



# RHC REGULATIONS AND COMPLIANCE

Robin VeltKamp  
Health Services Associates, Inc  
2 East Main Street  
Fremont, MI 49412  
PH: 231-924-0244  
Email: [rveltkamp@hsagroup.net](mailto:rveltkamp@hsagroup.net)  
Web: [www.hsagroup.net](http://www.hsagroup.net)

# J TAG REGULATIONS

- ▶ CMS Form 30 (select the most current)
- ▶ Federal Regulations
- ▶ Surveyors utilize as tool of measurement
- ▶ Office must remain compliant to J tags as daily operation compliance.

# CONDITION VS STANDARD

- ▶ Subpart A of 42 CFR 491 sets forth the conditions that RHCs must meet in order to qualify for certification under Medicare and Medicaid.
- ▶ Standards are the clinic operating processes. You may receive deficiencies in Standards such as expired medications, etc.
- ▶ Conditions are severe deficiencies. You may receive deficiencies in Conditions if you don't have a midlevel 50%, policies are not current. No current annual meeting.

# TOP 10 DEFICIENCIES

- ▶ J22 Physical Plant and Environment
- ▶ J23
- ▶ J47 Staffing and Staff Responsibilities
- ▶ J51
- ▶ J56 Patient Care Policies
- ▶ J57
- ▶ J58
- ▶ J61 Direct Services
- ▶ J62
- ▶ J70 Patient Health Records

# TOP 10 DEFICIENCY

- ▶ J22
- ▶ § 491.6(b)(1) All essential mechanical, electrical and patient care equipment is maintained in safe operating condition.

# PHYSICAL PLANT

- ▶ All equipment has been inspected. YEARLY
- ▶ Adult and pediatric scales are balanced/calibrated.
- ▶ Digital Thermometers/ BP equipment is calibrated.
- ▶ Patient care equipment is appropriately calibrated.

# PHYSICAL PLANT

- ▶ Exit sign are appropriately place.
- ▶ Emergency exits routes are free of barriers.
- ▶ Exit door(s) prevent unauthorized access from the outside but allows emergency exit from within.
- ▶ Secondary doors are locked at all times.
- ▶ Shatter proof light bulbs are used for all exposed lights.

# PHYSICAL PLANT

- ▶ If you have an AED, it is maintained tested in accordance with manufacturer recommendations.
- ▶ Equipment log is current and AVAILABLE to the surveyor.
- ▶ Trainings are documented with participation for biohazard trainings.
- ▶ Sanitation plan for toys in place if needed.

# PHYSICAL PLANT

## ▶ ADDITIONAL HELPS

- Refrigerators labeled.
  - Food Only
  - Meds Only
  - Labs Only
- DO NOT UNPLUG signs for refrigerators.
- Notice on how to handle medications during power outage.

# HOW DO I MEET THIS DEFICIENCY?

- ▶ Provider based typically utilize their maintenance or biomed department.
  - Sticker system or log is utilized for EACH item.
  - If you have policies of various levels of responsibilities, have the policy in your manual.
    - Ex: 2 prong inspection by office staff, etc.
- ▶ Independent RHC's need to either work with the local hospital or obtain an inspection log from a licensed electrician.



# TOP 10 DEFICIENCY

- ▶ J23
- ▶ 491.6(b)(2) Drugs and biologicals are appropriately stored.

# DRUGS & BIOLOGICALS

- ▶ All medications are stored in locked cabinets, cupboards, and/or drawers. This includes samples.
- ▶ Medications are locked up at the end of each day.
- ▶ Medications, biological, and sterile supplies are inventoried monthly for expiration dates.
- ▶ Multi-injectable vials, ointments, and solutions are dated when opened and discarded in accordance with hospital or clinic policy.

# DRUGS & BIOLOGICALS

- ▶ Expired medications, biologicals, and supplies are discarded in accordance with hospital or clinic policy.
- ▶ Refrigerator and freezer temperatures are recorded daily; and twice daily if storing vaccines.
- ▶ The clinic does not store medications in the door of the refrigerator or freezer.
- ▶ Sample medications are logged out when dispensed to include: Date, Patient Name, Medication, Lot #, Expiration Date, Amt. Dispensed, and NDC #.

