

# State Operations Manual

## Appendix U - Survey Procedures and Interpretive Guidelines for Responsibilities of Medicare Participating Religious Nonmedical Healthcare Institutions

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## **I – General Information**

Section 4454 of the Balanced Budget Act of 1997 (BBA'97, Public Law No. 105-33, enacted August 5, 1997) deletes statutory references to Christian Science Sanatoria and amended the following sections of the Social Security Act (the Act): §§1821, 1861(e), (y) and (ss), 1869, and 1878 (Medicare provisions); 1902(a) and 1908(e)(1) (Medicaid provisions); and §1122(h) and §1162 (conforming provisions). Additionally, §4454 provides for coverage of inpatient services furnished in qualified religious nonmedical health care institutions (RNHCIs) under Medicare and as a State Plan option under Medicaid. The new amendments make it possible for RNHCIs meeting the defining criteria in §4454 of BBA'97 or §1861(ss)(1), to participate in the Medicare and/or Medicaid program. The RNHCI provider is responsible for meeting both Conditions of Coverage and Conditions of Participation to qualify as a Medicare provider and that portion of the Conditions of Coverage that define an RNHCI and the Conditions of Participation to qualify as a Medicaid provider.

The Boston Regional Office has the primary responsibility for the approval and certification process to ensure and verify that the RNHCI conforms to specific Conditions of Coverage and all of the Conditions of Participation. An RNHCI is a provider that meets the definition as described in §1861(ss)(1) of the Act and meets the following qualifying Medicare Conditions of Coverage provisions (§403.720). To qualify as a Medicare or Medicaid RNHCI an institution must meet all ten of the following requirements:

1. Is described in subsection (c)(3) of §501 of the Internal Revenue Code of 1986 and is exempt from taxes under subsection 501(a);
2. Is lawfully operated under all applicable Federal, State, and local laws and regulations;
3. Furnishes only nonmedical nursing items and services to beneficiaries who choose to rely solely upon a religious method of healing, and for whom the acceptance of medical services would be inconsistent with their religious beliefs. (**NOTE:** Religious components of the healing are not covered);
4. Furnishes nonmedical items and services exclusively through nonmedical nursing personnel who are experienced in caring for the physical needs of nonmedical patients. For example, caring for the physical needs such as assistance with activities of daily living; assistance in moving, positioning, and ambulation; nutritional needs; and comfort and support measures;
5. Furnishes nonmedical items and services to inpatients on a 24-hour basis;

6. Does not furnish, on the basis of religious beliefs, through its personnel or otherwise, medical items and services (including any medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs) for its patients;
7. Is not owned by, under common ownership with, or has an ownership interest of 5 percent or more in, a provider of medical treatment or services and is not affiliated with a provider of medical treatment or services or with an individual who has an ownership interest of 5 percent or more in a provider of medical treatment or services (permissible affiliations are described in §403.738(c));
8. Has in effect a utilization review plan that meets the requirements of §403.720(a)(8);
9. Provides information CMS may require to implement §1821 of the Act, including information relating to quality of care and coverage determinations; and
10. Meets other requirements CMS finds necessary in the interest of the health and safety of the patients who receive services in the institution.

#### **A - Other Medicare Conditions of Coverage**

The remaining Conditions of Coverage are specific to Medicare; however, a State may elect to employ any or of all these requirements within their optional Medicaid State plan amendment.

#### **B - Valid Election Requirements**

The regulations at §403.724, present the elements necessary for a Medicare beneficiary to complete an election to receive care in an RNHCI. The RO determines whether or not the RNHCI has adequately ensured that the Medicare beneficiary's valid election statement has been included with the RNHCI's administrative records and/or patient care records.

**NOTE** - The facility is to provide the fiscal intermediary the original of the election statement that will be used for each Medicare beneficiary in the RNHCI and retain a copy in its files.

The provisions for valid elections include the following general requirements:

- The election statement must be made by the Medicare beneficiary or by his or her legal representative. It must include written statements that:
  - The beneficiary is conscientiously opposed to acceptance of nonexcepted medical treatment;

- o The beneficiary acknowledges that acceptance is inconsistent with his or her sincere religious beliefs;
- o The beneficiary acknowledges that receipt of nonexcepted medical care constitutes a revocation of the election and may limit further receipt of services in an RNHCI;
- o The beneficiary acknowledges that the election may be revoked by submitting a written statement to CMS; and
- o The beneficiary acknowledges that the revocation will not prevent or delay access to medical services available under Medicare Part A in other types of facilities.

A valid election must also:

- Be signed and dated by the beneficiary or by his or her legal representative, not prior to reaching Medicare eligibility and beneficiary status;
- Be notarized;
- Include an original copy submitted on file to CMS (CMS is represented for this purpose by the intermediary); and
- Include any other information obtained regarding prior elections or revocations.

A beneficiary's election is revoked by one of the following:

- The beneficiary receives nonexcepted medical treatment for which Medicare payment is made;  
or
- The beneficiary voluntarily revokes the election and notifies CMS in writing.

**NOTE** - Excepted" and "nonexcepted" medical care are defined in §403.702. The receipt of excepted medical care or treatment as defined in §403.702 does not revoke the election made by a beneficiary.

The beneficiary's ability to elect is limited once the election has been made and revoked twice (see §403.724(c)).

## **II - Survey/Resurvey**

### **Task 1 - Presurvey Preparation**

The RO reviews various documents of record and various sources of information available about the facility. Presurvey preparation is useful in identifying questions and concerns related to the Conditions of Coverage, Conditions of Participation, and in determining composition of the survey team and the time required to perform a survey/resurvey.

Presurvey preparation includes reviewing such information as:

- Current IRS religious not-for-profit status;
- Provider information on file, including agreement with CMS, as an extended care hospital;
- Applicable State and local laws, particularly as they relate to licensure and monitoring of operations;
- Previous OSCAR survey data;
- Form CMS-855 and Form CMS-1513 (for Medicaid only facilities);
- Other elements of the Conditions of Coverage, to be sure the provider is meeting the definition of an RNHCI before starting the onsite visit;
- Licensure records;
- Fire inspection reports;
- Complaints; and
- Previous survey reports including Life Safety Code (LSC).

