



RHC REGULATIONS AND COMPLIANCE PHYSICAL PLANT AND SAFETY CFR 42 491.6

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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.

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.

CFR 42 491.6

- ▶ § 491.6 Physical plant and environment.
- ▶ (a) *Construction*. The clinic or center is constructed, arranged, and maintained to insure access to and safety of patients, and provides adequate space for the provision of direct services.
- ▶ (b) *Maintenance*. The clinic or center has a preventive maintenance program to ensure that:
 - ▶ (1) All essential mechanical, electrical and patient-care equipment is maintained in safe operating condition;
 - ▶ (2) Drugs and biologicals are appropriately stored; and
 - ▶ (3) The premises are clean and orderly.
- ▶ (c) *Emergency procedures*. The clinic or center assures the safety of patients in case of non-medical emergencies by:
 - ▶ (1) Training staff in handling emergencies;
 - ▶ (2) Placing exit signs in appropriate locations; and
 - ▶ (3) Taking other appropriate measures that are consistent with the particular conditions of the area in which the clinic or center is located.

CMS J 20

- ▶ J20
- ▶ § 491.6(a) Physical plant and environment – *Construction*
- ▶ The clinic is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of direct services.

CMS J 20

- ▶ Exit doors are appropriately identified.
- ▶
- ▶ Clinic does not have any exposed building materials, i.e. insulation, holes in walls, etc.
- ▶
- ▶ Fire extinguishers are inspected on a monthly basis.
- ▶
- ▶ Emergency exits routes are free of barriers.
- ▶
- ▶ Exit signs are appropriately placed.
- ▶

CMS J 20

- ▶ Exit door(s) prevent unauthorized access from the outside but allows emergency exit from within.
- ▶
- ▶ Secondary doors are locked at all times.

CMS J 20

- ▶ Shatter proof light bulbs are used for all exposed lights.
- ▶
- ▶ Overhead ceiling lights are free of bugs and debris.
- ▶
- ▶ List of Hazardous Chemicals was available.
- ▶
- ▶ Plug protectors were present in all outlets.
- ▶
- ▶ Sharps were secured throughout clinic.

CMS J 20

- ▶ Sharps were secured throughout clinic. Sharps are dated according to MIOSHA.
- ▶
- ▶ The clinic has an OSHA approved eye wash station.
- ▶
- ▶ Clean and dirty work surfaces are clearly defined in the lab.
- ▶ Floor plans were posted throughout the clinic

CMS J 20

- ▶ All treatment trays are free of dust and debris
- ▶ There is nothing under the exam room sinks.
- ▶ Closed trash containers are utilized in patient care areas. Open containers are an invitation for little hands.
- ▶ Patient bathroom has an emergency notification system.

CMS J 21-22

- ▶ J21



- ▶ § 491.6(b) Physical plant and environment – *Maintenance*.
- ▶ The clinic has a preventive maintenance program to ensure that:

- ▶ J22



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



CMS J 21-22

- ▶ All equipment has been inspected
- ▶
- ▶ Adult and pediatric scales are balanced
- ▶
- ▶ Patient care equipment is appropriately calibrated
- ▶
- ▶ AED is maintained and tested in accordance with manufacturer recommendations
- ▶
- ▶ Equipment log is current and available to the surveyor

CMS J 23

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

CMS J 23

- ▶ All medications are stored in locked cabinets, cupboards, and/or drawers
- ▶
- ▶ 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
- ▶
- ▶ Expired medications, biologicals, and supplies are discarded in accordance with hospital or clinic policy

CMS J 23

- ▶ 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 #.
- ▶
- ▶ Controlled substances are inventoried on a weekly basis and stored and dispensed in accordance with State Pharmacy regulations.

CMS J 24

- ▶ J24
- ▶ § 491.6(b)(3) The premises are clean and orderly.

CMS J 24

- ▶ The clinic has a Housekeeping policy and the clinic is maintained in accordance to that policy
- ▶ The clinic has closed trash receptacles
- ▶ Flooring is free from hazards
- ▶ Patient restrooms are free of staffs' personal hygiene products
- ▶ The clinic is free from clutter

CMS J 24

- ▶ Hallways and exits are free of obstructions
- ▶ Clean and dirty work surfaces are clearly defined
- ▶ All treatment trays are free of dust and debris
- ▶ There is nothing under the exam room sinks.
- ▶ There is a sanitation plan to clean the toys.

CMS J 25–J26

- ▶ J25
- ▶ §491.6(c) Physical plant and environment – *Emergency procedures.*
- ▶ The clinic assures the safety of patients in case of non–medical emergencies by:
- ▶ J26
- ▶ § 491.6(c)(1) Training staff in handling emergencies.

CMS J 25-26

- ▶ All staff have participated in emergency training, i.e. fire, evacuation, tornado, acts of terrorism
- ▶ Training is documented
- ▶ Staff clearly understands their role in the event of an emergency

CMS J 27

- ▶ J27
- ▶ § 491.6(c)(2) Placing exit signs in appropriate locations.

CMS J 27

- ▶ Exit signs are clearly identified
- ▶ Floor plans are posted throughout the clinic

CMS J 28

- ▶ J28
- ▶ § 491.6(c)(3) Taking other appropriate measures that are consistent with the particular conditions of the area in which the clinic is located.

CMS J 28

- ▶ Clinic has a tornado evacuation plan
- ▶ Fire Drills are conducted yearly AT A MINIMUM
- ▶ Emergency evacuation plan

CFR 42 491.6

▶ 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 THE 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.

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 corrective action if temperature is in shaded section* | | | | | | | | | | | | | | | |
| | 48° | | | | | | | | | | | | | | | | |
| Refrigerator temperature | 47° | | | | | | | | | | | | | | | | |
| | 46° | | | | | | | | | | | | | | | | |
| | 45° | | | | | | | | | | | | | | | | |
| | 44° | | | | | | | | | | | | | | | | |
| | 43° | | | | | | | | | | | | | | | | |
| | 42° | | | | | | | | | | | | | | | | |
| | 41° | | | | | | | | | | | | | | | | |
| | 40° | | | | | | | | | | | | | | | | |
| | 39° | | | | | | | | | | | | | | | | |
| | 38° | | | | | | | | | | | | | | | | |
| | 37° | | | | | | | | | | | | | | | | |
| | 36° | | | | | | | | | | | | | | | | |
| Too cold | 35° | Take immediate corrective action if temperature is in shaded section* | | | | | | | | | | | | | | | |
| | 34° | | | | | | | | | | | | | | | | |
| | 33° | | | | | | | | | | | | | | | | |
| | ≤32° | | | | | | | | | | | | | | | | |
| Freezer temp | ≥8° | Take immediate corrective 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)



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SAMPLE MEDICATION LOG

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