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Rural Health Clinics and Hospital-Based Provider Clinics

Carolyn St.Charles
Chief Clinical Officer, HealthTech | June 2024

Presenter

Carolyn St. Charles is the Chief Clinical Officer for HealthTech. Carolyn has extensive experience working with rural hospitals. St. Charles earned a master's degree in Business Administration from the Foster School of Business at the University of Washington and a Bachelor's Degree in Nursing from Northern Arizona University.

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April - August webinars

All webinars are recorded for on-demand viewing.

Everything you ever wanted to know about Swing Bed! Part 3: Strategies to hardwire your Swing Bed program for success

Presenter: Carolyn St. Charles, RN, BSN, MBA – Chief Clinical Officer
Date: Apr 12, 2024 | Time: 11am CST
URL: https://bit.ly/3S31QAp

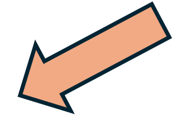
Adaptive leadership in a changing environment

Presenter: Cheri Benander, RN, MSN, CHC, C-NHCE – Director of Clinical Services
Date: Apr 26, 2024 | Time: 12pm CST
URL: https://bit.ly/3Shw6sg

Career ladders: Turning talk into action – How to retain your talent

Presenter: Scott Manis – Regional Vice President
Date: May 22, 2024 | Time: 12pm CST
URL: https://bit.ly/3U1fPbW

Survey readiness for Rural Health Clinics and hospital based physician clinics



Presenter: Carolyn St. Charles, RN, BSN, MBA – Chief Clinical Officer
Date: Jun 21, 2024 | Time: 12pm CST
URL: https://bit.ly/4ajp3WG

Survey readiness for Critical Access Hospitals clinical departments

Presenter: Carolyn St. Charles, RN, BSN, MBA – Chief Clinical Officer
Date: Jul 26, 2024 | Time: 12pm CST
URL: https://bit.ly/3IXXR3X

Survey readiness for Skilled Nursing Facilities

Presenter: Cheri Benander, RN, MSN, CHC, C-NHCE – Director of Clinical Services
Date: Aug 16, 2024 | Time: 12pm CST
URL: https://bit.ly/3TZH6eN

HealthTech Certificate Courses

Care Coordination / Chronic Care Management

- Advance Care Planning
- Annual Wellness Visit
- Behavioral Health Integration: What A Care Coordinator Should Know
- Care Coordination Fundamentals
- Transitional Care Management: Patients are moving; Are you moving with them

Leadership Development (NEW)

Lean Practitioner

Swing Bed

- Swing Bed Basics
- Swing Bed Beyond the Basics

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Swing Bed

Mock Surveys

CMS, CIHQ, DNV, TJC

- Hospitals
- Rural Health Clinics
- Long Term Care

Care Coordination / Chronic Care Management

Productivity and Staffing

Lean

Business Office and Revenue Cycle

Strategic Planning

Operational Assessments

Let me know if you are interested and we will be glad to send you a proposal

Agenda

1. Survey Readiness
2. Regulatory Sources
3. Rural Health Center
4. Physical Plant / Biomedical
5. Life Safety
6. Infection Prevention
7. Providers and Staff
8. Physician, NP, PA – RHC Only
9. Medications and Emergency Response
10. Policies and Procedures
11. Laboratory
12. Health Records documentation
13. Program Evaluation
14. Emergency Preparedness

Disclaimer

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Survey Readiness

Survey Readiness

- ❑ Regularly scheduled, at least quarterly, environment of care rounds
- ❑ Regularly scheduled, at least quarterly, infection prevention rounds
- ❑ Mock survey at least annually (internal or external)

Keep a survey binder of items surveyors will request - or - where to locate them

RHC Survey Binder

- ❑ If the RHC provides VNS, ask for a list of visits scheduled during the survey period. If visits are scheduled, explain that at least one visit will be observed
- ❑ Names, locations, and telephone numbers of key RHC staff and their responsibilities
- ❑ A list of all patients scheduled for that day. The list should include, at a minimum, the date, each patient's name, purpose of office visit, and the physician/mid-level furnishing the office visit.
- ❑ All office visits from the past six months
- ❑ All cases in the past year, if any, where the patient was transferred from the RHC to another health care facility for emergency services; The list should include, at a minimum, the date, each patient's name, purpose of office visit, and the physician/mid-level furnishing the office visit.

RHC Survey Binder

- ❑ A list including the names of the Medical Director, active Medical Staff, Allied Health professionals, and all other staff providing patient care
- ❑ Copy of the facility's organizational chart
- ❑ Policies and procedures
- ❑ Selected RHC personnel records identified by the surveyor
- ❑ Written documentation related to the RHC's program evaluation or QAPI for ongoing self-assessment of quality
- ❑ A list of services provided through agreement or arrangements
- ❑ A copy of the facility's floor plan

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Regulatory Sources

Regulatory Requirements Hospital-Based Provider Clinics

Appendix W Critical Access Hospitals

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_w_cah.pdf

Appendix A Hospitals

https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107ap_a_hospitals.pdf

Appendix Z Emergency Preparedness

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Downloads/Appendix-Z-EP-SOM-February-2019.pdf

Regulatory Requirements Rural Health Clinics

Appendix G Rural Health Clinics
https://www.cms.gov/files/document/appendix-g-state-operations-manual

Appendix Z Emergency Preparedness
https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Downloads/Appendix-Z-EP-SOM-February-2019.pdf

Types of Survey Findings

Standard Level

- Standard level deficiencies are deficient practices that pose low threat to health and safety. Must be resolved with in 60 calendar days from the date of survey.