### **Task 2 – Entrance Conference**

Upon entering the facility, the surveyor introduces him/herself to the authorized representative (governing body, administrator) to outline the survey plan and to talk with other staff/personnel to obtain information. Indicate that the surveyor(s) will be looking at both Conditions of Coverage and Conditions of Participation.

The authorized representative is considered as the key contact person in the facility. The surveyor interviews the authorized representative first. There are elements related to each condition that the surveyor may need to discuss with the authorized representative.

He/she will be able to direct the surveyor to other staff to interview relative to specific standards and other requirements. However, contacts are not limited solely to the authorized representative. Even if the authorized representative feels that he/she can answer most of the questions, the facts must be verified through record reviews, other source documents and interviews. The RO investigation must be complete enough to document whether the CMS requirements are met and the provider is in compliance with the related condition(s).

Inform the authorized representative that there will be interviews with staff, patients, family members, friends, and legal representative. Convey that these interviews are conducted privately, unless the interviewee requests the presence of another person. Ask the authorized representative to ensure that there are times during the survey when patients can contact the surveyor without facility staff being present. Have the facility provide the following items immediately:

- The facility's roster showing patients' names, gender, age, length of stay, utilization review plan, discharge, and/or transfer with destinations of each patient. Also indicate patients who communicate with non-oral communication devices, sign language, or who speak a language other than the dominant language of the facility;
- Names of key facility personnel, their title(s), and a description of their responsibilities associated with patient care/services, such as administrator, director, nursing staff, volunteers, food service supervisor, plant engineer, housekeeping supervisor, governing body personnel, and persons responsible for quality assessment;
- A copy of the written information on file that is provided to patients regarding their rights and election statements;
- A description of and the hours of operation for food services and housekeeping;
- A copy of the facility admission contract(s) for all patients regarding Medicare, Medicaid, and other payment sources;
- Identification of any transfer or discharge that is planned (not yet completed);
- Records or reports of abuse/accident/incident;
- A copy of the actual **working schedules** for all staff for the days of survey;
- A description/copy of meals times, dining location, copies of all menus; and
- Any new information or changes that have occurred from the preparation time to the actual time of the survey occurrence.

During the introductory meeting with the authorized representative, the surveyor alerts him/her that if the facility is planning to record the exit conference, a copy of the tape must be made available to the surveyor(s) at the conclusion of the conference. A surveyor(s) should not accept a promise that a copy of the tape will be mailed at a later date.

### **Task 3 - Tour of the Facility**

The authorized representative informs staff that the surveyor will be communicating with them throughout the survey and will ask for facility assistance when needed. Staff are advised that they have the opportunity to provide surveyors with any information that would clarify any issue. The authorized representative or staff/personnel should take the surveyor(s) on a tour of the facility. This will allow facility staff sufficient time to gather the information requested during the Entrance Conference. The purpose of the facility tour is two-fold. First, it gives the surveyor(s) their first understanding of the layout of the facility and the location of different areas that will be investigated during the survey. Second, it is a good opportunity to make notes concerning the environment or atmosphere of the facility as a whole and how the patients and staff function within it.

### **Task 4 -Information Gathering**

Information gathering techniques include **observation, interviews, and record review** as critical components of making decisions as to whether the RNHCI has met requirements. The objective is to provide the surveyor with enough information about the facility, patients, staff, and environmental conditions to make compliance decisions. These techniques are interrelated and may often be performed concurrently.

#### **A - §403.720(a) Conditions for Coverage (Medicare and Medicaid)**

Building on information obtained by review of documents and interview with staff/personnel, determine if all ten critical conditions in this section are met in order for the facility to meet the RNHCI definition.

#### **B - §403.720(b) Conditions for Coverage (Medicare only)**

Surveyors review election documents for: all of the elements required; beneficiary's or his/her legal representative's signature, valid notarization; and dated on or before the date of admission to the RNHCI (see §403.724).

#### **C - §403.730 Patient Rights**

Surveyors conduct interview of patients, family members, or visitors in order to assess his/her understanding and staffs' knowledge of and involvement in:

- Patients' rights process of being informed before furnishing care to the patients, election process, prompt resolution of grievance process;
- Participation in the development and implementation of the plan of care in a safe setting;
- Formulation of advance directives;
- Freedom from verbal, psychological and physical abuse and misappropriation of property; and freedom from the use of restraints; and
- Confidentiality of records and disclosure.

The interviews provide information about the relationship between staff and patients that will assist you in deciding what additional observations and record information are necessary.

Surveyors must observe the facility environment to determine the relationship between the patient needs and preferences, determine what staff do with and for the patient throughout the day or evening, and to assess whether the physical features of the environment endangers a patient's, visitor's, or staff's safety and well-being.

Review patient's records to ensure proper documentation of patient rights. Review facility policies and procedures regarding how the facility is addressing complaints, misappropriation of property, and confidentiality of records. Conduct a detailed review of individual patient's records for what you need, not the whole record.

## **D - §403.732 Quality Assessment and Performance Improvement**

Surveyors are to conduct interviews of staff to assess staffs' knowledge, understanding and involvement in the facility's quality assessment program and the extent to which it measures, analyzes, tracks and improves, performance. Surveyors must keep focused on the fact that the RNHCI is a nonmedical model and will not use diagnosis, laboratory findings, medical/surgical procedures or therapies as part of quality assessment and performance improvement.

Surveyors are to observe staff as they address identified priorities put in place by the governing body in all program departments, functions and contracted services performed.

Surveyors must review facility policies, procedures, staff training programs, and where adverse outcome is identified and indications of action taken.

## **E - §403.734 Food Services**

Surveyors must interview patients, religious nonmedical nursing staff, kitchen staff, and housekeeping staff on aspects of food services.

Surveyors observe the facility's food storage, preparation, and distribution of food served. Appearance of kitchen staff and kitchen environment is important. Note whether food substitutes are available.

Surveyors review policy and procedures for kitchen and housekeeping procedures.

