Assurances:

- € <u>I certify that the following statements related to the preparation of this Change in Scope (CIS)</u> request are true, complete and accurate:
 - This CIS request is complete and responsive to all applicable criteria relating to the CIS checklist. Refer to http://www.bphc.hrsa.gov/programrequirements/scope.html for all applicable policies and guidance.
 - The health center consulted with its Project Officer prior to submitting this CIS request.
 - The proposed CIS implementation date is at least 60 days from the submission date to HRSA.
 Note: HRSA recognizes that there may be circumstances where submitting a CIS request at least 60 days in advance of the desired implementation date may not be possible; however, the goal is to minimize these occurrences through careful planning. Refer to http://www.bphc.hrsa.gov/policiesregulations/policies/pdfs/pal201410.pdf)
 - The health center's governing board approved this CIS request prior to submission to HRSA, as documented in board minutes (must be made available upon request).
 - The health center has examined the potential impact of this CIS under the requirements of other programs as applicable (e.g., 340B Program, FTCA).
 - The health center understands that HRSA will consider its current compliance with Health

 Center Program requirements and regulations (i.e., the status and number of any progressive action conditions) when making a decision on this CIS request. (See PAL: 2014-08 Health Center Program Requirements Oversight for more information on progressive action).
- € I will ensure the health center complies with the following statements related to the implementation of this Change in Scope (CIS) request, if approved:
 - All Health Center Program requirements
 (http://www.bphc.hrsa.gov/programrequirements/index.html) will apply to this CIS. Note:
 Compliance with Health Center Program requirements across sites and services will be assessed through all appropriate means, including site visits and application reviews.

Checklist for Adding a New Service

- This CIS will be undertaken directly by or on behalf of the health center for the benefit of the current or proposed health center patient population, and the health center's governing board will retain oversight over the provision of any services and/or sites.
- This CIS will be accomplished without additional Health Center Program Federal award funding and will not shift resources away from carrying out the current HRSA-approved scope of project.
- The impact of this CIS will be reflected in the total budget submitted with the health center's next annual competing or non-competing or designation application.
- This CIS will be implemented and verified within 120 days of receiving the NoA or HRSA notification approving the change. Refer to http://www.bphc.hrsa.gov/policiesregulations/policies/pdfs/pal201410.pdf.
- This CIS will not diminish the patient population's access to and quality of services currently provided by the health center.
- No additional changes in scope are necessary to implement this CIS (e.g., approval of a new site does not entail approval of any new services to be provided at the new site).
- The health center will take all applicable steps related to the requirements of other programs impacted by this change in scope request.

Change in Scope Questions:

Is this request to add a service linked to another recently submitted, in progress or planned CIS request? (e.g., the health center will be adding a new site where this service will be provided) – Y/N – require text box explanation if Y

- 1. OVERVIEW: Provide a brief description of:
 - The proposed service to be added (reference the Form 5A Service Descriptors);
 - The level of services requested. Include a summary of typical services, consults and procedures to be provided and/or attach a copy of the providers' privileging list.
 - Staff that would be involved in providing the service (providers, contractors, and/or support

Checklist for Adding a New Service

staff)

Requires narrative response.

<u> Optional Attachment: Privileging List</u>

Proposed Date of Service Addition: mm/dd/yyyy

Note: Please review Program Assistance Letter 2014-10: Updated Process for Change in Scope Submission, Review and Approval Timelines and Policy Information Notice 2008-01: Defining Scope of Project and Policy for Requesting Changes. In cases where a health center is not able to determine the exact date by which a CIS will be fully accomplished, BPHC will allow up to 120 days following the date of the CIS approval Notice of Award (NoA) or look-alike Notice of Look-Alike Designation (NLD) for the health center to implement the change (e.g., begin providing a new service). Review Program Assistance Letter 2009-11: New Scope Verification Process for more information.

- 2. <u>NEED & UTILIZATION: Discuss why and how the addition of the proposed service will meet the</u> health needs of the population served by the health center.
- a. How was the need for the proposed service identified? (check all that apply) Checkboxes €UDS trend data and/or a needs assessment indicate a high need for the service.
 - €Community-based data such as survey, focus group, request from community group, etc., indicate a high need for the service.
 - €An existing provider is closing a site and/or is no longer offering the service to the patient population.
 - €Other describe: requires narrative response
- b. Provide evidence that the proposed service will meet the health needs of the population served by the health center. Provide data only for the new service.

