arodell@SeamonCorporation.com. Purpose: The Discretionary Advisory Committee on Heritable Disorders in Newborns and Children (Committee), as authorized by Public Health Service Act (PHS), 42 U.S.C. 217a: Advisory councils or committees, was established to advise the Secretary of the Department of Health and Human Services about the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. Note: the Committee's recommendations regarding additional conditions/inherited disorders for screening that have been adopted by the Secretary are included in the Recommended Uniform Screening Panel and constitute part of the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA). Pursuant to section 2713 of the Public Health Service Act, codified at 42 U.S.C. 300gg-13, nongrandfathered health plans are required to cover screenings included in the HRSAsupported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (i.e., policy years) beginning on or after the date that is 1 year from the Secretary's adoption of the condition for screening.

Agenda: The meeting will include: (1) A discussion and vote on a systematic approach to evaluate the impact of adding newborn screening conditions on state public health systems; (2) a presentation on the impact of the rapid implementation of electronic health records on the Early Hearing Detection and Intervention State programs; (3) a discussion on a potential national infrastructure to conduct research on population-based screening; (4) a presentation on the impact of new CPT codes for molecular diagnostics on laboratories; and (5) updates from the Committee's Laboratory Standards and Procedures, Follow-up and Treatment, and Education and Training subcommittees. Tentatively, the Committee is expected to review and/or vote on a systematic approach to evaluate the impact of adding newborn screening conditions on state public health systems. This tentative vote does not involve any proposed addition of a condition to the Recommended Uniform Screening Panel.

Agenda items are subject to change as necessary or appropriate. The agenda,