## **F - §403.740 Staffing**

Surveyor observations are important in determining what relationship exists between the staff and patient. As a result of any observation, the surveyor should be able to determine:

- Whether the RNHCI attempts to find out what patients need;
- How needs are assessed, care is delivered and if care modifications are incorporated as appropriate; and
- Whether effective interaction occurs between staff and patients.
- Determine from observations of RNHCI staff if staff communicates with each patient in a manner understandable to that patient, and others. In the absence of finding appropriate interaction between staff and patients during observations, it may be necessary to determine whether or not staff members are knowledgeable about patient care needs and services. If possible, interview the particular staff member following the interval in which the patient was observed. Interviews are intended to:
  - Provide staff the opportunity to give what they believe is pertinent information, and to determine how the patient perceives the services delivered by the RNHCI; and
  - Collect and clarify information gathered during observations.

RNHCI personnel should collectively provide care services that maintain or improve the patient's quality of care and are as error-free as possible. Staff members will bring different knowledge and experience to the patient care services team.

Based on staff interviews, determine the extent family, guardians or advocates are involved with the patient. Some of these individuals may be selected for more in-depth interview. Include staff or patients who use alternate means of communication, such as sign language. Interviews of staff members will include persons involved with direct and indirect patient services (e.g. admission, discharge planning, religious nonmedical nursing personnel, food services, etc.). If the person responsible for a specific service is not available, a designee may be interviewed. Early in the survey process identify which

individuals may be interviewed. Interview staff about training and supervision along with administrative areas. Find out about roles and responsibilities.

Interview questions are open ended to allow for more complete responses that will assist the surveyor in determining whether the RNHCI has staff that are qualified and experienced to meet patients needs (see §493.740).

The record review is intended to:

- Obtain information to direct initial and/or additional observations and interviews;
- Provide the surveyor a picture of the current status of the RNHCI's operations and care services provided to patients; and
- Assist the surveyor in evaluating assessments and care plans.

Review the personnel records. Record review will include a review of work experience, as well as staff health and training.

The religious aspects of care are the financial responsibility of the patient.

**NOTE** - Use the record review to obtain information necessary to validate and/or clarify (existing and modified) information obtained through offsite pre-survey and/or onsite observation and interviews.

## **G - §403.742 Physical Environment**

The objective is to view all patient, staff and public areas of the facility to ensure a safe physical plant and overall environment. The RNHCI facility must be toured as a whole, even areas not specifically for patient use. This is to ensure that there are adequate and properly maintained emergency systems, fire detection alarm and extinguishing systems. Procedures should be in place for proper storage, disposal of trash, proper ventilation, lights, and temperature controls. In addition, a written disaster plan to address loss of power, water, sewer, facilities emergency gas and water supply, and effective pest control should be evident.

## **H - §403.744 Life Safety Code**

The objective is to use collective onsite observations and interviews with RNHCI staff/patients as a mechanism to report any questionable information that should be noted and referred to the Life Safety Code inspector. Surveyors should keep routine Life Safety Code requirements in mind when conducting their investigation of the physical environment of the facility.

## **I - §403.746 Utilization Review (UR)**

The objective is to determine from surveyor observation, interview, and record review that the RNHCI has a utilization review plan (and other documentation) to determine the needs and appropriateness of those services furnished by the RNHCI staff to patients.

Record review establishes whether the RNHCI has in effect a utilization review plan that is:

- Responsible and has the approval of the governing body;
- Conducted by a committee that maintains a system of records on deliberations and decisions;
- Reviewing the necessity of inpatient admission and continued stay for all patients who are eligible for benefits under Medicare Part A or Medicaid;
- Providing written notification of a recommendation to all involved parties on a timely basis, and
- Administered by a committee which is composed of at least the following members:
  - (a) The governing body;
  - (b) Administrator or other individual responsible for the oversight of the RNHCI;
  - (c) The supervisor of religious non-medical nursing staff; and
  - (d) Other staff as appropriate.
- Review the minutes of the UR committee to verify that they include:
  - Dates of meetings and names of members in attendance;
  - Efficient use of available resources;
  - Number of extended stay reviews approved since the last meeting with reasons for all recommendations for or against; and
  - Status report on any action taken.

## **Task 5 – Arriving At A Determination**

A deficiency determination is made when the facility has failed to meet one or more of the condition level requirements.

A facility's compliance with the Conditions of Coverage (including election requirements), and the Conditions of Participation is a decision that is based on the objective input of each member of the team, including specialty surveyors. If the survey was performed by a team, then all team members should meet to discuss the findings and collaboratively reach a positive or negative determination.

## **Task 6 - Exit Conference**

### **A – Purpose of Exit Conference**

The purpose of the exit conference is to inform the RNHCI staff of the survey team's observations and preliminary findings. It is not to provide the facility with a full accounting of the deficiencies that will be cited. These will be determined upon review of the team's observations and findings during the survey write-up. This should be made clear to the facility.

The exit conference also provides an opportunity for the RNHCI to present additional information it believes is pertinent to the preliminary identified findings. Because of the ongoing dialogue between surveyors and facility staff during the survey, there should be few instances where the RNHCI is not aware of surveyor concerns or has not had an opportunity to present additional information prior to the exit conference.

### **B – Conducting the Exit Conference**

Conduct the Exit Conference with the RNHCI personnel and other invited staff/individuals. The team may provide an abbreviated exit conference specifically for patients after completion of the RNHCI's exit conference. Do not discuss survey results in a manner that reveals the identity of an individual staff member or patient. Provide information in a manner that is understandable to those present.

## **Interpretive Guidelines**

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**R93**

### **§403.720 Conditions for Coverage**

**Medicare covers services furnished in an RNHCI if the following conditions are met.**

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## R94

### §403.720(a)

**The provider meets the definition of an RNHCI as defined in §1861(ss)(1) of the Act. That is, it is an institution that:**

#### **Guideline: §403.720(a)**

The provider must meet all 10 of the regulatory requirements in order to meet the definition of an RNHCI:

**(1) Is described in section 501(c)(3) of the Internal Revenue Code of 1986 and is exempt from taxes under section 501(a).**

#### **Procedure: §403.720(a)(1)**

Verify with IRS current 501(c)(3) status of the RNHCI, which may have changed since initial application.