Total number of patients projected to be served annually:

New patients

Existing patients

Of the total projected patients, anticipated % of patients with incomes at or below 200% of the Federal Poverty Guidelines:

Briefly explain how these projections were derived:

- c. Using the most recent UDS data and/or other data specific for the patient population and/or service area, describe any demographic characteristics (e.g., age range, gender(s), race/ethnicity) and associated risk factors (e.g., occupational, environmental, behavioral, social/cultural, housing status) that demonstrate the need for and/or benefit of the proposed service.
 Requires narrative response
- d. If specialty selected on 5A

Checklist for Adding a New Service

Specialty Service and Support of Primary Care: Discuss how the proposed specialty service will:

- Support the provision of the health center's required primary care services; and
- Function as a logical extension of these required primary care services.

Note that not all specialist care is appropriate for inclusion within the federal Health Center Program scope of project (e.g., inpatient/hospital-based services such as critical care and chemotherapy infusion).

Requires narrative response

- e. ACCESS FOR CURRENT PATIENTS: Demonstrate how the health center will ensure all current patients will have access to the proposed new service. Check all that apply. Multiple choice checkboxes.
 - € This service is being provided at all existing site(s)
 - € Provider(s) will travel between sites
 - € Patient transportation will be provided between sites
 - € Patient transportation will be provided to a non-health center site
 - € Other please describe: requires narrative response
- f. ACCESS FOR NEW PATIENTS: Describe how the health center will ensure any new patients accessing this new service will have access to the health center's existing in scope services (including coordination with primary care providers of new patients, if applicable).

Requires narrative response.

3. SERVICE DELIVERY METHOD AND LOCATION (not required if health center is proposing to provide the service directly via Column I)

For Services Provided via Formal Written Agreement With the Health Center (Form 5A, Column II):

For a proposed service provided via a Formal Written Agreement (where the health center is accountable for paying/billing for the direct care provided via the agreement – generally under a contract), describe:

- The activities to be performed by the contractor/provider in the provision of the service;
- How the services provided under the agreement will be documented in the health center patient record; and
- How the health center will bill and/or pay for these services provided to health center patients.

Requires narrative response

No attachment requested/required

For Services Provided via Formal Written Referral Arrangement With the Health Center (Form 5A, Column III):

For a proposed service provided via a **Formal Written Referral Arrangement** (where the referral is within the scope of project but the actual service is provided and paid/billed for by another entity (the referral provider) and thus the service itself is NOT included in the health center's scope of project

Checklist for Adding a New Service

(Note: The establishment of the actual referral arrangement and any follow-up care provided by the health center subsequent to the referral are included in scope), describe:

- How the referral arrangement is documented (i.e., via an MOU, MOA, or other formal agreement);
- How the referral arrangement addresses the manner by which the referral will be made and managed; and
- How the referral arrangement addresses the tracking and referral of patients back to the health center for appropriate follow-up care.

Requires narrative response

No attachment requested/required

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0285. Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 14N-39, Rockville, Maryland, 20857.

Change Checklist DEPARTMENT OF HEALTH AND HUMAN SERVICES Health Resources and Services Administration CHECKLIST FOR ADDING A SERVICE (CHKLST001) CIS Tracking Number: Questions for Addition of Service(s) Unless otherwise noted, responses are required for all questions when requesting to add a Required OR Additional (including Specialty) Service.

In t	his CIS request, you have proposed to add the following service to scope:
₩h	en do you plan to start providing the service(s)?
	(mm/dd/yyyy):
Res	NEED Spond to ALL of the following questions to clearly address why and how the addition of the proposed service will address met need and further the mission of the health center by maintaining or increasing access and maintaining or improving ality of care for the target population.
	1a. How was the need for the proposed service identified (check all that apply)?
	UDS Trend Data and/or a needs assessment indicated a high need for services. UDS Data Year (20) Needs assessment completed on (mm/dd/yyyy): Community asked us to provide the service and provided supporting needs data. An existing clinic is closing and/or a referral provider is no longer offering the service to our patients and we wish to offer the service directly.
	Other (Describe): Maximum paragraph(s) allowed approximately: 3 (3000 character(s) remaining) I a second control of the cont
	1b. Using the most recent UDS data and/or other data specific to your target population and/or service area, describe any demographic characteristics of the current patient and/or target population (e.g. age range and gender(s), and race/ethnicity, as appropriate) that support the need for and/or benefit of the proposed service.