Condition Level

- Condition level deficiencies are deficient practices that pose a serious threat to health and safety. Must be resolved within 45 calendar days from the date of survey.
- Multiple standard level deficiencies could lead to a CONDITION level citation.

Immediate Jeopardy

- Immediate threat to health or safety and requires immediate attention and resolution.

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Rural Health Center

Types of RHCs

Provider-based RHCs are owned and operated as an essential part of a hospital, nursing home, or home health agency participating in the Medicare program. RHCs operate under the licensure, governance, and professional supervision of that organization. Most provider-based RHCs are hospital-owned

Independent RHCs are free-standing clinics owned by a provider or a provider entity. They may be owned and/or operated by a larger healthcare system, but do not qualify for, or have not sought, provider-based status.

Compliance with Federal, State and Local Laws

J-0012 §491.4(a) The clinic . . . is licensed pursuant to applicable State and local law.

Mobile Units

J-0022 §491.5(a)(3) An RHC that consists only of a mobile unit must comply with all of the CfCs in that unit, including the location requirements.

All **mobile units**, regardless of whether they are the entire RHC or a part of an RHC that also has a permanent structure, **must have a fixed set of locations in which the unit is scheduled to be providing services at specified dates and times, and each unit must adhere to this schedule**.

Medical Supervision

J-0061§.491.7(a)(1) The clinic . . . is under the medical direction of a physician, and has a health care staff that meets the requirements of §491.8.

J-0061§.491.7(a)(b) The clinic . . . discloses the names and addresses of: . . .

(3) The person responsible for medical direction.

Owners

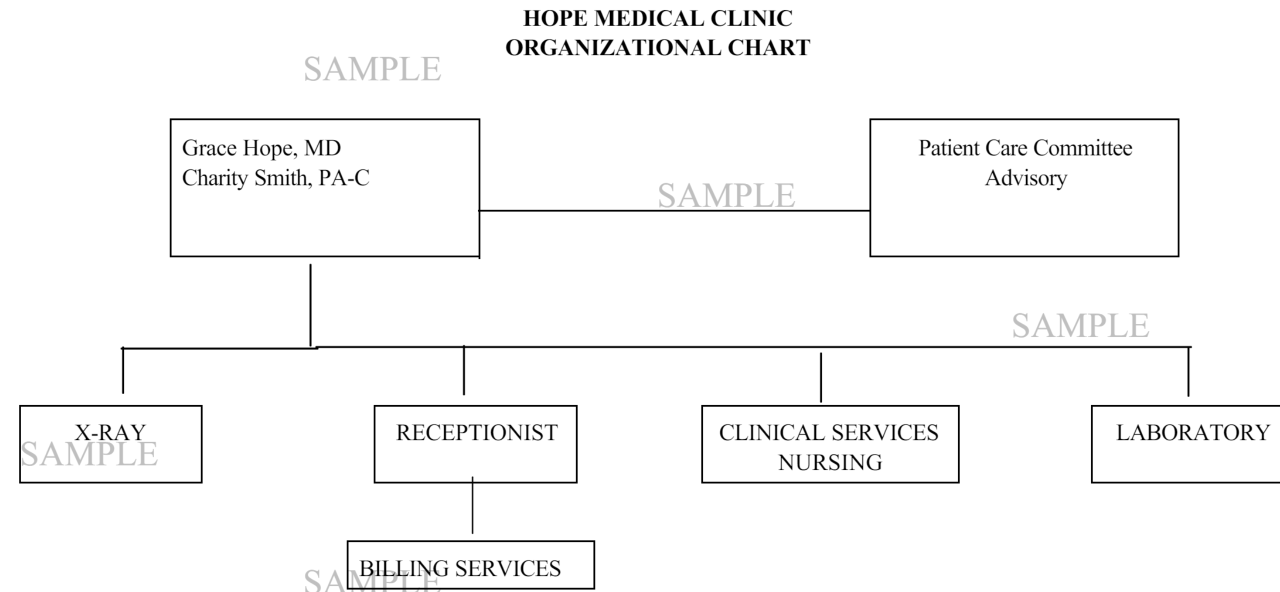
J-0062 §491.7(a)(2)(b) The clinic . . . discloses the names and addresses of:

(1) Its owners, in accordance with section 1124 of the Social Security Act (42 U.S.C. 132 A-3);

(2) The person principally responsible for directing the operations of the clinic . . .

Lines of Authority

J-0062 §491.7(a)(2) The organization's policies and its lines of authority and responsibilities are clearly set forth in writing.



Posted Hours

J-0085 §491.8(a)(5) The staff is sufficient to provide the services essential to the operation of the clinic . . .

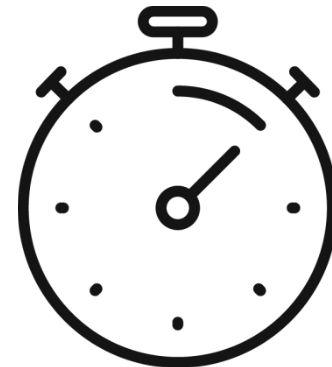
(6) A physician, nurse practitioner, physician assistant, certified nurse-midwife, clinical social worker, or clinical psychologist is available to furnish patient care services **at all times** the clinic . . . operates. . . .

The clinic may only be open and furnishing RHC services if there is a physician, NP, PA, certified nurse midwife, clinical social worker, or clinical psychologist on site and available to furnish services.

Posted Hours

Your posted hours must only include those hours when a provider is on-site!