**(2) Is lawfully operated under all applicable Federal, State, and local laws and regulations.**

#### **Procedure: §403.720(a)(2)**

Since these are nonmedical facilities there is a wide range in how States view or consider these facilities. Prior to going onsite find out if the given State licenses or monitors the facilities

**(3) Furnishes only nonmedical nursing items and services to beneficiaries who choose to rely solely upon a religious method of healing and for whom the acceptance of medical services would be inconsistent with their religious beliefs.**

#### **Guideline: §403.720(a)(3)**

Only nonmedical nursing services are provided to beneficiaries. The religious services provided to the beneficiary are not to be considered as part of religious nonmedical nursing services

**(4) Furnishes nonmedical items and services exclusively through nonmedical nursing personnel who are experienced in caring for the physical needs of nonmedical patients.**

**Guideline: §403.720(a)(4)**

Alternative medicine is considered medical care in reviewing the care or services provided to these beneficiaries.

**(5) Furnishes nonmedical items and services to inpatients on a 24-hour basis.**

**Procedure: §403.720(a)(5)**

Verify that services are provided on a 24-hour basis.

**(6) Does not furnish, on the basis of religious beliefs, through its personnel or otherwise medical items and services (including any medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs) for its patients.**

**Guideline: §403.720(a)(6)**

Immunizations may only be administered if required by law and a health care practitioner comes to the facility for the mandated administration of the vaccine.

**(7) Is not owned by, is not under common ownership with, or does not have an ownership interest of 5 percent or more in, a provider of Medical treatment services and is not affiliated with a provider of medical treatment or services or with an individual who has an ownership interest of 5 percent or more in, a provider of medical treatment or services. (Permissible affiliations are described at §403.738(c).)**

**Procedure: §403.720(a)(7)**

Verify ownership using Form CMS-855 and/or Form CMS-1513 as applicable.

**(8) Has in effect a utilization review plan that sets forth the following:**

**(i) Provides for review of the admissions to the institution, the duration of stays, and the need for continuous extended duration of stays in the institution, and the items and services furnished by the institution.**

**(ii) Requires that reviews be made by an appropriate committee of the institution that included the individuals responsible for overall administration and for supervision of nursing personnel at the institution.**

**(iii) Provides that records be maintained of the meetings, decisions, and actions of the review committee.**

**(iv) Meets other requirements as the Secretary finds necessary to establish an effective utilization review plan.**

**(9) Provides information CMS may require to implement section 1821 of the Act, including information relating to quality of care and coverage decisions.**

**Procedure: §403.720(a)(9)**

Review the facility system of records to assure that they support coverage decisions and quality of care issues. Review all files for beneficiary elections for religious nonmedical health care institution services.

**(10) Meets other requirements CMS finds necessary in the interest of the health and safety of the patients who receive services in the institution. These requirements are the conditions of participation in this subpart.**

**Guideline: §403.720(a)(10)**

In addition to the Conditions of Coverage in accordance to 1821 of the act, a facility must meet the Conditions of Participation and be surveyed accordingly.

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## **R95**

**§403.720(b)**

**The provider meets the conditions of participation cited in §§403.730 through 403.746. (A provider may be deemed to meet conditions of participation in accordance with part 488 of this chapter.)**

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## **R96**

**§403.720(c)**

**The provider has a valid provider agreement as a hospital with CMS in accordance with part 489 of this chapter and for payment purposes is classified as an extended care hospital.**

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## **R97**

**§403.720(d)**

**The beneficiary has a condition that would make him or her eligible to receive services covered under Medicare Part A as an inpatient in a hospital or extended care services furnished in a hospital or skilled nursing facility.**

**Procedure: §403.720(d)**

Review the utilization review committee notes and nurses' notes.

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## **R98**

### **§403.720(e)**

The beneficiary has a valid election as described in §403.724 in effect for Medicare covered services furnished in an RNHCI

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## **R99**

### **§403.724 Valid Election Requirements**

#### **§403.724(a) General Requirements**

An election statement must be made by the Medicare beneficiary or his or her legal representative.

(1) The election must be a written statement that must include the following statements:

(i) The beneficiary is conscientiously opposed to acceptance of nonexcepted medical treatment.

(ii) The beneficiary acknowledges that the acceptance of nonexcepted medical treatment is inconsistent with his or her sincere religious beliefs.

(iii) The beneficiary acknowledges that the receipt of nonexcepted medical treatment constitutes a revocation of the election and may limit further receipt of services in an RNHCI.

(iv) The beneficiary acknowledges that the election may be revoked by submitting a written statement to CMS.

(v) The beneficiary acknowledges that revocation of the election will not prevent or delay access to medical services available under Medicare Part A in facilities other than RNHCIs.

(2) The election must be signed and dated by the beneficiary or his or her legal representative.

(3) The election must be notarized.

(4) The RNHCI must keep a copy of the election statement on file and submit the original to CMS with any information obtained regarding prior elections or revocations.

**(5) The election becomes effective on the date it is signed.**

**(6) The election remains in effect until revoked**

**Guideline: §403.724(a)**

The Election means a written statement signed by the patient to choose to receive nonmedical care for religious reasons. Excepted medical care means medical care that is received involuntarily or required under Federal, State, or local law.

Each RNHCI has the ability to customize the election form used by beneficiaries. However, the prescribed list of content stated in the regulation must be included in order to qualify as a legal election of RNHCI care or services. The six major items in the regulatory column may be used as a check list in reviewing elections.