Maximum paragraph(s) allowed approximately: 3 (3000 character(s) remaining)



1c. Using the most recent UDS data and/or other data specific to your target population and/or service area, describe any risk factors within the current patient and/or target population not already noted in the demographic characteristics (e.g., occupational, environmental, behavioral, social/cultural, or housing status) that support the need for and/or benefit of the proposed service.

Maximum paragraph(s) allowed approximately: 3 (3000 character(s) remaining)



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ONLY APPLICABLE FOR ADDITIONAL SERVICES, INCLUDING SPECIALTY SERVICES

2. MAINTENANCE OF CURRENT SERVICE CAPACITY

Clearly address how adding this service will NOT eliminate or reduce access to a required service; and/or result in the diminution of the health center's total level or quality of health services currently provided to the target population by addressing ALL of the following questions.

2a. Describe your <u>current capacity and ability, utilizing at minimum the most recent UDS data available, to provide all REQUIRED primary care services (e.g. Preventive Dental, OB/GYN, etc.) either directly and/or through formal arrangements, to the target population (e.g. Is the health center at capacity for preventive dental visits?).</u>

Maximum paragraph(s) allowed approximately: 3 (3000 character(s) remaining)

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1	P P

2b. Specifically, utilizing at minimum the most recent UDS data available and if necessary, other data sources specific to your target population and/or service area, demonstrate why this proposed service has been determined to be a <u>priority</u> over any other area of unmet need (e.g. why is the health center adding this particular Additional Service instead of expanding adult preventive dental services?).

Maximum paragraph(s) allowed approximately: 3 (3000 character(s) remaining)



ONLY APPLICABLE FOR ADDITIONAL SERVICES, INCLUDING SPECIALTY SERVICES

3. PROJECTED SERVICE UTILIZATION

Provide evidence that the proposed service will appropriately focus on the current patient and/or target population by providing the following information about the population that will utilize the new service.

3a.Number of patients projected to be served annually

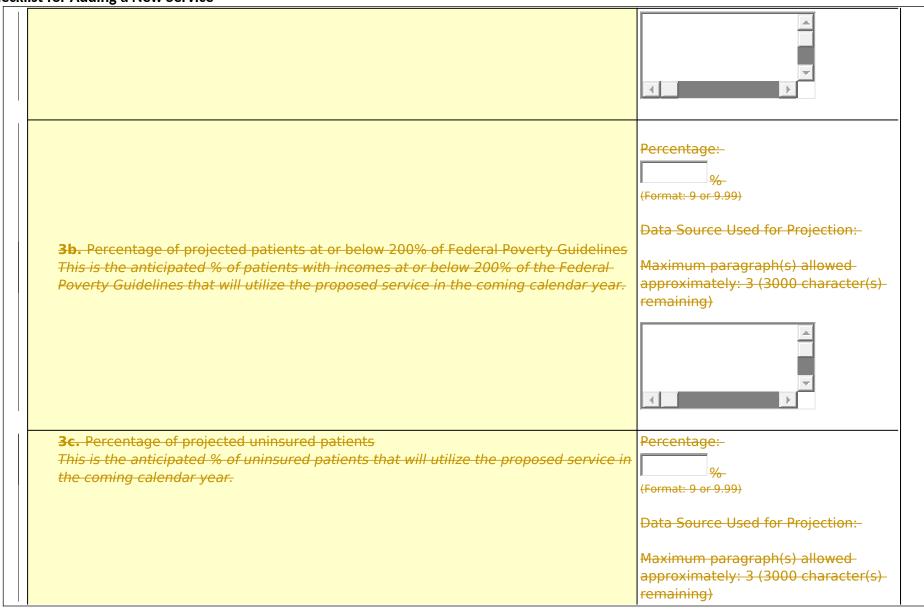
This is the anticipated number of patients that will utilize the proposed service in the coming calendar year.

