



Center for Clinical Standards and Quality

Ref: QSO-25-27-RHC

DATE: September 26, 2025

TO: State Survey Agency Directors

FROM: Directors, Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: Rural Health Clinic (RHC) Changes in Regulations for Primary Care Services and Laboratory Requirements

Memorandum Summary

The Centers for Medicare & Medicaid Services (CMS) is revising the survey process following regulatory updates to 42 CFR Part 491 – Provision of Services:

- Updated Process for Provision of Services – Surveyors will no longer review if Rural Health Centers (RHCs) are “primarily engaged” in the delivery of primary care,
- RHCs are no longer required to provide hemoglobin and hematocrit testing or examination of stool specimens for occult blood.
- RHCs do not have to perform "primary culturing" on site, but they are required to collect specimens for culture and transmit them to a certified lab.

Background:

This memo clarifies changes made to 42 CFR 491.9-Provision of Services, that became effective on January 1, 2025. On December 9, 2024, the Centers for Medicare & Medicaid Services (CMS) published the final rule ([89 FR 97710](#)), “Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments,” which included updates to the Rural Health Clinic (RHC) Conditions for Certification (CfCs) located at 42 CFR Part 491.

Discussion:

CMS redesignated the former paragraph §491.9(a)(3) as paragraph (a)(4) and added a new (a)(3), which states, “The RHC must provide primary care services.” This revision removes the need to quantify specialized services or primary care. In regard to primary care, surveyors only need to determine that

some primary care services are provided. Surveyors should cite RHCs that provide no primary care services. This change does not remove the statutory requirement that RHCs cannot be a rehabilitation agency or a facility primarily for the care and treatment of mental diseases. RHCs can provide services that focus on the needs of the community (including behavioral health services) as long as they also meet the primary care needs of their community. As stated in the regulations at CFR 491.9(a)(2), surveyors should ensure that RHCs are primarily engaged in providing outpatient health services.

In addition, CMS revised the required RHC laboratory services at Section § 491.9(c) - Direct Services. Specifically, RHCs are no longer required to provide onsite testing for hemoglobin and hematocrit (H&H) nor test stool specimens for occult blood. Further, RHCs are only required to collect patient specimens for transmittal to a certified lab for culturing, rather than perform primary culturing onsite. The revised regulation sections read as follows:

§491.9 Provision of services.

(a)(3) The RHC must provide primary care services.

(c)(2) **Laboratory.** These requirements apply to RHCs but not to FQHCs. The RHC provides laboratory services in accordance with part 493 of this chapter, which implements the provisions of section 353 of the Public Health Service Act. The RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including:

- (i) Chemical examinations of urine by stick or tablet method or both (including urine ketones);
- (ii) Blood glucose;
- (iii) Pregnancy tests; and
- (iv) Collection of patient specimens for transmittal to a certified laboratory for culturing.

Surveyors should continue to cite RHCs that do not perform the remaining lab tests (chemical examination of urine, blood glucose, and pregnancy). However, if a surveyor observes that the RHC is performing the now omitted tests (H&H and stool for occult blood), they may inform the clinic that those tests are no longer required RHC laboratory services. Surveyors should cite a clinic if they are unable to collect specimens for culturing and transmittal to a certified lab.

For questions, please contact the CMS RHC mailbox at CMS QSOG_RHC-FQHC@cms.hhs.gov.

Effective Date:

Immediately. Please communicate to all appropriate staff within 30 days.

Karen L. Tritz
Director, Survey & Operations Group

/s/

David R. Wright
Director, Quality, Safety & Oversight Group

Resources to Improve Quality of Care:

Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to provider types and aim to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid.

Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus*

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