# DRUGS & BIOLOGICALS

- ▶ Controlled substances are inventoried on a weekly basis and stored and dispensed in accordance with State Pharmacy regulations.
- ▶ Have a disposal plan for expired medications/samples.
- ▶ Store medications in the body of the refrigerator for proper viability of the medication.
- ▶ PT ALLERGY MEDICATIONS need to be monitored for expiration.

# Temperature Log for Refrigerator and Freezer — Fahrenheit

Month/Year: \_\_\_\_\_ Days 1–15

**Completing this temperature log:** Check the temperatures in both the freezer and the refrigerator compartments of your vaccine storage units at least twice each working day. Place an “X” in the box that corresponds with the temperature and record the ambient (room) temperature, the time of the temperature readings, and your initials. Once the month has ended, save each month’s completed form for 3 years, unless state or local jurisdictions require a longer time period.

**If the recorded temperature is in the shaded zone:** This represents an unacceptable

temperature range. Follow these steps:

1. Store the vaccine under proper conditions as quickly as possible.
2. Temporarily mark exposed vaccine “do not use” until you have verified whether or not the vaccine may be used.
3. Call the immunization program at your state or local health department and/or the vaccine manufacturer to determine whether the vaccine is still usable: (\_\_\_\_) \_\_\_\_\_.
4. Document the action taken on the reverse side of this log.

Day of Month		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Staff Initials																	
Room Temp.																	
Exact Time																	
°F Temp		am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm
Too warm	≥49°	Take immediate <b>corrective</b> action if temperature is in shaded section*															
	48°																
Refrigerator temperature	47°																
	46°																
	45°																
	44°																
	43°																
	42°																
	41°																
	40°																
	39°																
	38°																
	37°																
Too cold	36°																
	35°																
	34°	Take immediate <b>corrective</b> action if temperature is in shaded section*															
	33°																
≤32°																	
Too warm	≥8°	Take immediate <b>corrective</b> action if temperature is in shaded section*															
	7°																
	6°																
	5°																
	4°																
	≤3°+																

\*Some frozen vaccines must not be stored colder than -58°F. Check the Prescribing Information on the vaccine manufacturer’s website for specific storage temperature instructions.

Adapted by the Immunization Action Coalition courtesy of the Michigan Department of Community Health and the California Department of Health Services.

www.immunize.org/catg.d/p3039f.pdf • Item #P3039F (8/11)



Technical content reviewed by the Centers for Disease Control and Prevention, August 2011.

# SAMPLE MEDICATION LOG

DATE	PATIENT NAME	MEDICATION	LOT NO.	DOSE	SAMPLES GIVEN	EXP. DATE	SIGNATURE

# TOP 10 DEFICIENCY

- ▶ J47
- ▶ § 491.8(b)(2) In conjunction with the physician's assistant and/or nurse practitioner member(s), the physician participates in developing, executing and periodically reviewing the clinic's written policies and the services provided to Federal program patients.

# STAFFING & REPONSIBILITIES

- ▶ A physician participated in the development, review and implementation of the clinic policies, yearly.
  - The participation is documented.

# TOP 10 DEFICIENCY

- ▶ J51
- ▶ § 491.8(c)(1) The physician's assistant and the nurse practitioner members of the clinic's staff: (i) participated in the development, execution and periodic review of the written policies governing the services the clinic furnishes; (ii) provide services in accordance with those policies; (iii) arrange for, or refer patients to needed services that cannot be provided at the clinic; (iv) assure that adequate patient health records are maintained and transferred as required when patients are referred; and (v) participates with a physician in a periodic review of the patient's health records.

# STAFFING & REPONSIBILITIES

- ▶ The midlevel provider participates in the development, review and implementation of the clinic's policies.
  - Participation is documented
- ▶ The midlevel provider participated with the physician in the medical record review. The physicians findings were shared with the midlevel provider.



# TOP 10 DEFICIENCY

- ▶ J56
- ▶ § 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's assistants or nurse practitioners. At least one member of the group is not a member of the clinic's staff.
- ▶

# TOP 10 DEFICIENCY

- ▶ J57
- ▶ § 491.9(b)(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; and (iii) rules for the storage, handling and administration of drugs and biologicals.

# TOP 10 DEFICIENCY

- ▶ J58
- ▶ § 491.9(b)(4) These policies are reviewed at least annually by the group of professional personnel required under (b)(2) above in this section, and reviewed as necessary by the clinic.