**§403.724(b) Revocation of election** - (included for your information rather than as a survey item)

**(1) A beneficiary's election is revoked by one of the following:**

**(i) The beneficiary receives nonexcepted medical treatment for which Medicare payment is requested.**

**(ii) The beneficiary voluntarily revokes the election and notifies CMS in writing.**

**(2) The receipt of excepted medical treatment as defined in §403.702 does not revoke the election made by a beneficiary.**

**§403.724(c) Limitation on subsequent elections** - (included for your information rather than as a survey item)

**(1) If a beneficiary's election has been made and revoked twice, the following limitations on subsequent elections apply:**

**(i) The third election is not effective until 1 year after the date of the most recent revocation.**

**(ii) Any succeeding elections are not effective until 5 years after the date of the most recent revocation.**

**(2) CMS will not accept as the basis for payment of any claim any elections executed on or after January 1 of the calendar year in which the sunset provision described in §403.756 becomes effective.**

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**R100****§403.730 Condition of Participation: Patient Rights**

**An RNHCI must protect and promote each patient's rights.**

**Intent: §403.730: Patient Rights**

The intent of this Condition of Participation is to ensure that patient rights are protected and that the facility actively promotes the exercising of rights for each patient. This includes anyone who faces barriers (such as communication problems, hearing problems, and cognition limits) in the exercise of these rights. All patients in RNHCIs have rights guaranteed under Federal and State law.

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**R101****§403.730(a) Standard: Notice of Rights**

**The RNHCI must do the following:**

**(1) Inform each patient of his or her rights in advance of furnishing patient care.**

**Procedure: §403.730(a)(1)**

Determine if individuals and representatives are aware of the individual's rights and the rules of the facility.

**Guideline: §403.730(a)(1)**

The RNHCI has provided information to the patient and representatives in terms and in a language he or she understands. If the patient's knowledge of English or the predominant language of the facility is inadequate for comprehension, a means to communicate in a language familiar to the patient must be available and implemented. The facility should have written translations, as applicable, of its statements of rights and responsibilities, and should make the services of an interpreter available if needed. For hearing impaired patients who communicate by signing, the facility is expected to provide an interpreter. Large print text of the facility statement of patient rights and responsibilities should also be available.

When State or Federal laws regarding patient rights change during a patient stay, the patient and/or his or her legal representative must be promptly informed of these changes.

**Probe: §403.730(a)(1)**

Does the facility have a formalized statement of rights and responsibilities?

Does the facility verify that patients have received and understand their rights and responsibilities?

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## **R102**

**§403.730(a)(2) Have a process for prompt resolution of grievances, including a specific person within the facility whom a patient may contact to file a grievance. In addition, the facility must provide patients with information about the facility's process as well as with contact information for appropriate State and Federal resources.**

**Intent: §403.730(a)(2)**

The intent of this regulation is to provide an opportunity for patients to express in a means or communicate in a familiar language grievances, and for the facility to resolve any grievances. It is expected that facilities will have a grievance process that allows patients to express concerns without retribution, and resolves grievances to the extent possible. The facility should maintain a system of receipt and resolution of grievances (such as a log) as well as provide patients with names, addresses, and telephone numbers of appropriate State and Federal resources.

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## **R103**

**§403.730(b) Standard: Exercise of Rights**

**The patient has the right to:**

**(1) Be informed of his or her rights and to participate in the development and implementation of his or her plan of care.**

**Procedure: §403.730(b)(1)**

Discuss with the patient, the services that he or she is receiving specific to the plan of care. Ask the patient how he or she was told of any changes in the plan of care. Discuss the changes and see if the patient has received written information and if the patient understands the information. Determine the extent to which the facility initiates activities that involve the patient in his or her care. If the patient refused to participate, interview the patient to verify his/her refusal.

**Probe: §403.730(b)(1)**

What do you observe about the interaction between staff and patients?

Is there evidence that the patient was included or proactively involved in his/her plan of care?

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**R104**

**(2) Make decisions regarding his or her care, including transfer and discharge from the RNHCI. (See §403.736 for discharge and transfer requirements.)**

**Probe: §403.730(b)(2)**

Is there evidence that each patient was given information regarding the right to make decisions?

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**R105**

**(3) Formulate advance directives and expect staff who furnish care in the RNHCI to comply with those directives, in accordance with part 489, Subpart I of this chapter. For purposes of conforming with the requirement in §489.102 that there be documentation in the patient's care records concerning advance directives, the patient care records of a beneficiary in an RNHCI are equivalent to medical records held by other providers.**

**Guideline: §403.730(b)(3)**

Advance directives are particularly important for a patient choosing to rely solely upon religious nonmedical methods of healing, as it makes his or her wishes known in the event he or she becomes incapacitated and unable to make health care choices. An advance directive could lead to the provision of nonexcepted medical care, and thus effectively revoke an Election, or support the choice made in that Election, and must be honored by the facility.

**Procedure: §403.730(b)(3)**

Ensure that an Election form that complies with §403.724(a) is on file for each patient. Revocations of elections must also be on file. Ensure that there is evidence that the patient has had the opportunity to formulate his or her advance directive. Corroborate through patient interviews.

## **§403.730(c) Standard: Privacy and Safety**

**The patient has the right to the following:**

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### **R106**

#### **(1) Personal privacy**

**Guidelines: §403.730(c)(1-2)**

Personal privacy includes accommodations, written and telephone communications, personal care, visits, and meetings of family and patient groups, but this does not require the facility to provide a private room for each patient.

Facility staff must examine and care for patients in a manner that maintains the privacy of patients' bodies. A patient must be granted privacy when toileting and in other activities of personal hygiene. If a patient requires assistance, authorized staff should respect the patient's need for privacy. People not involved in the care of the patient should not be present during care, nor should video or other electronic monitoring/recording methods be used without the patient's consent. Prior to the provision of personal care and services, staff should remove the patient from public view to prevent unnecessary exposure of the patient's body parts (using means such as privacy curtains, closed patient room doors, clothing and/or draping).

The intention of this requirement is to specify that each patient receive care in an environment that is considered to be reasonably safe. For example, RNHCI staff should follow current standards of practice for patient environmental safety, infection control, and security.

Other safe setting includes but is not limited to properly maintained assistive devices (wheelchair, walker, cane, hearing aide), bathing facilities with non-slip surfaces, electrical appliances without frayed wires or exposed heating elements, proper radiator temperatures, proper water temperatures in hand sinks, and bathing facilities which cannot scald or harm patients.

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### **R107**

#### **(2) Care in a safe setting**

**Probe: §403.730(c)(2)**

What are the RNHCI's policies and procedures for patient environmental safety, infection control, and security?

Does the facility notify appropriate agencies of public health concern as required?

