

PROGRAM ASSISTANCE LETTER

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Center Scope of Project

TO: Health Centers

Primary Care Associations

National Health Center Training and Technical Assistance Partners

Health Center Controlled Networks

I. PURPOSE

This Program Assistance Letter (PAL) highlights some of the important issues for health centers to consider when utilizing telehealth as a means to increase access to care for health center patients. It also provides clarifying information to health centers on the utilization and documentation of telehealth within the scope of project.

Telehealth is a rapidly changing area of health care that will impact Health Center Program policy over time. Therefore, this document is not exhaustive and does not cover all possible aspects of telehealth. This document is based on existing scope policy as outlined in Policy Information
Notice (PIN) 2008-01: Defining Scope of Project and Policy for Requesting Changes, and does not reflect a new program or policy from the Health Resources and Services Administration (HRSA). It also does not reflect any temporary changes HRSA makes to established policy that occur in response to declared emergencies. All Health Center Program requirements apply to the entire health center scope of project, regardless of whether telehealth is used.

II. APPLICABILITY

This PAL applies to all organizations funded/designated under the 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."

III. BACKGROUND

The provision of health care via telehealth¹ is a mechanism to increase access to health care services by allowing health care providers to assess, diagnose, and treat patients without requiring both individuals to be physically co-located. Health centers are increasingly using telehealth as a means of delivering comprehensive primary care services to health center patients. In addition, the range of health services that may be provided through telehealth has expanded along with the role of technology in improving and coordinating care.

Within the context of the Health Center Program scope of project, "telehealth" is not a service or a service delivery method³ requiring specific HRSA approval; rather, telehealth is a mechanism or means for delivering a health service(s) to health center patients using telecommunications technology or equipment.⁴ As such, health centers are not required to seek prior approval from HRSA for a change in scope to use telehealth, nor separately record the use of telehealth as the means, to deliver a service that is already in scope on Form 5A: Services Provided or to explicitly indicate the use of telehealth on Form 5A.

HRSA supports the use of telehealth to enhance patient access and early intervention that may improve clinical outcomes, provider efficiency and quality of care, and potentially reduce the need for hospitalization. The use of telehealth as a service delivery mechanism also involves complex issues relating to, among others, provider licensure, informed consent, fraud and abuse laws, the corporate practice of medicine, standard of care, and liability concerns.

IV. PLANNING CONSIDERATIONS

HRSA strongly encourages health centers that provide or are planning to provide health services via telehealth to consult with professional organizations, regulatory bodies, and private counsel to help assess, develop, and maintain written telehealth policies that are compliant with Health Center Program requirements; federal, state, and local requirements; and applicable standards of practice. Likewise, HRSA encourages health centers to consider the range of issues that would support successful implementation of telehealth, which may include the following:

• <u>Provider Licensure/Scope of Practice</u>: Complying with standards of care/practice and all applicable federal, state, and/or local requirements regarding provider licensure and scope

https://bphc.hrsa.gov/programrequirements/scope/form5aservicedescriptors.pdf

http://bphc.hrsa.gov/about/requirements/scope/form5acolumndescriptors.pdf

¹ For ease of reference this resource will utilize the term "telehealth" throughout to refer to both telehealth and telemedicine.

² See Form 5A Services Descriptor Resource at:

³ See Form 5A Column Descriptor Resource at:

⁴ This resource does not address provider-to-provider telephone or email consultations concerning health center patients.

⁵ For services provided by health centers to be considered in-scope, they must be fully compliant with all Health Center Program requirements.

⁶ This list does not address all health center legal or clinical responsibilities related to the provision of services via telehealth.

of practice, including those that may apply to staff, with particular consideration for requirements and limitations applicable to the use of telehealth to provide services across state lines.

- <u>Facility Licensing Requirements</u>: Complying with all applicable federal, state, and/or local standards/accreditation and licensing requirements related to telehealth that may apply to the locations/facilities where health services will be provided via telehealth.
- <u>Equipment/Training</u>: Utilizing the appropriate equipment, internet security, and connectivity required for telehealth, with staff appropriately trained to operate such equipment.
- <u>Privacy/Confidentiality</u>: Maintaining the confidentiality of patient information and records, including all information as to personal facts and circumstances obtained by the health center staff about recipients of services delivered via telehealth.
- Medical Records: Documenting services provided via telehealth in the health center patient's medical records and, as applicable, reporting related data in the HRSA Uniform Data System (UDS).
- <u>Patient Consent</u>: Considering how patients will be fully informed about and consent to the delivery of health services via telehealth.
- <u>Billing and Third Party Payments</u>: Complying with any requirements associated with billing and reimbursement⁷ for telehealth visits/activities, including those imposed by states or third party payor sources (e.g., Medicare, Medicaid, 8 Children's Health Insurance Program (CHIP), private insurance).
- <u>Liability Coverage</u>: Obtaining appropriate malpractice and/or other liability coverage, including, in the case of Federal Tort Claims Act (FTCA) deemed health centers, gap coverage for services that are not provided or that may reasonably be considered not to have been provided on behalf of the health center or otherwise within the scope of the provider's or the health center's deemed federal employment.