Sunday	Closed
Monday	8AM – Noon and 1PM – 4PM
Tuesday	8AM – Noon and 1PM – 4PM
Wednesday	8AM - Noon and 1PM – 4PM
Thursday	Closed
Friday	8AM - Noon and 1PM – 4PM
Saturday	Noon – 4PM



Federal, State and Local Laws

J-0121 §491.9(a)

(1) All services offered by the clinic . . . are furnished in accordance with applicable Federal, State, and local laws;

Scope of Services

J-0122 §491.9(a)

(2) The clinic . . . is primarily engaged in providing outpatient health services and meets all other conditions of the subpart.

(1) General. The clinic…staff furnishes those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at the entry point into the health care delivery system. These include medical history, physical examination, assessment of health status, and treatment for a variety of medical conditions.

Contractual Agreements for Services

J-0140 §491.9(d) Services provided through agreements or arrangements.

(1) The clinic . . . has agreements or arrangements with one or more providers or suppliers participating under Medicare or Medicaid to furnish other services to its patients, including:

(i) Inpatient hospital care;

(ii) Physician(s) services (whether furnished in the hospital, the office, the patient's home, a skilled nursing facility, or elsewhere); and

(iii) Additional and specialized diagnostic and laboratory services that are not available at the clinic or center.

(2) If the agreements are not in writing, there is evidence that patients referred by the clinic or center are being accepted and treated.

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Physical Plant Biomedical

Clean and Orderly

J-0044 §491.6(b)(3) The premises are clean and orderly.

C-0924 §485.623(b)(4) The premises are clean and orderly

J-0041 §491.6(a) The clinic . . . is constructed, arranged, and maintained to insure access to and safety of patients, and provides adequate space for the provision of direct services.

C-0912 §485.623(a) The CAH is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of services.

Frequent Findings
Clean, Orderly, Safe Environment

- ❑ Sharps Container above fill line
- ❑ Sharps containers not mounted on wall
- ❑ Sharps containers in patient exam rooms not mounted to wall and/or open top
- ❑ Exam rooms cluttered
- ❑ Housekeeping or maintenance closets with hazardous chemicals not locked

Preventive Maintenance

J-0042 §491.6(b) The clinic . . . has a preventive maintenance program to ensure that:

(1) All essential mechanical, electrical and patient-care equipment is maintained in safe operating condition

C-0914 §485.623(b) The CAH has housekeeping and preventive maintenance programs to ensure that–

(1) All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition

Frequent Findings
Preventive Maintenance

- No documentation of electrical or biomedical check prior to equipment being put into service
- No documentation of preventative maintenance. May be kept in an excel spread sheet or stickers on the equipment. Required at least annually but depends on type of equipment. Defibrillators for example require more frequent checks.
- Scales, ophthalmoscopes or other small equipment do not have biomed check

PREVENTIVE MAINTENANCE

I.D. __________

BY __________ DATE __________

DUE __________

EOC and Biomedical Checklist

1. Preventative Maintenance
   - All equipment has a current preventative maintenance sticker or evidence of preventative maintenance
2. Equipment Not in Use
   - All equipment that is broken or not working properly has sticker / label indicating Do Not Use
3. Cleanliness
   - All equipment is clean
   - Floors and walls clean
   - Cubicle curtains clean and free of tears
   - Furniture clean and in good condition
4. Cleaning Agents
   - Cleaning agents kept out of reach of patients/visitors and appropriately labelled
5. Physical Plant Condition
   - Walls free of holes, chipping paint, etc.
6. Sharps Containers
   - Sharps containers not more than ¾ full
   - Sharps container attached to the wall, not sitting on a cabinet
   - Sharps containers locked and only exchanged when full by qualified staff
7. Spray Bottles
   - Spray bottles are identified with contents and safety warnings

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Life Safety

Exit Signs

E-0020 RHCs and FQHCs must also place exit signs to guide patients and staff in the event of an evacuation from the facility

Hospital requirements are included in Life Safety regulations NPFA 101

Life Safety Code

J-0041 §491.6(a)

The physical plant must be designed and constructed in accordance with applicable State and local building, fire, and safety codes

C-0930 §485.623(c)(1) Except as otherwise provided in this section,

(i) The CAH must meet the applicable provisions and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4.)

Life Safety Checklist

1. Fire extinguishers tested / inspected monthly
(annual for RHC if business occupancy)

2. Documentation of fire drills
    - Once per quarter per shift
    - Fire drills unannounced
    - Fire drills vary by at least one hour from shift-to shift each quarter
    - Documentation of attendees
    - Results of drill documented
    - Corrective actions if appropriate

3. Fire doors close with no gap more than 1/8 inch between door and center panel and bottom

4. Fire alarms are tested annually

Life Safety Checklist

5. No ceiling penetrations in IT closets, telephone closets, etc.

6. Documentation battered powered lights tested monthly for 30 seconds and annually for 90 minutes

7. Documentation monthly visual inspection of exit signs

8. Oxygen cylinders – single cylinders secured in tank holder or secured in storage racks.

9. Sprinkler heads clean and not covered by lint/dirt

Life Safety Checklist

10. No missing escutcheons (rings) around sprinkler heads

11. Ceiling tiles are smoke tight, damaged tiles with holes or chips are replaced and spaces around conduits/pipes thru the ceiling are sealed

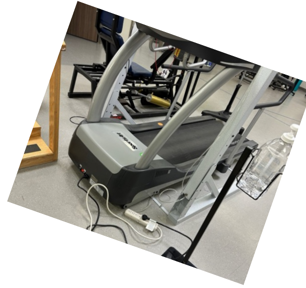
12. Clear egress
- All exits and hallways clear on one side
- Nothing blocking fire extinguishers, electrical panels, or medical gas shut-off valves
- No items stored in stairwells