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## **R108**

### **(3) Freedom from verbal, psychological, and physical abuse, and misappropriation of property.**

#### **Guideline: §403.730(c) (3)**

Patients must not be subjected to any type of abuse by any individual, including but not limited to staff, other patients, consultants, volunteers, family members, legal guardians, friends or other individuals.

“Abuse” means the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish (see 42 CFR §488.301). This includes staff neglect or indifference to infliction of injury or intimidation of one patient by another.

Neglect means a failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness. (See 42 CFR §488.301)

Surveyor should keep in mind that this is non-medical model and should not expect to see medical care given. Patient should receive the care indicated in their care plan.

This also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. This presumes that instances of abuse of all patients, even those in a coma, cause physical harm, or pain or mental anguish.

“Misappropriation of property” means the deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a patient's belongings or money without the patient's consent. (See 42 CFR §488.301)

The facility must have a mechanism in place that is designed to identify potential abuse situations, investigate allegations, and protect patients and staff during investigations. Through the quality assessment and performance improvement system and staff training, the facility must demonstrate ongoing attempts to prevent future incidents of abuse.

#### **Procedure: §403.730(c)(3)**

If during the course of a survey, surveyors identify potential abuse situations, investigate allegations through interviews, observations, and record reviews. Report and record any instances where the survey team observes an abusive incident. Completely document who committed the alleged abusive act, nature of the abuse, and where and when it occurred. Ensure that the facility addresses the incident immediately.

**Probes: §403.730(c)(3)**

What type of complaints do individuals report (if any) and how well does the facility respond?

Are adequate systems in place to protect patients from abuse and misappropriation of property?

Are incidents reported appropriately?

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**R109**

**(4) Freedom from the use of restraints**

**Guidelines: §403.730(c)(4) and (5)**

Restraint and seclusion use may constitute an accident hazard. Professional standards of practice have eliminated the need for physical restraints except under limited medical circumstances. **RNHCI's may not use restraints.**

The facility may not use restraints in violation of the regulation solely because a surrogate or representative has approved or requested them.

Restraints means any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that the individual cannot remove easily which restricts freedom of movement or normal access to one's body.

Restraints include, but are not limited to, leg restraints, arm restraints, hand mitts, soft ties or vests, lap cushions and lap trays the patient cannot remove. Also included as restraints are facility practices such as:

- Using bed rails to keep a patient from voluntarily getting out of bed as opposed to enhancing mobility while in bed;
- Tucking in a sheet so tightly that a bed bound patient cannot move;
- Using wheelchair safety bars to prevent a patient from rising from the chair;
- Placing a patient in a chair that prevents rising; and
- Placing a patient who uses a wheelchair so close to a wall that the wall prevents the patient from rising.

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## **R110**

### **(5) Freedom from involuntary seclusion**

#### **Guideline: §403.730(c)(5)**

Involuntary seclusion is the involuntary confinement of a person alone in a room or an area where the person is physically prevented from leaving. A patient who is involuntarily in a room isolated from the rest of a unit should be considered in seclusion.

**RNHCI may not use seclusion.**

### **§403.730(d) Standard: Confidentiality of Patient Records**

**For any patient care records or election information it maintains on patients, the RNHCI must establish procedures to do the following:**

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## **R111**

**(1) Safeguard the privacy of any information that identifies a particular patient. Information from, or copies of, records may be released only to authorized individuals, and the RNHCI must ensure that unauthorized individuals cannot gain access to or alter patient records. Original patient care records must be released only in accordance with Federal or State laws, court orders, or subpoenas.**

#### **Guidelines: §403.730(d)(1-4)**

The patient has the right to have his or her care records maintained in a confidential manner.

#### **Probes: §403.730(d)(1-4)**

How does the facility ensure the confidentiality of patient records?

Does the facility instruct the caretaker and authorized individual about protecting the confidentiality of the record, if the facility leaves a portion of the record with the caretaker and/or authorized individual?

What evidence indicates that each patient is informed of policies and procedures concerning his/her record disclosure?

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## **R112**

**(2) Maintain the records and information in an accurate and timely manner**

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**R113**

**(3) Ensure timely access by patients to the records and other information that pertains to that patient.**

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**R114**

**(4) Abide by all Federal and State laws regarding confidentiality and disclosure for patient care records and election information.**

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**R125****§403.732 Condition of Participation: Quality Assessment and Performance Improvement**

**The RNHCI must develop, implement, and maintain a quality assessment and performance improvement program.**

**Intent: §403.732**

The facility must have in place a program that has a definitive scope and which can be used to measure, analyze, track, and improve performance. The plan should address the full range of services offered by the facility.

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**R126****§403.732 (a) Standard: Program Scope**

**(1) The quality assessment and performance improvement program must include, but is not limited to, measures to evaluate:**

- (i) Access to care.**
- (ii) Patient satisfaction.**
- (iii) Staff performance.**
- (iv) Complaints and grievances.**
- (v) Discharge planning activities.**
- (vi) Safety issues, including physical environment.**

**Guideline: §403.732 (a)(1)**

The facility must objectively evaluate the required areas. The facility must also objectively evaluate any additional areas which they decide to include in their quality assessment and evaluation program.

Specifically, at a minimum, the facility must define and describe quality assessment and performance improvement activities that are appropriate for the services furnished in the facility. CMS has not provided a specific definition of quality nor provides an outline for what activities are appropriate to meet this standard due to the unique nature of the RNHCI program.

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**R127**

**(2) In each of the areas listed in paragraph (a)(1) of this section, and any other areas the RNHCI includes, the RNHCI must do the following:**

- (i) Define quality assessment and performance improvement measures.**
- (ii) Describe and outline quality assessment and performance improvement activities appropriate for the services furnished by or in the RNHCI.**
- (iii) Measure, analyze, and track performance that reflect care and RNHCI processes.**
- (iv) Inform all patients, in writing, of the scope and responsibilities of the quality assessment and performance improvement program.**

**Procedure: §403.732(a)(2)**

Review facility policies and procedures on the quality assessment and performance improvement program.

Determine if the facility has a formal method to identify issues in the facility, that require quality assessment and performance improvement.