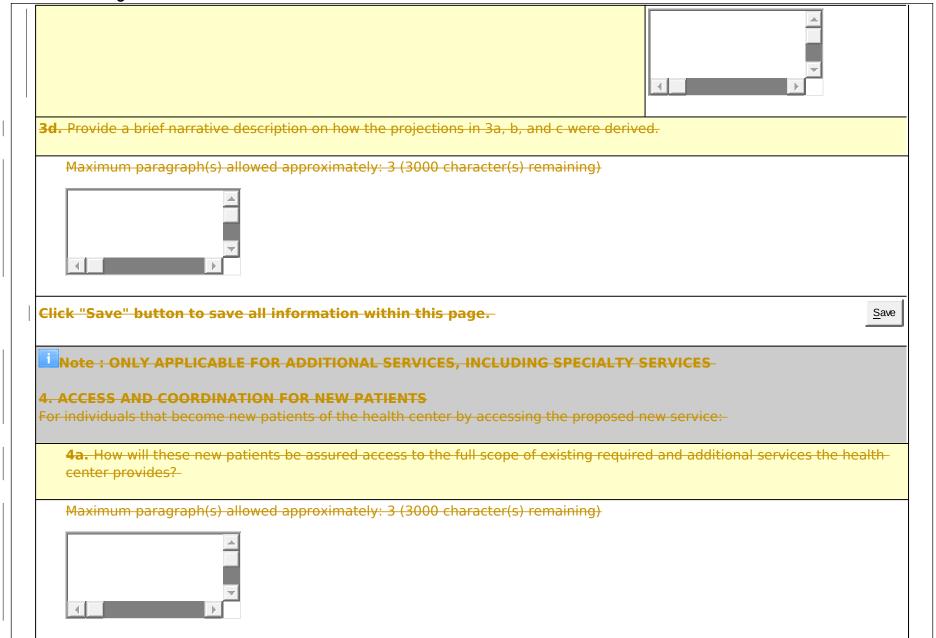
Number:

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Data Source Used for Projection:

Maximum paragraph(s) allowed approximately: 3 (3000 character(s) remaining)





	patients have existing (non-health center) primary care providers, describe how the health center will coordinate up with such providers.
Maximum	paragraph(s) allowed approximately: 3 (3000 character(s) remaining)
5. ACCESS TO	NEW SERVICE FOR CURRENT PATIENTS
Describe the happropriate.	ealth center's plans to assure all patients will have reasonable access to the proposed new service, as
Maximum	paragraph(s) allowed approximately: 3 (3000 character(s) remaining)
4	
	EE-DISCOUNT PROGRAM-
	center offer <u>its current</u> sliding fee discount program <u>(sliding fee discount schedule, including any nominal fees</u> plementing policies and procedures) for the proposed service to patients with incomes at or below 200 percent o
	verty Guidelines, and ensure that no patients will be denied access to the service due to inability to pay?
O Yes O	No No
6a. Will th	e sliding fee discount schedule for the proposed service differ from the health center's existing sliding fee discour)?

	Sliding	Fee Discount Sch	nedule (Maximum 6 at	ttachments)	· 	
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330 how	Health adequa	Center Program f ate revenue will b	unds. Specifically (reference	cing the att	ached Financial Impact	sustained without additional section and section and section are section as necessary) described share of overhead costs incurred
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Maximum paragraph(s) allowed approximately: 3 (3000 character(s) remaining)



7b. Is this change in scope dependent upon any special grant, foundation or other funding that is time-limited, e.g., will only be available for 1 or 2 years?



If Yes, how will the new service be supported and sustained when these funds are no longer available? Describe a clear planfor sustaining the service.

All time-limited or special one-time funds should be clearly identified as such in the Financial Impact Analysis.