13. No door stops holding doors open

14. No space heaters (unless approved by facilities) agencies.

Life Safety Checklist

16. No extension cords for patient use unless approved by Facilities with proper UL rating UL 1363 or UL60601-1



17. No items stored within 18 inches of ceiling-mounted sprinkler heads

18. Exit signs can be observed (not blocked) with other directional signs in the corridor

19. Written evidence of regular inspection by State or local fire control

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Infection Prevention

Prevent Infectious Disease

J-0044 § 491.6(b)(3) Measures to prevent the spread of infectious diseases. At a minimum the following must be addressed:

- Hand hygiene for staff having direct patient contact

C-1206 §485.640(a)(2) The infection prevention and control program, as documented in its policies and procedures, employs methods for preventing and controlling the transmission of infections within the CAH and between the CAH and other healthcare settings

Frequent Findings - Hand Hygiene

- ❑ No documentation of hand hygiene compliance
- ❑ Providers or Staff observed NOT using appropriate hand hygiene

Frequent Findings

- ❑ Cuts or tears in covering for exam tables
- ❑ Exam tables not cleaned with disinfectant per **manufacturer instructions** between patients
- ❑ BP cuffs, etc. not cleaned between patients
- ❑ High Touch surfaces not disinfected at least daily (door knobs, etc.)

High Level Disinfection and Sterilization

J-0044 § 491.6(b)(3) Measures to prevent the spread of infectious diseases. At a minimum the following must be addressed:

- when applicable, high-level disinfection and sterilization

C-1206 §485.640(a)(2) The infection prevention and control program, as documented in its policies and procedures, employs methods for preventing and controlling the transmission of infections within the CAH and between the CAH and other healthcare settings

Frequent Findings - Sterile Processing

- No staff competency
- No separation of clean and dirty
- Washing dirty instruments in a clean area
- Washing dirty instruments without PPE
- Solution used to wash instruments not correct concentration
- Not following manufacturer directions
- Not using test strips / biological indicators / weekly spore test
- Not using separators for hinged instruments
- Reprocessing single – use items (Made in Pakistan)

Frequent Findings – Transport of Instruments

- Instruments not transported in closed, puncture and leak-proof container
- Instruments not washed / cleaned before transport or put in solution to prevent rust or dried blood
- If cleaned and packaged before transport – **everything on prior slide!**

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Providers and Staff

License, Certified, or Registered

J-0013 §491.4(b) Staff of the clinic . . . are licensed, certified or registered in accordance with applicable State and local laws.

C-0818 §485.608(d) Staff of the CAH are licensed, certified, or registered in accordance with applicable Federal, State, and local laws and regulations.

Frequent Findings

- ❑ License expired
- ❑ License not verified by primary source
- ❑ Certification(s) expired

Staff Personnel Files

- ❑ Application
- ❑ Reference
- ❑ Background Checks (required if Hospital-based clinic and provide Swing Bed)
- ❑ Drug Test per policy
- ❑ I-9
- ❑ W-4
- ❑ License – primary source
- ❑ OIG Exclusion Check
- ❑ Signed Current Job Description
- ❑ Code of Conduct
- ❑ Performance Appraisals
- ❑ Orientation
- ❑ Training/Education
- ❑ Competency
- ❑ Employee Health Requirements
- ❑ FIT Testing as required

Competency

At a minimum:

1. Medication Administration for adults, neonates and children including administration and dose calculations
2. Medication Reconciliation
3. Laboratory Tests
4. Triage, if done by MA or RN
5. Special assessments/screening (depression, anxiety, etc.)

Education is NOT Competency

Competency Means Verified!
Demonstration of competency is not documentation that staff attended a training, listened to a lecture, or watched a video. A staff's ability to use and integrate the knowledge and skills that were the subject of the training, lecture or video must be assessed and evaluated by staff already determined to be competent in these skill areas.

Methods for verifying competency:

- **Observation**
- **Demonstration**
- **Simulation**
- **Verbal**
- **Written Test**
- **Documentation Audit**

Competencies must be based on role and responsibilities

Provider Credential File

- ❑ Application
- ❑ References (usually 3)
- ❑ Background Checks (required if Hospital-based clinic and provide Swing Bed)
- ❑ Drug Test per policy
- ❑ I-9 and W-4
- ❑ Employee Health Requirements
- ❑ License - Primary Source
- ❑ OIG Exclusion Check
- ❑ AMA
- ❑ NPDB
- ❑ Privilege Request (Approved by governing board)
- ❑ Evidence of ability to perform privileges (education, board certification, experience, etc.)
- ❑ For PAs, supervision agreement

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Physician, NP, PA RHC Only

Physician

J-0081 §491.8(a)

(1) The clinic . . . has a health care staff that includes one or more physicians . . .

(2) The physician member of the staff may be the owner of the rural health clinic, an employee of the clinic . . ., or under agreement with the clinic . . . to carry out the responsibilities required under this section.

J-0100 §491.8(b) The physician performs the following:

(1) . . . provides medical direction for the clinic's . . . health care activities and consultation for, and medical supervision of, the health care staff.

(3) . . . provides medical orders, and provides medical care services to the patients of the clinic or center.

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Physician Assistants & Nurse Practitioners

J-0082 §491.8(a) Rural health clinic staffs must also include one or more physician's assistants or nurse practitioners.

(3) The physician assistant, nurse practitioner, . . . may be the owner or an employee of the clinic . . ., or may furnish services under contract to the clinic . . . **In the case of a clinic, at least one physician assistant or nurse practitioner must be an employee of the clinic.**

J-0086 § **491.8(a)** Staffing.] (6) . . . for RHCs, a nurse practitioner, physician assistant or certified nurse-midwife is available to furnish patient care services at least **50 percent** of the time the RHC operates.