V. GENERAL GUIDELINES FOR SERVICES PROVIDED VIA TELEHEALTH

Health centers may use telehealth as a means of delivering comprehensive primary care services to health center patients consistent with the considerations listed above. Current scope of project policy, outlined in PIN 2008-01: Defining Scope of Project and Policy for Requesting Changes, provides the parameters of what may be included in a health center's scope of project and how to accurately document services and related sites in a health center's scope of project.

⁷ Health centers would contact their Medicare Administrative Contractor and state Medicaid/CHIP agency to determine if the telehealth service/arrangement is a billable service under these programs.

⁸ For additional information, see https://www.medicaid.gov/medicaid/benefits/telemed/index.html.

⁹ Deemed health centers should review the FTCA Health Center Policy Manual (see https://bphc.hrsa.gov/ftca/healthcenters/healthcenterpolicies.html) and may wish to consult with HRSA regarding general policy issues and/or with private counsel regarding ensuring appropriate liability protection.

¹⁰ See 42 U.S.C. 233(g)-(n) and (q), 42 C.F.R. part 6, and the FTCA Health Center Policy Manual.

A. SERVICES

Services and service delivery methods documented on Form 5A: Services Provided as outlined in PIN 2008-01 are included in the health center's scope of project and can be provided using telehealth. Health centers are not required to seek prior approval from HRSA for a change in scope to use telehealth or separately record the use of telehealth as the means by which an inscope service is delivered.

Supportive activities (e.g., taking vital signs, monitoring an EKG, operating a monitor) provided by health center clinical staff to facilitate a service provided via telehealth for a health center patient are considered part of general primary medical care and within the health center's scope of project. Therefore, supportive activities do not require additional documentation in the scope of project.

B. SITES

Service sites as described in current policy in PIN 2008-01 are defined as locations where all of the following conditions are met and may also be locations where services are delivered or received via telehealth:

- Health center visits are generated by documenting in the patients' records face-to-face contacts between patients and providers;
- Providers exercise independent judgment in the provision of services to the patient;
- Services are provided directly by or on behalf of the grantee, whose governing board retains control and authority over the provision of the services at the location; and
- Services are provided on a regularly scheduled basis (e.g., daily, weekly, first Thursday
 of every month). However, there is no minimum number of hours per week that
 services must be available at an individual site.

Locations where all services are exclusively delivered via telehealth would <u>not</u> meet the "face-to-face" criterion of the service site definition above and therefore, would not be considered service sites under PIN 2008-01.

VI. TELEHEALTH SCENARIOS WITHIN THE HEALTH CENTER SCOPE OF PROJECT

This table indicates¹¹ how health centers would accurately reflect sites, services, and service delivery methods in a health center's scope of project.

¹¹ The absence of a particular scenario from the table does not preclude that activity from potentially being part of the health center's scope of project.

Scenario	Location of Health Center Patient	Location of Provider and Service Delivery Method	Form 5A: Services Provided Scope Documentation	Form 5B: Service Sites Scope Documentation		
A.	Patient and Provider at Different In-Scope Service Sites					
	A health center patient presents at a health center's in-scope service site "X."	A health center staff provider, located at inscope service site "Y," is delivering the service.	The service is recorded in Column I , "Directly by Health Center." 12	Both in-scope service sites (X and Y) are recorded on the health center's Form 5B.		
В.	Patient at In-Scope Service Site, Provider at Another Location					
	A health center patient presents at a health center's in-scope service site "X."	A health center staff provider is delivering the service at a location that is not an in-scope service site. For example, a community facility or the provider's home.	The service is recorded in Column I , "Directly by Health Center."	Only the health center in-scope service site (X) (i.e., where the patient is physically located) is recorded on Form 5B.		
C.	Patient at In-Scope S A health center patient presents at a health center's in-scope service site "X."	The health center pays another provider/entity, with which it has a contractual agreement to deliver the service at a location that is not an in-scope service site.	The service is recorded in Column II , "Formal Written Contract/Agreement," to indicate that the health center pays an outside entity to provide the service to health center patients.	Only the health center in-scope service site (X) (i.e., where the patient is physically located) is recorded on Form 5B.		