Maximum paragraph(s) allowed approximately: 3 (3000 character(s) remaining)



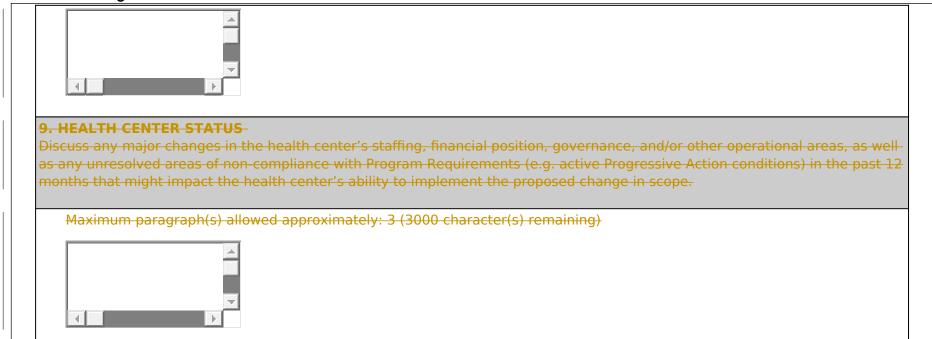
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8. STAFFING

Provide a clear and comprehensive description of the relevant staffing arrangements made to support the proposed new service and to ensure staffing is/will be sufficient to meet any projected patient/visit increases. (The discussion of "staffing" should include non-health center employees if the service will be provided via contract/contracted providers or subrecipient arrangements.) In addition, describe any potential impact on the overall organization's staffing plan (reference the Financial Impact Analysis as applicable).

Maximum paragraph(s) allowed approximately: 3 (3000 character(s) remaining)



10. CREDENTIALING AND PRIVILEGING

How has the health center planned for the appropriate credentialing and privileging of the provider(s) that will provide the proposed service in accordance with PIN 2002-22?

In responding, consider the following:

- It is the responsibility of the health center to ensure that all credentialing and privileging of providers have been completed BEFORE providing the service as part of their Federal scope of project. This includes services provided either Directly (Column I) OR via a (Column II) Formal Written Agreement (e.g. contract). For services provided via a Formal Written Referral Arrangement (Column III), the referral provider should be able to assure (within the arrangement) to the health center that all their providers are appropriately credentialed and privileged individually.
- The health center's current board approved policy must cover the required verification of credentials and establishment of privileges to perform any new activities and procedures expected of providers by the health center or be updated to do so (for services provided either Directly (Column I) OR via a (Column II) Formal Written Agreement). In addition, a new or updated privileging list approved by the Clinical Director/Chief Medical Officer or other appropriate Clinical Leadership that delineates the specific services and procedures that the provider is privileged to provide on behalf of the health center (i.e. specific to the health center and not other organizations where the provider might serve patients e.g. hospitals) must also be in place.

Maximum paragraph(s) allowed approximately: 3 (3000 character(s) remaining)



Attach the relevant <u>Clinical Director/Chief Medical Officer-approved</u> Privileging Lists. Note that the attached Privileging Lists <u>Must Address:</u>

- Typical level of services to be provided on behalf of the health center (e.g. consults vs. procedures and/or a specific list of services)
- Typical procedures to be provided as part of the service on behalf of the health center (i.e. a specific list of procedures)

MEDICAL DIRECTOR/CMO-APPROVED PRIVILEGING LIST(S) (Maximum 6 attachments)

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11. QUALITY IMPROVEMENT/ASSURANCE PLAN-

How will the proposed new service be integrated into and assessed via the health center's quality improvement/assurance and risk management plans? In responding, address the following:

- Will it be integrated into the QI/ QA plan using existing performance measures be applied to the service or will new measures be created specifically for the new service?
- Are board approved peer and chart review policies in place by which any provider(s) of the proposed new service will be assessed?
- Are risk management plans in place to assure the new service has appropriate liability coverage (e.g. non-medical/dental professional liability coverage, general liability coverage, automobile and collision coverage, fire coverage, theft-coverage, etc.)?