Physician Assistants & Nurse Practitioners

J – 0102 §491.8(c)(2) The physician assistant or nurse practitioner performs the following functions, to the extent they are not being performed by a physician:

(i) Provides services in accordance with the clinic's . . . policies;

(ii) Arranges for, or refers patients to, needed services that cannot be provided at the clinic . . . .; and

(iii) Assures that adequate patient health records are maintained and transferred as required when patients are referred.

Record Review

J-0101 §491.8(b) The physician performs the following:]

(3) **Periodically reviews** the clinic's . . . patient records . . .

§491.8(c) Physician assistant and nurse practitioner responsibilities.

(1) The physician assistant and the nurse practitioner members of the clinic's . . . . staff:

(ii) **Participate with a physician in a periodic review** of the patients' health records.

THERE MUST BE EVIDENCE OF PARTICIPATION IN THE REVIEW –

NOT JUST THAT THE RECORD WAS SIGNED

Participation in Record Review

J-0101 §491.8(b) The RHC's NP(s) and/or PA(s) must participate in the physician's review of the clinical records.

Participation may be face-to-face or via telecommunications.

If there is more than one NP or PA in the clinic, the NP or PA would participate only in the review of records of those patients for which the NP or PA provided care.

Where co-signature is not required, the regulation still requires periodic physician review of the clinical records of patients cared for by non-physician practitioners.

Physician - Co-Signature on Records

J-0101 §491.8(b) A physician must review periodically the RHC's patient clinical records.

In States where State law requires a collaborating physician to review medical records, co-sign medical records, or both for outpatients whose care is managed by a non-physician practitioner, an RHC physician must review and sign all such records.

If there is more than one physician on the RHC's staff, it is permissible for staff physicians other than/in addition to the medical director to review and co-sign the records.

Record Review

J-0101 §491.8(b) If the RHC has more than one physician on its staff, it is permissible for physicians other than/in addition to the medical director to conduct the periodic review of clinical records, so that this task might be divided or shared among the physicians.

If the RHC has more than one physician, its policies and procedures must specify who is authorized (i.e. whether it is the medical director alone, or may include other staff physicians) to review and, if required under State law, co-sign clinical records of patients cared for by a non-physician practitioner.

Frequency of Record Review

J-0101 §491.8(b) The regulation does not specify a particular timeframe to satisfy the requirement for "periodic" review of clinical records, but the RHC must specify a maximum interval between record reviews in its policies and procedures. The RHC is expected to take into account the volume and types of services it offers in developing its policy.

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Medications Emergency Response

Drugs and Biologics appropriately stored

J-0043 §491.6(b)(2) Drugs and biologicals are appropriately stored

C-0922 §485.623(b)(3) Drugs and biologicals are appropriately stored

C-1016 §485.635(a)(3)(iv) Interpretive Guidelines

The CAH's rules must address: Ensuring that outdated, mislabeled, or otherwise unusable drugs are not used for patient care

For individual drug containers: each floor stock drug container is expected to be labeled with the name and strength of the drug, lot and control number equivalent, and expiration date.

In addition, where applicable, each patient's individual drug container is expected to be labeled with the patient's full name and quantity of the drug dispensed.

Drugs and Biologics P&Ps

J-0125 §491.9(b)(3) The policies include:

(iii) Rules for the storage, handling, and administration of drugs and biologicals.

- Storage of drugs and biologicals
- Proper environmental conditions
- Security
- Handling
- Compounding
- Expiration & Beyond Use Dates
- Basic safe practices for medication administration

Drugs and Biologics Frequent Findings

- ❑ Open multi-dose vial not dated when opened
- ❑ Multi-dose vial not discarded after 14-days or sooner based on manufacturer recommendations
- ❑ Medications not secure (not stored in locked cupboard or refrigerator)

Sample medications

Always an issue and always a focus of surveyors

There are no specific requirements related to sample drugs – but **all** of the Medication Management regulations apply.

Sample Medications

1. Track all samples by lot, NDC and expiration date. Keep a sample log with one page per medication so quantities can be easily tracked. Reconcile all sample medications at least monthly (quantify available vs. quantity per log)

2. Ensure consistent record-keeping for dispensing and disposing of medication samples
   - Date received.
   - Date dispensed (or disposed of)
   - Prescribing clinician’s name
   - Quantity and dosage dispensed
   - Date dispensed

3. Store in conditions appropriate for mediation (i.e., refrigerated, etc.)

Sample Medications

4. Access is limited to licensed personnel only

5. All sample medications are properly labeled before dispensing to patient

6. Only providers dispense medication – **cannot** be dispensed by nursing staff unless medication is reviewed and signed off on by the provider (and this is documented)

7. Documentation of patient education

Frequent Findings Sample Drugs

- No accurate inventory – or inventory cannot be verified (Use perpetual inventory with one page per drug)

- Sample drugs provided by RN or MA ---- not provider

- No documentation of sample drugs provided to patients – or – no documentation of drug, log number, expiration **and education**

RHC Emergency Procedures

J-0136 §491.9(c)

(3) The clinic . . . provides medical emergency procedures as a first response to common life-threatening injuries and acute illness and has available the drugs and biologicals commonly used in life saving procedures, such as

- Analgesics
- Anesthetics (local)
- Antibiotics
- Anticonvulsants
- Antidotes and emetics, serums and toxoids

Not required for non-RHC -- but recommended

RHC Emergency Procedures

J-0136 §491.9(c) While each category of drugs and biologicals must be considered, all are not required to be stored. For example, it is appropriate for a RHC to store a small volume of a particular drug/biological, if it generally handles only a small volume/type of a specific emergency. Likewise, it may be acceptable if the clinic did not store a particular drug/biological because it is located in a region of the country where a specific type of emergency is not common (e.g., snake bites). Nonetheless, when determining which drugs and biologicals it has available for purposes of addressing common life-threatening injuries and acute illnesses, the RHC should consider, among other things, the community history, the medical history of its patients and accepted standards of practice. **The clinic should have written policies and procedures for determining what drug/biologicals are stored and that address the process for determining which drugs/biologicals to store, including identifying who is responsible for making this determination.** The RHC should be able to provide a complete list of the drugs/biologicals that are stored and in what quantities.