# POLICIES

- ▶ Written policies are consistent with clinic operations.
  - The policies include medical guidelines
  - The policies include program evaluation
- ▶ The Advisory Group has met within the past 12 months to review the clinic's policies.
  - This group includes a community member. This must be someone that is NOT paid under the TAX ID that is being reviewed.

# POLICIES

- ▶ Clinic policies identify ALL the services that are performed onsite.
  - If you do it, you need a policy.
  - If you have a policy, you must follow it

# POLICIES

- ▶ Follow CFR 42 for sections to create the policy manual.
  - Administration
  - Physical Plant and Safety
  - Organizational Structure (Human Resources)
  - Patient Care
    - Medical Guidelines
    - Laboratory
    - Patient Care additional policies
  - Medical records
  - Program Evaluation

# J TAG REGULATIONS

- ▶ J61
- ▶ § 491.9(c)(2) Laboratory.
- ▶ The clinic provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including: (i) chemical examinations of urine by stick or tablet methods or both (including urine ketones); (ii) hemoglobin or hematocrit; (iii) blood sugar; (iv) examination of stool specimens for occult blood; (v) pregnancy test; and (vi) primary culturing for transmittal to a certified laboratory.

# LABORATORY

- ▶ External controls are performed on ALL CLIA waived tests, if applicable.
  - Controls are logged and documented
- ▶ Lab supplies and reagents are inventoried monthly and stored appropriately.
- ▶ The clinic is able to perform IMMEDIATE DIAGNOSIS and TREATMENT for the following:
  - Urinalysis
  - Blood Glucose
  - Hemoglobin or Hematocrit
  - Occult Blood
  - Pregnancy
  - Primary Culturing

# LABORATORY

- ▶ The lab is clearly labeled/ marked with DIRTY/CLEAN areas.
- ▶ The clinic has a process for tracking labs that are referred out.

# TOP 10 DEFICIENCY

- ▶ J62
- ▶ § 491.9(c)(3) Emergency.
- ▶ 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.

# EMERGENCY SERVICES

- ▶ The clinic has drugs for each of the following drug classifications:
  - Analgesics
  - Anesthetics (local)
  - Antibiotics
  - Anticonvulsants
  - Antidotes
  - Emetic
  - Serums
  - Toxoids

# EMERGENCY SERVICES

- ▶ All clinical staff have current BLS certifications on file.
- ▶ No labs are drawn unless a provider is on site. Another opinion is that if patients are allowed in the clinic prior to a provider being on the premises, clerical staff must have current BLS certifications on file.
- ▶ The clinic needs to have a spill kit and staff are aware of its location.

# TOP 10 DEFICIENCY

- ▶ J70
- ▶ § 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 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.

# MEDICAL RECORDS

- ▶ There are medical records policies in place.
- ▶ The person ultimately responsible for the medical records is clearly identified.
- ▶ Identification and social data.
- ▶ Evidence of consent forms.
  - General consent to treat
  - Procedural consent to treat
- ▶ Medical History.

# MEDICAL RECORDS

- ▶ Assessment of health status and needs of the patient.
- ▶ Summary of the episode/encounter and instructions to the patient.
- ▶ Documented education (if applicable).
- ▶ Physical examinations.
- ▶ Diagnostic and laboratory findings.

# MEDICAL RECORDS

- ▶ Consultation reports.
- ▶ Provider orders.
- ▶ Medications.
- ▶ Patient's progress monitoring.

# MEDICAL RECORDS

- ▶ There is a policy regarding the storage and handling of patient health information.
- ▶ The clinic has a patient authorization for release policy.
- ▶ The clinic has HIPAA policies for release of information to:
  - Government entities
  - Law enforcement
  - Friends and family
  - Faxed items
  - Transferring records to another facility
- ▶ Policies consistent with State law

# REMINDER

- ▶ The regulations are not just to be expected to pass for RHC certification but are a DAILY COMPLIANCE EXPECTATIONS.
- ▶ There will be recertifications conducted for each RHC clinic.



Robin VeltKamp, VP of Medical Practice Compliance & Consulting  
Email: [rveltkamp@hsagroup.net](mailto:rveltkamp@hsagroup.net)

Health Services Associates, Inc.  
2 East Main Street  
Fremont, MI 49412

PH: 231.924.0244 FX: 231.924.4882

[www.hsagroup.net](http://www.hsagroup.net)