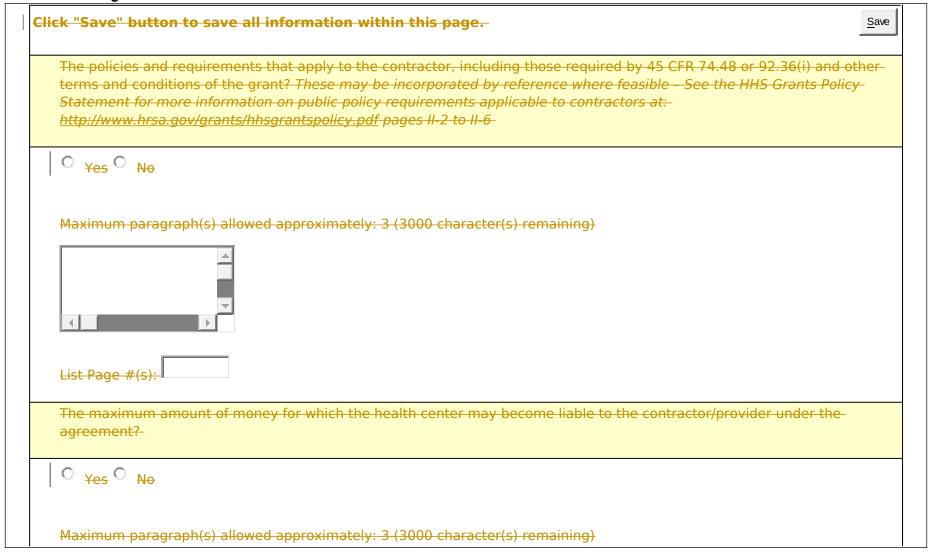
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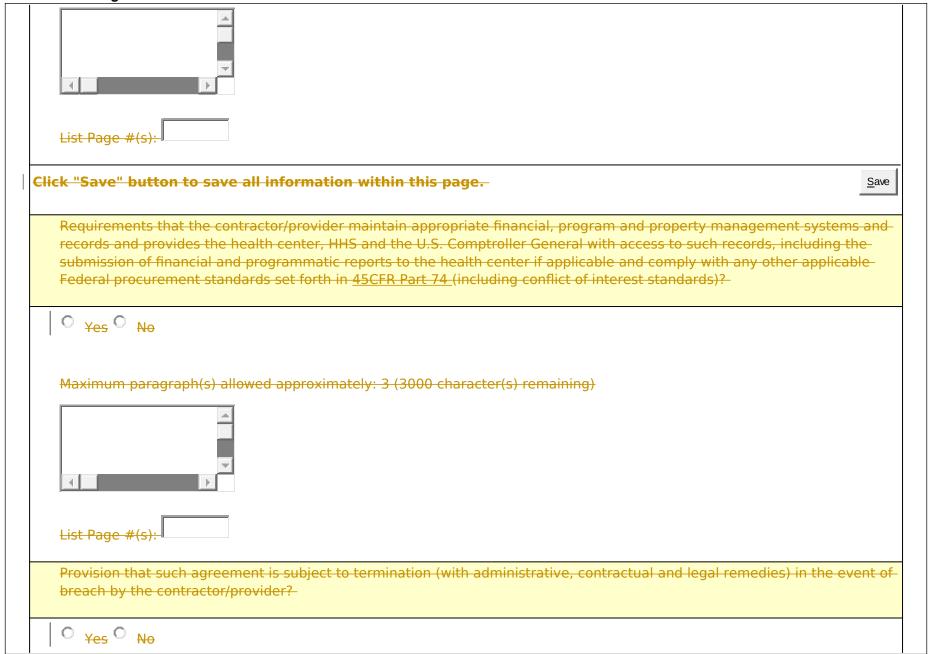
12. SERVICE DELIVERY METHOD AND LOCATION

12a. If the proposed service will be provided via a **Formal Written Agreement (Form 5A, Column II)** where the health center is accountable for paying/billing for the direct care provided via the agreement (generally a contract) – does the formal written agreement between the health center and the contractor/provider(s) state, address or include:

The activities to be performed by the contractor/provider in the provision of the service, specifically including:
 How the services provided will be documented in the health center patient record? How the health center will bill and/or pay for these services provided to health center patients?
O Yes O No
Maximum paragraph(s) allowed approximately: 3 (3000 character(s) remaining)
List Page #(s):
The time schedule for such activities (e.g. provider hours/schedule)?
O Yes O No
Maximum paragraph(s) allowed approximately: 3 (3000 character(s) remaining)
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List Page #(s):
Provisions consistent with the health center's board approved procurement policies and procedures in accordance with 45CFR Part 74.41-48?
○ Yes ○ No
Maximum paragraph(s) allowed approximately: 3 (3000 character(s) remaining)
List Page #(s):
Assurances that no provisions will affect the health center's overall responsibility for the direction of the services to be provided and accountability to the Federal government by reserving sufficient rights and control over the services to the health center to enable it to fulfill its responsibilities?
○ Yes ○ No
Maximum paragraph(s) allowed approximately: 3 (3000 character(s) remaining)