Emergency Procedures Frequent Findings

- ❑ Not ALL emergency drugs are available per regulation or policy
- ❑ Emergency drugs are outdated
- ❑ Emergency drugs are not readily available

(have to search for them)

- ❑ Oxygen not available
- ❑ Oxygen tanks not checked at least weekly (recommend two – and at least one completely full)
- ❑ Oxygen tanks not labeled (Full/Partial/Empty)
- ❑ No AED on site
- ❑ No staff training / certification (CPR or how to use AED)

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Policies & Procedures

Policies and Procedures

The *grand kahuna* of all standards

J-0123 § 491.8(b)§ 491.9(b)
(1) The clinic's … health care services are furnished in accordance with appropriate written policies which are consistent with applicable State law.

C-1006 §485.635(a)
The CAH’s health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law.

RHC Policies and Procedures

J-0123 §491.8(b) The physician performs the following:

(2) In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinic's . . . written policies and the services provided to Federal program patients.
§491.8(c) (1) The physician assistant and the nurse practitioner members of the clinic's . . . staff:
(i) Participate in the development, execution and periodic review of the written policies governing the services the clinic . . . furnishes;

J-0123 § 491.8(b)§ 491.9(b (2) The policies are developed with the advice of a group of professional personnel that includes one or more physicians and one or more physician assistants or nurse practitioners. At least one member is not a member of the clinic . . . staff.
(4) These policies are reviewed at least biennially by the group of professional personnel required under paragraph (b)(2) of this section and reviewed as necessary by the clinic . . .

Hospital Clinic Policies and Procedures

C-0982 §485.631(b)(1)(ii)

In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the CAH'S written policies governing the services it furnishes.

C-1008 §485.635(a)(2)

The policies are developed with the advice of members of the CAH's professional healthcare staff, including one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of §485.631(a)(1). §485.635(a)(4)

These policies are reviewed at least biennially by the group of professional personnel required under paragraph (a)(2) of this section, and reviewed as necessary by the CAH.

Policies and Procedures

J-0124 §491.9(b) Patient care policies.

(3) The policies include:

(i) A description of the services the clinic . . . furnishes directly and those furnished through agreement or arrangement.

(ii) Guidelines for the medical management of health problems which include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the clinic . .

(iii) Rules for the storage, handling, and administration of drugs and biologicals.

Frequent Findings

- ❑ P&Ps have not been reviewed within the last 2 years
- ❑ Missing P&Ps
- ❑ P&Ps not current (i.e., do not reflect current practice)
- ❑ Hospital-based clinic -- **Only hospital policies, no Clinic P&Ps**
- ❑ P&Ps aren't followed by staff

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Laboratory

Laboratory

J-0135 §491.9(a)(3) 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) Hemoglobin or hematocrit;

(iii) Blood glucose;

(iv) Examination of stool specimens for occult blood;

(v) Pregnancy tests; and

(vi) Primary culturing for transmittal to a certified laboratory.

Frequent Findings

- ❑ CLIA License not current (If under laboratory license, laboratory is responsible)
- ❑ No competency for staff performing waive tests
- ❑ Controls not documented
- ❑ Normal ranges not documented
- ❑ Results not documented

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Health Records Documentation

Health Information

J-0151 §491.10(a).

(1) The clinic . . . maintains a clinical record system in accordance with written policies and procedures.

(2) A designated member of the professional staff is responsible for maintaining the records and for insuring that they are completely and accurately documented, readily accessible, and systematically organized

Medical Record

J-0152 §491.10(a)

(3) For each patient receiving health care services, the clinic . . .. maintains a record that includes, as applicable: (i) Identification and social data, evidence of consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient; (ii) Reports of physical examinations, diagnostic and laboratory test results, and consultative findings; (iii) All physician's orders, reports of treatments and medications, and other pertinent information necessary to monitor the patient's progress; (iv) Signatures of the physician or other health care professional.

Patient Health Information

J-0153 §491.10(b) Protection of record information. (1) The clinic . . . maintains the confidentiality of record information and provides safeguards against loss, destruction or unauthorized use. (2) Written policies and procedures govern the use and removal of records from the clinic or center and the conditions for release of information. (3) The patient's written consent is required for release of information not authorized to be released without such consent

C-1102 §485.638(a) (1) The CAH must have a system of patient records, pertinent medical information, author identification, and record maintenance that ensures the integrity of the authentication and protects the security of all record entries

Frequent Findings Health Information

- ❑ Records unsecured on provider desks after-hours
- ❑ Records unsecured (not in locked cabinet or drawer) after-hours
- ❑ Patient Information left in fax machine after-hours

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Program Evaluation RHC

Program Evaluation

J-0161§491.11(a) The clinic . . . carries out, or arranges for, a biennial evaluation of its total program. (b) The evaluation includes review of: (1) The utilization of clinic . . . services, including at least the number of patients served and the volume of services; (2) A representative sample of both active and closed clinical records; and (3) The clinic's . . . health care policies. (c) The purpose of the review is to determine whether:

(1) The utilization of services was appropriate; (2) The established policies were followed; and (3) Any changes are needed.