Determine if the facility has a method to respond to identified issues and the means to evaluate the response to the issues.

Verify through interviews with staff, patients, and governing body member(s) that the facility has established a protocol or method for addressing quality in the facility, and those issues that the facility believes have now been resolved.

Verify that the staff and patient know how to access that process.

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**R128**

**(3) The RNHCI must set priorities for performance improvement, considering the prevalence of and severity of identified problems**

**Probe: §403.732(a)(3)**

Are RNHCI improvement priorities based on problems identified and is performance improvement realistic or achievable based on the prevalence and severity of the problem?

Are priorities specific to identified problems with timeline for measuring each objective?

Are there demonstrable steps toward improvement?

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**R129**

**(4) The RNHCI must act to make performance improvements and must track performance to assure that improvements are sustained.**

**Guideline: §403.732(a)(4)**

The facility must use an objective means of tracking performance. Each facility is allowed the flexibility to identify its own measures of performance for the activities it identifies as priorities in its quality assessment and performance improvement strategy. The facility meets this requirement by conducting an analysis when adverse outcomes are identified and the facility takes action to sustain correction and improvement of the identified issue.

For a RNHCI to consider that it is “doing better” is a subjective statement and is not an acceptable measure of performance. There must be some identifiable units of measurement that a knowledgeable person can distinguish as evidence of change.

**Probe: §403.732(a)(4)**

Does the RNHCI take action to enact long-term correction and improvement?

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**R130**

**§403.732(b) Standard: Program Responsibilities**

**(1) The governing body, administration, and staff are responsible for ensuring that the quality assessment and performance improvement program addresses identified priorities in the RNHCI and are responsible for the development, implementation, maintenance, and performance improvement of assessment actions.**

**Probe: §403.732(b)(1)**

How does the RNHCI ensure that responsibilities for quality assessment are identified, performed and monitored with the goal of continuous performance improvement?

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**R131**

**(2) The RNHCI must include all programs, departments, functions, and contracted services when developing, implementing, maintaining, and evaluating the program of quality assessment and performance improvement.**

**Guideline: §403.732(b)(2)**

This includes all services provided under contract with outside agencies.

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**R140**

**§403.734 Condition of Participation: Food Services**

**The RNHCI must have an organized food service that is directed and adequately staffed by qualified personnel.**

**Intent: §403.734 Food Service**

“Qualified personnel” is defined based on State and local laws for the provision of food services. Food service personnel must demonstrate safe food handling (see §403.734).

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**R141**

**§403.734(a) Standard: Sanitary Conditions**

**The RNHCI must furnish food to the patient that is obtained, stored, prepared, distributed, and served under sanitary conditions.**

**Guideline: §403.734(a)**

Sanitary conditions means storing, preparing, distributing, and serving food properly to prevent food-borne illness. Potentially hazardous foods must be subject to continuous time/temperature controls to prevent either the rapid and progressive growth of infectious or toxigenic micro-organisms, such as Salmonella, or the slower growth of Clostridium Botulinum. In addition, foods of plant origin become potentially hazardous when the skin, husk, peel, or rind is breached, thereby possibly contaminating the fruit or vegetable with disease-causing micro-organisms. Potentially hazardous food tends to focus on animal products, including but not limited to milk, eggs, and poultry.

Improper holding temperature is a common contributing factor of food borne illness. The facility must follow proper procedures in cooking, cooling, and storing food according to time, temperature, and sanitary guidelines. Improper handling of food can cause Salmonella and E-Coli contamination.

The RNHCI is expected to follow accepted standards of practice in regards to food storage and handling.

**Procedure and Probe: §403.734(a)**

Observe storage, cooling, and cooking of food. Record the time and date of all observations performed. If a problem is noted, conduct additional observations to verify findings.

Observe that employees are effectively cleaning their hands prior to preparing, distributing and serving food. Observe that food is covered to maintain temperature and protect from other contaminants when transporting meals to patients.

Refrigerated storage: Check all refrigerators and freezers for temperatures. Use the facility's or the surveyor's own properly sanitized thermometer to evaluate the internal temperatures of potentially hazardous foods with a focus on the quantity of leftovers and the container sizes in which bulk leftovers are stored.

Food preparation: Use a sanitized thermometer to evaluate food temperatures. In addition, how do kitchen staff process leftovers? Are they heated to the appropriate temperatures? How is frozen food thawed? How is potentially hazardous food handled during multi-step food preparation (e.g., chicken salad, egg salad)? Is hand contact with food minimized?

Food service: Using a properly sanitized thermometer, check the temperature of hot and cold food prior to serving. How long is milk held without refrigeration prior to distribution?

Food distribution: Is the food protected from contamination as it is transported to the dining rooms and residents' rooms?

Are hand washing facilities convenient and properly equipped for dietary services staff use? (Staff uses good hygienic practices and staff with communicable diseases or infected skin lesions do not have contact with food if that contact will transmit the disease.)

Are toxic items (such as insecticides, detergent, polishes) properly stored, labeled, and used separate from the food?

**Probe: §403.734(a)**

Observe food storage rooms and food storage in the kitchen. Are containers of food stored off the floor and on clean surfaces in a manner that protects it from contamination? Are other areas under storage shelves monitored for cleanliness to reduce attraction of pest?

Are potentially hazardous foods stored at 41° F or below and frozen foods kept at 0° F or below?

Do staff handle and cook potentially hazardous foods properly?

Are potentially hazardous foods kept at an internal temperature of 41° F or below in a cold food storage unit, or at an internal temperature of 140° F or above in a hot food storage unit during display and service?

Is food transported in a way that protects against contamination (i.e., covered containers, wrapped, or packaged)?

Is there any sign of rodent or insect infestation?

**Dishwashing**

The current 1993 Food Code, DHHS, FDA, PHS recommends the following water temperature and manual washing instructions:

**Machine:**

1. Hot Water:
  - a. 140° F Wash (or according to the manufacturer's specifications or instructions).
  - b. 180° F Rinse (180°, 160° or greater at the rack and dish/utensils surfaces).
2. Low temperature:
  - a. 120° F + 25ppm (parts per million) Hypochlorite (household bleach) on dish surface.