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included in the health center's scope of project but the establishment of the actual referral arrangement and any follow-upcare provided by the health center subsequent to the referral are included in scope – is the proposed referred service: Documented via an MOU, MOA, or other formal agreement that at a minimum describes the manner by which the referralwill be made and managed, and the process for tracking and referring patients back to the health center for appropriate follow-up care? O Yes O No Maximum paragraph(s) allowed approximately: 3 (3000 character(s) remaining) List Page #(s): Available equally to all health center patients, regardless of ability to pay? O Yes O No Maximum paragraph(s) allowed approximately: 3 (3000 character(s) remaining)

	Service Delivery Method and Location B (Maximum 6 attachments)					
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The service must be provided at an approved site within the scope of project, a proposed new site with reasonable access to all available services in the health center's scope of project, or at a location where in-scope services or referrals are provided but that does not meet the definition of a service site.

ADDITION OF SPECIALTY SERVICES ONLY APPLICABLE TO SPECIALTY SERVICES THAT WILL BE PROVIDED DIRECTLY AND/OR THROUGH FORMAL WRITTEN AGREEMENTS (FORM 5A COLUMNS I AND/OR II)

In this CIS request, you have proposed to add the following specialty service to scope: Service has not been selected.

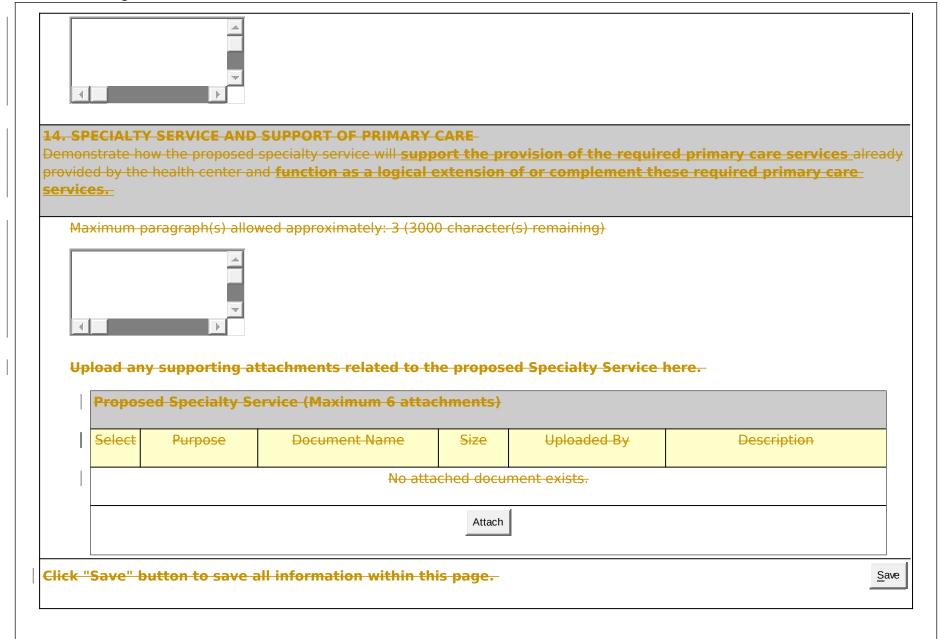
If the proposed specialty service is approved for addition to the scope of project, health centers are reminded that the full range of services within a specialist's area of expertise may or may not be within the Federal scope of project. Rather ONLY those specific aspects of the specialty service as described within this change in scope request will be considered included within the approved scope of project.

13. SPECIALTY SERVICE DESCRIPTION

Describe the proposed specialty service; address all of the following elements.

- The specialty area (e.g., endocrinology, ophthalmology)
- IF NOT ALREADY ADDRESSED IN QUESTION 8, discuss the specific level of staffing necessary to implement the proposed specialty service, in particular whether additional staff (above and beyond the specialist provider, e.g. nurses, additional medical assistants) and/or equipment (e.g. echocardiogram) will need to be added to scope and supported under the health center's budget in order to implement the Specialty Service. As a reminder, these costs should be appropriately reflected in the change in scope Financial Impact Analysis.