J-0162 §491.11(d) The clinic . . . staff considers the findings of the evaluation and takes corrective action if necessary.

QAPI Program

J-0161§491.11(a) If a RHC has developed a QAPI program and that program meets/exceeds the regulatory requirements for a Program Evaluation, the QAPI program would be acceptable.

Quality Assurance Performance Improvement

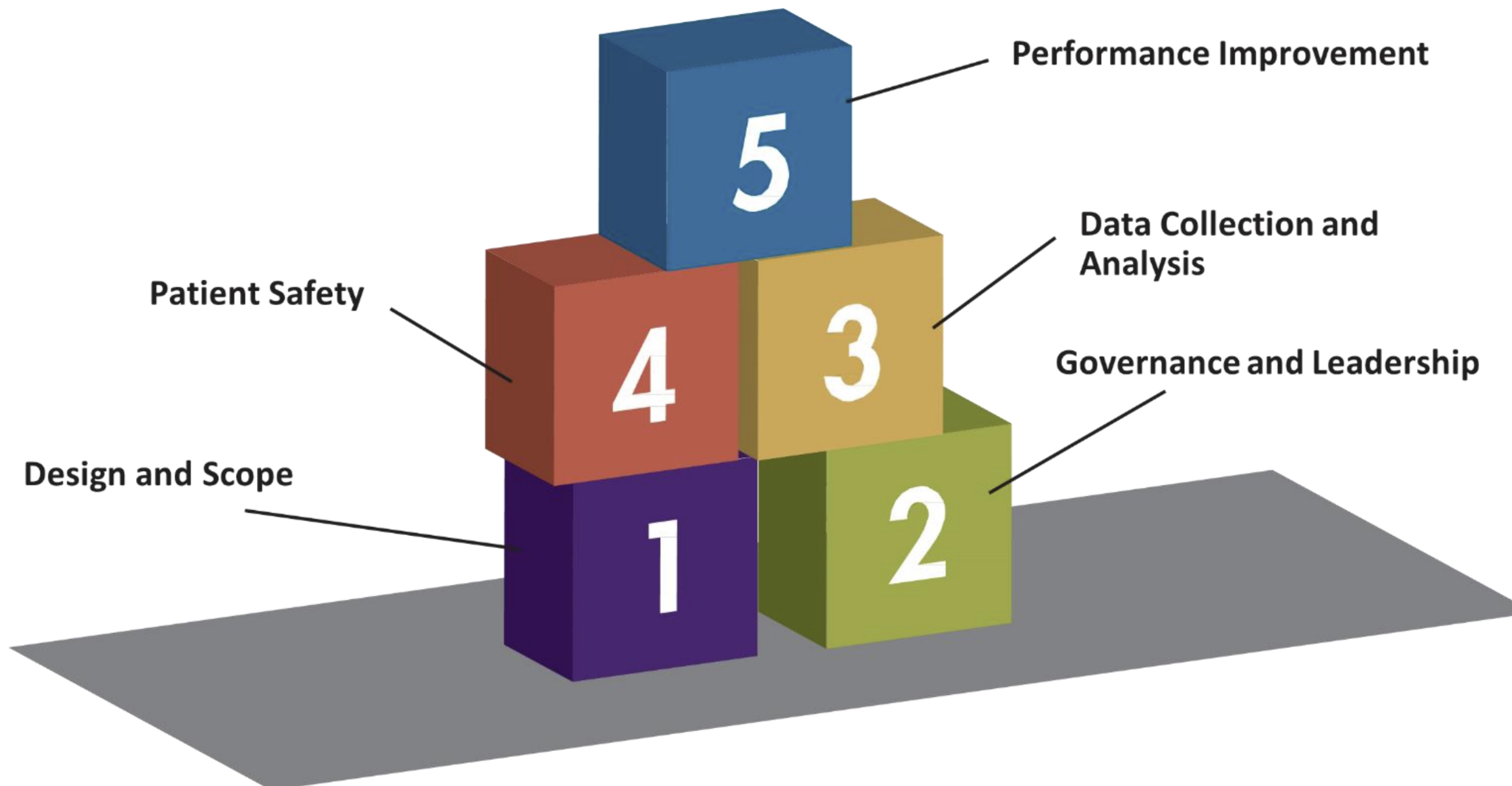
Coordination of QA and PI
QAPI is the coordinated application of two mutually-reinforcing aspects of a quality management system: Quality Assurance (QA) and Performance Improvement (PI). QAPI takes a systematic, comprehensive, and data-driven approach to maintaining and improving safety and quality while involving all caregivers in practical and creative problem solving. (CMS)

The focus of a QAPI program is to ***proactively maximize quality improvement activities and programs, even in areas where no specific deficiencies are noted.*** (CMS).

Activities of QAPI involve members at all levels of the organization to:

- Identify opportunities for improvement
- Address gaps in systems or processes
- Develop and implement an improvement or corrective plan
- Continuously monitor effectiveness of interventions

QAPI Strategic Framework



The QAPI Plan should address all five elements

QAPI Strategic Framework

1. **Design and Scope**
Ongoing and comprehensive

2. **Governance and Leadership**
Governance and leadership develops a culture of improvement where QAPI is a value and organizational cornerstone

3. **Data Collection and Analysis**
Systems to monitor care and services

4: Patient Safety
Absence of preventable harm

5. **Performance Improvement**
Process Improvement Projects to examine and improve care or services

QAPI Program

C-1300

Quality Assessment and Performance Improvement Program

The CAH must develop, implement, and maintain an **effective**, **ongoing, CAH-wide, data-driven** quality assessment and performance improvement (QAPI) program.

The CAH must **maintain and demonstrate evidence** of the effectiveness of its QAPI program.

