



# PROGRAM ASSISTANCE LETTER

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DOCUMENT TITLE: Updated Process for Change in Scope Submission, Review and Approval Timelines

TO: Health Center Program Grantees and Look-Alikes  
Primary Care Associations  
National Cooperative Agreements

## I. Purpose

This Program Assistance Letter (PAL) updates existing Health Center Program Change in Scope (CIS) processes and clarifies how timelines for CIS submission and review align with existing scope policies. This PAL expands upon *PAL 2013-03: Alignment of EHB Change in Scope Module with Change in Scope Policy*,<sup>1</sup> issued in January 2013, which provided further clarification on what is required to facilitate the submission of responsive and complete CIS requests.

## II. Applicability

This PAL applies to all organizations funded/designated under the Health Resources and Services Administration's (HRSA) Health Center Program, which includes those with health service delivery grants awarded under section 330 of the Public Health Service (PHS) Act and designated look-alike entities, collectively referred to in this document as "health centers." However, the PAL notes where processes vary between grantees and look-alikes.

## III. Background on Change in Scope Planning and Preparation

Alignment of the Electronic Handbooks system's (EHB) CIS process with existing scope policies will facilitate the effective and timely submission, review and, if appropriate, approval of CIS requests. *Policy Information Notice (PIN) 2008-01: Defining Scope of Project and Policy for Requesting Changes* and *PIN 2009-03: Technical Revision to PIN 08-01, Defining Scope of Project and Policy for Requesting Changes*<sup>2</sup> establish the process and timeline for CIS prior approval.

As a reminder, health centers should review the applicable CIS Checklist, including the Assurances section<sup>3</sup>, in EHB to ensure each CIS request is complete and responsive prior to submission.

<sup>1</sup> Available at <http://bphc.hrsa.gov/policiesregulations/policies/pal201303.html>.

<sup>2</sup> Available at <http://bphc.hrsa.gov/policiesregulations/policies/pin200801.html> and <http://bphc.hrsa.gov/policiesregulations/policies/pin200903technical.html>.

<sup>3</sup> Previews of CIS Checklists are available at <http://bphc.hrsa.gov/about/requirements/scope/>.

#### IV. Submission and Review<sup>4</sup>

- **Health Center CIS Submission**

- **Initial Submission:** As stated in PIN 2008-01, health centers should submit **complete and comprehensive** CIS requests **at least** 60 days in advance of their desired implementation date for changes in scope for service delivery sites and services provided. A CIS request is complete if it includes all necessary information for HRSA review. HRSA may request clarifying and/or additional information (via a Change Request in EHB) when information necessary to review the application is not included in the original submission. Returned CIS requests will result in an extended review timeframe to account for any additional time necessary for health center submission of clarifying information and for subsequent HRSA review.
- **Deactivation of Inactive CIS Requests:** In order to ensure the submission of accurate and up-to-date CIS requests, HRSA will automatically deactivate a CIS request, converting the request to a read-only format, when there have been 60 days of inactivity (i.e., no opening or editing) of the request in EHB. HRSA will send EHB notifications/alerts to health centers with CIS submissions that are nearing potential deactivation. When HRSA deactivates a CIS request, the health center will have to submit a new CIS request in order to propose this change in scope for HRSA's consideration.

- **HRSA Review**

- **Standard Time for HRSA Review:** HRSA will notify the health center of its final decision within 60 days of receiving a **complete** CIS request submission, notwithstanding the exceptions referenced below.
  - **Additional Time for HRSA Review:** In unique cases, HRSA may extend the review period beyond 60 days if additional analysis is warranted. For example, in cases where potential service area overlap concerns are identified, additional consultation may add time to HRSA's review. In such cases, HRSA will notify the health center of the extended review timeline within the initial 60-day review period.
- **Change Request:** As noted above, if additional information or clarification is needed, the Project Officer will notify the health center of the deficiencies (via a Change Request in EHB), and the health center will be given up to 60 days to provide the requested information. The HRSA 60-day review period will begin anew upon receiving the re-submission. If the health center does not resubmit by the end of 60 days, HRSA will deactivate the CIS request, converting the request to a read-only format. When HRSA deactivates a CIS request, the health center will have to submit a new CIS request in order to propose this change in scope for HRSA's consideration.

#### V. Effective Date of an Approved Change in Scope and HRSA Notification

This PAL clarifies that the effective date for a change in scope will correspond to the date that the Bureau of Primary Health Care (BPHC) recommends approval of the CIS request in EHB. If the CIS is approved, HRSA will notify the health center of HRSA's decision in accordance with the following:

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<sup>4</sup> HRSA acknowledges that there may be rare time-sensitive cases that preclude the health center from following the timeline described in this PAL. In these cases, the health center should contact their Project Officer as soon as possible and prior to CIS request submission.

- For grantees, HRSA will issue a Notice of Award (NoA). The date BPHC recommends approval will be the effective date of the approved change in scope and this date will be populated in a term approving the CIS on a NoA (pending verification – see Section VI of this PAL).
- For look-alikes, HRSA will issue a notification via EHB. The date of BPHC approval will be the effective date of the approved change in scope and HRSA will include this date approving the CIS in the EHB notification (pending verification – see Section VI of this PAL).

If the CIS is disapproved, HRSA will inform both grantees and look-alikes via an EHB notification.

## **VI. Implementation and Verification**

HRSA expects health centers to implement approved changes (e.g., open the approved site or begin providing the approved new service) within 120 days of receiving the NoA or HRSA notification approving the change.<sup>5</sup>

As described in *PAL 2009-11: New Scope Verification Process*<sup>6</sup>, grantees must verify when they implement the CIS by responding to the Scope Verification submission within the EHB system for HRSA acknowledgement. Grantees may submit this Scope Verification upon receipt of the NoA and, when applicable, may select an implementation date as early as the effective date of the approved CIS. Once verified, HRSA will issue a new NoA noting the implemented date of the CIS. This verification step **MUST** be completed for any addition or deletion of a site or service to be officially documented in the grantee's approved scope of project.

Look-alikes should consult with their Project Officer regarding the verification process outside of the EHB system.

## **VII. Additional Considerations**

Key benefits that health centers should consider and/or actively plan to address prior to requesting a CIS include Medicaid and Medicare FQHC reimbursement, Federal Tort Claims Act coverage (eligible to grantees only), and 340B Drug Pricing benefits for a specific site/service, as appropriate.<sup>7</sup> Health centers should be aware of these other programs' requirements and how the approval date and/or implemented date of the CIS may impact eligibility/participation in those programs.

## **VIII. Technical Assistance and Contact Information**

Information on submitting a CIS request, including the PINs and PALs cited above, is available at <http://bphc.hrsa.gov/about/requirements/scope/>.

If you have questions or require additional assistance regarding an individual CIS request, please contact your Project Officer.

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<sup>5</sup> If a health center determines it is unable to implement the change in 120 days, an extension may be possible via EHB, contingent upon HRSA review. Refer to *PAL 2009-11: New Scope Verification Process* for more information.

<sup>6</sup> Available at <http://bphc.hrsa.gov/policiesregulations/policies/pal200911verification.html>.

<sup>7</sup> While identification within a scope of project is required for participation in these programs, it is not a guarantee that these benefits will be realized. Each of these programs has a specific application process and a comprehensive set of requirements, of which scope of project is only one.