

# ***OLC Insight into the Most Common Challenges in RHC Certification Process and Compliance in Virginia***

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# Office of Licensure and Certification

## Division of Acute Care Services Overview

- 21 Medical Facilities Inspectors (MFIs) and 4 MFI Supervisors for Virginia
- 4 licensure programs (Home Care Organizations, Inpatient Hospitals, Outpatient Surgical Hospitals, Hospice)
- Inspections: Complaint, Initial Licensure, Biennial Licensure
- 10 CMS certified providers (Hospitals, ASC, ESRD, RHC, OPT, PRTF, CMHC, mobile XR, HHA, Hospice)
- Surveys: Complaint validation, Initial Certification, Recertification
- Administrative function for state and federal programs

# Rural Health Clinic overview

- Number of RHC in Virginia
  - 62 Deemed
  - 29 Non-deemed
- OLC has contractual federal survey obligations under the Section 1864 Agreement (a federally mandated contract with CMS)
  - Initial certification surveys
  - Recertification surveys
  - Revisit surveys
  - Complaint validation surveys
  - Administrative certification and compliance tasks

# RHC regulations

- **CMS SOM Appendix G: Conditions for Certification for RHC**  
(42 CFR Part 491 Subparts 2 - 11, Rev 223, Issued 6/7/24)  
**Appendix Z: Emergency Preparedness for All Provider  
and Certified Supplier Types**  
(42 CFR Part 491 Subpart 12, Rev 204, Issued 4/16/21)
- OSHA – Occupational Safety and Health Administration (US Department of Labor) 29 CFR 1910.1030 Bloodborne Pathogens
- VOSH – Virginia Occupational Safety and Health (VA Department of Labor and Industry)
- Health Insurance Portability and Accountability Act (HIPAA)

# Survey Process

- Unannounced, on-site visit
- Conducted by  
State Survey Agency (SA) – OLC in Virginia  
CMS approved Accrediting Organization: TCT

QUAD A (AAAASF)  
TJC

<https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/accrediting-organization-contacts-for-prospective-clients-.pdf>

# Survey Challenges

## E Tags (Emergency Preparedness)

E-0039: EP testing

E-0006: All Hazard Risk Assessment

E-0013: Development of EP Policies & Procedures

E-0024: Policies and Procedures – Volunteers and Staffing

E-0029: Development of Communication Plan

E-0032: Primary/Alternate Means for Communication

E-0036 & 37: EP Training and Testing

## Survey Challenges cont.

### J Tags (RHC Conditions for Certification)

§491.6 Condition for Certification: Physical plant and environment

- Preventive maintenance program for mechanical, electrical and patient-care equipment

- Storage of biologicals and drugs

(Clean and orderly environment in all patient care areas (incl. hand hygiene, injection practices, and when applicable, single-use devices, high-level disinfection, point-of-care devices))

## **Survey Challenges cont.**

§491.11 Condition for Certification: Program evaluation

**Biennial, by qualified staff and with documented findings/recommendations including:**

- Number of patients served and the volume of services provided  
(Clinical records sample: active & closed (min 5% of current patient census or 50 MR, completed by MD/DO)

- RHC policies and procedures
- Review by RHC leadership and action plan

## Survey Challenges cont.

### §491.9 Condition for Certification: Provision of services

- RHC's MD/DO and PA/NP with input from one outside healthcare practitioner develop written policies for clinical services and review them biennially
- Patient care policies to include rules for the storage, handling, and administration of drugs and biologicals
- basic laboratory services (urine analysis, blood glucose, pregnancy test, collect primary cultures) **Effective January 1, 2025, not required to directly provide Ht/Hb lab tests and examination of stool specimens for occult blood.**
- First response to common life-threatening injuries and acute illness and has available drugs commonly used in life saving procedures

## Survey Challenges cont.

### §491.10 Condition for Certification: Patient health records

- Complete, accurate, readily accessible, organized, legible, confidential, safeguarded and maintained
- Clinical record content (medical Hx, health assessment, consent, physical exam, visit summary, patient instructions, dx & lab results, consultative reports)

# Certification Process

- **CMS State Operations Manual Chapter 2 Section 2240**

(Rev. 227; Issued: 12-13-24)

- Complete and file CMS – 855 form, RHC Application

<https://www.cms.gov/medicare/cms-forms/cms-forms/downloads/cms855a.pdf>

- CMS SOM Chapter 2 (specifically 2242 - Conditions to Be Assessed Prior to Scheduling RHC Survey) and complete CMS -29 Verification

Form of Clinic Data <https://www.cms.gov/medicare/cms-forms/cms-forms/cms-forms-items/cms008849>

<https://www.cms.gov/medicare/cms-forms/cms-forms-items/cms008849>

- **Initial Certification Survey** – results in CMS 2567 or Statement of Deficiencies and Plan of Corrections (aka survey report)

## Certification Process cont.

- **SA compiles and reviews initial certification documents:**
  - CMS 855 form
  - survey report and AO accreditation letter if applicable
  - CMS 29
  - CMS 1561A- Health Insurance Benefit Agreement-Rural Health Clinic, <https://www.cms.gov/medicare/cms-forms/cms-forms/cms-forms-items/cms019485>
  - Assurance of Compliance certificate from OCR portal <https://ocrportal.hhs.gov/ocr/aoc/instruction.jsf>

# Certification Challenges

- Initial certification documents transmitted to SA (VDH OLC)
- RHC changes reported via CMS 855 to MAC
- RHC personnel updates captured in CMS 29 reported to SA
- Waiver requests must be transmitted to SA

(temporary waiver of mid-level staffing requirement for up to one year for existing RHC if they demonstrate they have been unable to hire a qualified NP, PA, or CNM in the previous 90-day period)

- Temporary/permanent relocations report via CMS 855 to MAC and promptly contact SA

## RHC Updates

- Direct supervision by the supervising practitioner: may provide supervision through a virtual presence using real-time, audio-visual communications (excluding audio-only)
- RHC no longer required to “primarily engaged” in the delivery of primary care
- RHCs no longer required to provide hemoglobin and hematocrit testing, examination of stool specimens for occult blood and perform “primary culturing” on site

## RHC Resources: CMS

<https://www.cms.gov/center/provider-type/rural-health-clinics-center>

<https://www.cms.gov/medicare/health-safety-standards/certification-compliance/rural-health-clinics>

<https://www.cms.gov/medicare/health-safety-standards/quality-safety-oversight-general-information/policy-memos/policy-memos-states-cms-locations>

● <https://www.cms.gov/priorities/health-equity/rural-health/stay-connected>

[www.cms.gov/files/document/mIn006398-information-rural-health-clinics.pdf](http://www.cms.gov/files/document/mIn006398-information-rural-health-clinics.pdf)

<https://www.cms.gov/training-education/medicare-learning-network/resources-training>

<https://www.cms.gov/files/document/r13133bp.pdf> (Medicare Benefit Policy Manual Chapter 13 Update)

<https://qsep.cms.gov/ProvidersAndOthers/publictraining.aspx>

## RHC Resources

- <https://www.osha.gov/laws-regs>
- <https://www.osha.gov/healthcare/standards>
- <https://www.osha.gov/complianceassistance/quickstarts/health-care>
- <https://doli.virginia.gov/vosh/>
- <https://www.ruralhealthinfo.org/topics/rural-health-clinics>
- <https://svhc.vhemp.org/>
- <https://www.vdh.virginia.gov/health-equity/state-office-of-rural-health/>
- <https://www.vdh.virginia.gov/haiar/>
- <https://vrha.org/rhc-resources/>

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# Questions?