(b) Standard: QAPI Program Design and scope. The CAH's QAPI program must:

C-1302

1) Be appropriate for the complexity of the CAH's organization and services provided.

QAPI Program

C-1306

2) Be ongoing and comprehensive
3) Involve all departments of the CAH and services (including those services furnished under contract or arrangement).

C-1309

4) Use objective measures to evaluate its organizational processes, functions and services.

C-1311

5) Address outcome indicators related to improved health outcomes and the prevention and reduction of medical errors, adverse events, CAH acquired conditions, and transitions of care, including readmissions.

C-1321 §485.641

3) Set priorities for performance improvement, considering either high volume, high-risk services, or problem prone areas.

So…. What does QAPI look like in a RHC or Hospital Clinic?

- ❑ Develop a QAPI Plan
- ❑ Develop priority goals based on criteria. Include providers and staff. For example…….
  - o Diabetes (A1C, annual eye exam, foot exam, etc.)
  - o Social Determinants of Health Assessment
  - o PHQ-9 Depression Screening 100% of patients
- ❑ Develop plan for implementing priority goals including measurable outcomes

So…. What does QAPI look like in a RHC or Hospital Clinic?

- ❑ Identify other high-risk / problem prone areas for improvement or monitoring – for example …..
  - Sample Drugs inventory current and accurate
  - Sample drugs documentation when distributed to patients
  - Controls documented for waive tests
- ❑ Develop indicators / measures (may not be an issue but need to monitor)
  - Biennial P&P review
  - Physician PA and NP chart review quarterly
- ❑ Report on QAPI at staff and provider meetings

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Emergency Preparedness

Integrated Emergency Preparedness RHC and Clinic

E-0042 If a [facility] is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the [facility] may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must- [do all of the following:]

Integrated Emergency Preparedness RHC and Clinic

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance [with the program].

Integrated Emergency Preparedness RHC and Clinic

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan, and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

Frequent Findings

- No evidence of Clinic participation in Emergency Preparedness Plan
- Plan does not include conditions / geography / hazards specific to the clinic(s), especially if the clinic is not physically attached to the hospital
- Emergency Preparedness drills are hospital-centric and don’t adequately include clinic(s)

Emergency Preparedness Stand-Alone (Not Integrated)

E-0006	Updated annually
E-0006	Include a facility-based and community-based risk assessment, utilizing an all-hazards approach
E-0007	The emergency plan must specify the population served within the facility, such as inpatients and/or outpatients, and their unique vulnerabilities in the event of an emergency or disaster
E-009	Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response
E-0013	Develop policies and update annually
E-0020	Facilities must develop policies and procedures that provide for the safe evacuation of patients from the facility and include all of the requirements of this standard. RHCs and FQHCs must also place exit signs to guide patients and staff in the event of an evacuation from the facility. Facilities must consider the patient population needs as well as their care and treatment

Emergency Preparedness Stand-Alone (Not Integrated)

E-0022	Emergency plans must include a means for sheltering all patients, staff, and volunteers who remain in the facility in the event that an evacuation cannot be executed. In certain disaster situations (such as tornadoes) , sheltering in place may be more appropriate as opposed to evacuation and would require a facility to have a means to shelter in place for such emergencies
E-0023	A system of care documentation that does the following: (i) Preserves patient information. (ii) Protects confidentiality of patient information. (iii) Secures and maintains the availability of records.
E-0024	The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency. The use of volunteers in an emergency and other emergency staffing strategies to address surge needs during an emergency.
E-0029	Develop and maintain an emergency preparedness communication plan that complies with Federal, State and local laws and must be reviewed and updated at least annually.

Emergency Preparedness Stand-Alone (Not Integrated)

E-0030	The communication plan must include all of the following:] (1) Names and contact information for the following: (i) Staff. (ii) Entities providing services under arrangement. (iii) Patients' physicians (iv) Other [facilities]. (v) Volunteers.
E-0031	Contact information for the following: (i) Federal, State, tribal, regional, and local emergency preparedness staff. (ii) Other sources of assistance.
E-0032	Primary and alternate means for communicating with the following: (i) [Facility] staff. (ii) Federal, State, tribal, regional, and local emergency management agencies.
E-0033	The communication plan must include all of the following: (4) A method for sharing information and medical documentation for patients under the [facility's] care, as necessary, with other health providers to maintain the continuity of care. (5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii)]A means of providing information about the general condition and location of patients under the [facility's] care as permitted under 45 CFR 164.510(b)(4). For RHCs/FQHCs at §491.12(c):] (4) A means of providing information about the general condition and location of patients under the facility’s care as permitted under 45 CFR 164.510(b)(4)

Emergency Preparedness Stand-Alone (Not Integrated)

E-0034	A means of providing information about the [facility's] occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.
E-0036	Maintain an emergency preparedness training and testing program. The training and testing program must be reviewed and updated at least annually
E-0032	Primary and alternate means for communicating with the following: (i) [Facility] staff. (ii) Federal, State, tribal, regional, and local emergency management agencies.
E-0037	Provide (i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, and volunteers, consistent with their expected roles. (ii) Provide emergency preparedness training at least annually. (iii) Maintain documentation of the training. (iv) Demonstrate staff knowledge of emergency procedures

Emergency Preparedness Stand-Alone (Not Integrated)

E-0039	(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the [facility] experiences an actual natural or man-made emergency that requires activation of the emergency plan, the [facility] is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event: (ii) Conduct an additional exercise that may include, but is not limited to the following: (A) A second full-scale exercise that is community-based or individual, facility-based. (B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. (iii) Analyze the [facility's] response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the [facility's] emergency plan, as needed.

Questions

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