 $^{^{12}}$ For more information regarding staff providers vs. individual contractors and how they should be recorded on Form 5A, refer to the Column Descriptor Resource at:

http://bphc.hrsa.gov/about/requirements/scope/form5acolumndescriptors.pdf

Scenario	Location of Health Center Patient	Location of Provider and Service Delivery Method	Form 5A: Services Provided Scope Documentation	Form 5B: Service Sites Scope Documentation	
D.	Patient at In-Scope Service Site, Referral Provider at Another Location				
	A health center patient presents at a health center's in-scope service site "X."	The health center has a formal written referral arrangement ¹³ with another provider/entity to deliver the service from a different location that is not an in-scope service site.	The service is recorded in Column III , "Formal Written Referral Arrangement."	Only the health center in-scope service site (X) (i.e., where the patient is physically located) is recorded on Form 5B.	
E.	Patient at a Location that is not an In-Scope Service Site, Provider at In-Scope Service Site				
	A health center patient presents at a physical location that is not an inscope service site and that is equipped for telehealth. For example, a community facility or a patient's home.	A health center staff provider is delivering the service from an inscope service site "X"	The service is recorded in Column I , "Directly by Health Center."	Only the health center service site (X) (i.e., where the health center provider is physically located) is recorded on Form 5B.	

¹³ Under a formal written referral arrangement (Form 5A, Column III), the health center maintains responsibility for the patient's treatment plan and will be providing, and/or paying/billing for appropriate follow-up care based on the outcome of the referral. Under these types of formal referral arrangements, if the actual service is provided and paid/billed for by another entity, then the service is not included in the health center's scope of project. However, establishment of the referral arrangement and any follow-up care provided by the health center subsequent to the referral is considered to be part of the health center's scope of project.

Scenario	Location of Health Center Patient	Location of Provider and Service Delivery Method	Form 5A: Services Provided Scope Documentation	Form 5B: Service Sites Scope Documentation		
F.	Patient at a Location that is not an in-Scope Service Site, Provider at a Location that is not an					
	In-Scope Service Site					
	A health center	A health center staff	The service is recorded	Neither location is		
	patient presents at	provider is delivering	in Column I , "Directly	recorded on Form		
	a physical location	the service at a location	by Health Center."	5B.		
	that is not an in-	that is not an in-scope				
	scope service site	service site. For				
	and that is	example, a non-health				
	equipped for	center community				
	telehealth. For	facility or the provider's				
	example, a	home.				
	community facility					
	or a patient's					
	home.					
	In Scenarios E and F, the health center would ensure the following: A clear delineation in health center policy of roles and responsibilities for health center staff (e.g., who provides oversight of staff at the community facility, how informed consent of patients to receive care by telehealth is obtained, including ability to opt out of receiving services by telehealth); individuals receiving the service via telehealth are established health center patients; how patients will have reasonable access to the health center's full scope of services; and the health center directly bills/pays for the service(s) provided via telehealth, including providing applicable sliding fee discounts in alignment with Health Center Program requirements.					

VII. TELEHEALTH SCENARIOS OUTSIDE THE HEALTH CENTER PROGRAM SCOPE OF PROJECT

There may be scenarios where health centers engage in telehealth activities that would not be included within the Health Center Program scope of project. For example, a scenario in which a non-health center entity enters into an arrangement to use the health center's telehealth equipment to see non-health center patients would be considered an "Other Line of Business" outside the health center's scope of project.

¹⁴ Other lines of business, which are those conducted <u>outside</u> the Health Center Program scope of project, are not subject to Health Center Program requirements (such as sliding fee scale, UDS reporting, etc.) and also are not eligible for the federal benefits that extend to activities within the health center's scope of project (including the 340B Drug Pricing Program, FTCA coverage under FSHCAA or reimbursement as an FQHC under Medicare/Medicaid/CHIP). For additional information see PIN 2008-01, Section III (page 3).

VIII. CONTACT INFORMATION

For questions or further guidance, please contact the Bureau of Primary Health Care (BPHC) Office of Policy and Program Development at <u>Health Center Program Support</u>. For questions or additional assistance regarding the process for requesting prior approval of changes in scope, please contact your Health Center Program Project Officer.