Maximum paragraph(s) allowed approximately: 3 (3000 character(s) remaining)



developed a plan for medical malpractice coverage?

Additional Considerations for Adding a Service to Scope While the following areas are not specific factors or criteria that will impact the CIS approval process, these are key elements that health centers should have considered or actively planned to address prior to adding a newservice to scope: A. Medical Malpractice Coverage Your health center must develop plans for medical malpractice coverage for any new providers including any specialty providers (e.g., extension of FTCA coverage, private malpractice coverage). Respond the following as applicable: For grantees deemed under the FTCA, have you reviewed the FTCA Health Center Policy Manual or if appropriate, consulted with BPHC to assure the applicability of FTCA coverage? The FTCA Health Center Policy Manual is available at: http://www.bphc.hrsa.gov/policiesregulations/policies/pin201101.html Forspecific questions, contact the BPHC HelpLine at: 1-877-974-BPHC (2742) or Email: bphchelpline@hrsa.gov. Available Monday to Friday (excluding Federal holidays), from 8:30 AM - 5:30 PM (ET), with extra hours available during high volume periods. Yes Not Applicable, health center is not deemed or FTCA coverage does not apply. If you selected "Not Applicable" respond to the question below. For health centers not deemed under the FTCA or if FTCA coverage is not applicable to the service, have you

C Yes C No

Briefly explain your response:

Maximum paragraph(s) allowed approximately: 3 (3000 character(s) remaining)



B. Section 340B Drug Pricing Program Participation: Health centers that participate in the 340B Drug Pricing Program are reminded that changes to the scope of project approved by BPHC do not automatically update within the 340B Program's Database. Health centers should contact the HRSA Office of Pharmacy Affairs to determine whether any updates to the 340 Database are necessary by contacting Apexus Answers at 888-340-2787, or Apexus Answers@340bpvp.com.

Will your health center complete all necessary 340B Program updates with the HRSA Office of Pharmacy Affairs?

Yes Not Applicable, health center does not participate in the 340B program

Briefly explain your response:

Maximum paragraph(s) allowed approximately: 3 (3000 character(s) remaining)

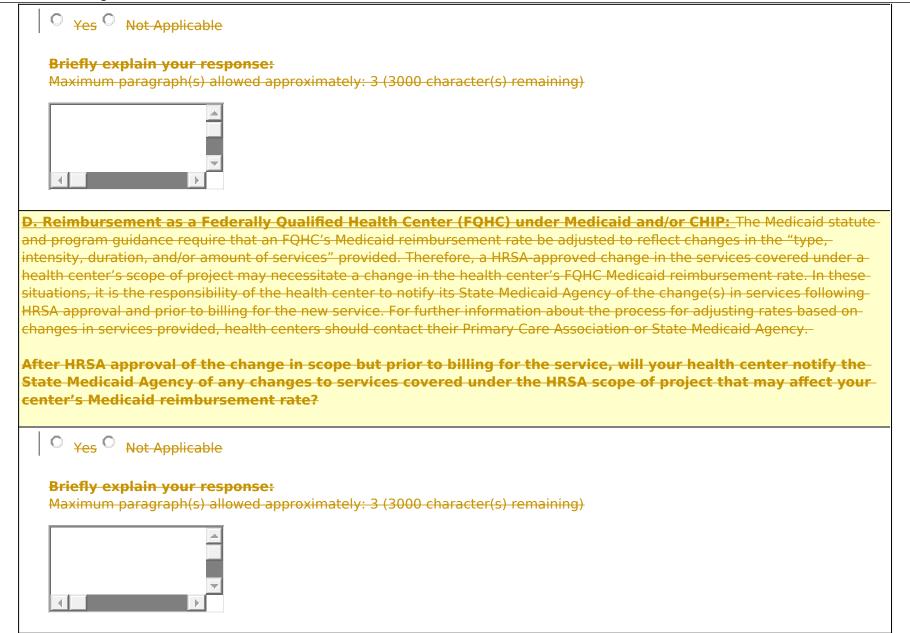


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C. Facility Requirements:

Has your health center assured that any/all Federal, State and local standards/accreditation requirements of the facility where the proposed new service will be provided have been fully met (including those associated with CMS FQHC certification)?



Checklist for Adding a New Service	
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