**§403.734(b) Standard: Meals**

**The RNHCI must serve meals that furnish each patient with adequate nourishment in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences. The RNHCI must do the following:**

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## **R142**

**(1) Furnish food that is palatable, attractive, and at the proper temperature and consistency.**

**Guideline and Probe: §403.734(b)(1)**

CMS prohibits prescription of therapeutic diets or parenteral nutrition in this program, as these are considered medical practices. However, altering food consistency (mechanically altered food; chopped, cut, ground, pureed, etc.) is not considered a medical practice, but is designed to meet the needs of the patient.

“Food-palatability” refers to the taste and/or flavor of the food.

“Food-attractiveness” refers to the appearance of the food when served to patients.

Evidence for palatability and attractiveness of food, from day to day and meal to meal, may be strengthened through sources such as additional observation, patient, and staff interviews.

- Does food have a distinct aroma or odor?
- Is the appearance varied in color and texture?
- Is food generally well seasoned (use of spices, herbs, etc.), and acceptable to patients?
- Is food served at preferable temperature (hot foods are served hot and cold foods are served cold) as discerned by the patient and customary practice? Is food held and served at proper temperatures?

Identify concerns such as appearance or meal quality (such as color and texture of vegetables or meats and, preparation and presentation of mechanically altered foods).

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## **R143**

**(2) Offer substitutes of similar nourishment to patients who refuse food served or desire alternative choices.**

**Guidelines: §403.734(b)(2-4)**

Observe food service to determine that meals are appropriate to each patient according to care plans.

Ask patients how well the food meets their taste needs. Are patients offered the opportunity to receive substitutes when refusing food on the original menu?

Ask patients when they eat breakfast, lunch, and dinner.

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**R144**

**(3) Furnish meals at regular times comparable to normal mealtimes in the community. There must be no more than 14 hours between a substantial evening meal and breakfast the following day.**

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**R145**

**(4) The RNHCI must offer snacks at bedtime.**

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**R150**

*(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)*

**§403.736 Condition of Participation: Discharge Planning**

The RNHCI must have in effect a discharge planning process that applies to all patients. The process must assure that appropriate post-institution services are obtained for each patient, as necessary. *The RNHCI must assess the need for a discharge plan for any patient identified as likely to suffer adverse consequences if there is no planning.*

*Interpretive Guidelines §403.736:*

*Guidance pending and will be updated in future release.*

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**R151**

*(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)*

**§403.736(a) Standard: Discharge Planning Evaluation**

*(1) Discharge instructions must be provided at the time of discharge to the patient or the patient's caregiver as necessary.*

*Interpretive Guidelines §403.736(a):*

*Guidance pending and will be updated in future release.*

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## R152

(ii) An assessment of the probability of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the RNHCI.

### Procedure: §403.736(a)(1)(ii)

Review closed records for discharge planning and post-institution services. Interview facility staff involved in the discharge planning process.

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## R153

*(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)*

*(2) If the patient assessment indicates a need for a discharge plan, the discharge plan must include instructions on post-RNHCI care to be used by the patient or the caregiver in the patient's home, as identified in the discharge plan.*

### *Interpretive Guidelines §403.736(a)(1 - 2):*

*Guidance pending and will be updated in future release*

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## R154

*(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)*

*(3) If the RNHCI's patient assessment does not indicate a need for a discharge plan, the beneficiary or his or her legal representative may request a discharge plan. In this case, the RNHCI must develop a discharge plan for the beneficiary.*

### *Interpretive Guidelines §403.736(a)(3):*

*Guidance pending and will be updated in future release*

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## R161

*(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)*

### **§403.736(b) Standard: Transfer or Referral**

The RNHCI must transfer or refer patients in a timely manner to another facility (including a medical facility if requested by the beneficiary, or his or her legal representative) in accordance with [§403.730\(b\)\(2\)](#)

### *Interpretive Guidelines §403.736(b):*

*Guidance pending and will be updated in future release*

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**R162**

*(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)*

**§403.736(c) Standard: Reassessment**

The RNHCI must reassess its discharge planning process on an ongoing basis. The reassessment must include a review of discharge plans to ensure that they are responsive to discharge needs.

*Interpretive Guidelines §403.736(c):*

*Guidance pending and will be updated in future release*

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**R175****§403.738 Condition of Participation: Administration**

An RNHCI must have written policies regarding its organization, services, and administration.

**§403.738(a) Standard: Compliance with Federal, State, and local laws.**

The RNHCI must operate in compliance with all applicable Federal, State, and local laws, regulations, and codes including, but not limited to, those pertaining to the following:

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**R176**

(1) Protection against discrimination on the basis of race, color, national origin, age, or handicap (45 CFR parts 80, 84, and 91).

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**R177**

(2) Protection of human research subjects (45 CFR part 455).

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**R178**

(3) Application of all safeguards to protect against the possibility of fraud and abuse (42 CFR part 455).

**Procedures: §403.738(a)(1-3)**

Determine whether the facility is in compliance with Federal, State and local laws.

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**R179**

**§403.738(b) Standard: Governing Body**

**(1) The RNHCI must have a governing body, or a person designated to function as a governing body, that is legally responsible for establishing and implementing all policies regarding the RNHCI's management and operation.**

**Guideline: §403.738(b)(1)**

The governing body provides, monitors, and revises, as necessary, policies and operating directions that ensure the necessary staffing, training resources, equipment and environment to provide patients care and ensure their health and safety.

How does the governing body exercise its responsibility for the entire operation of the RNHCI and evaluation of the RNHCI and its patients' outcomes?

The responsibility for direction includes areas such as health, safety, sanitation, maintenance and repair, and utilization and management of staff. When deficiencies are identified during the survey, interview the administrator or review the minutes of governing body meetings, if available, to determine to what extent the governing body has identified and attempted to address the problem.

If staff have been trained, but are not implementing programs or are inappropriately deployed (e.g., there are enough staff but they are assigned to duties like record keeping which prevents them from delivering needed services), this may indicate a failure of the governing body to adequately direct staff activities.

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**R180**

**(2) The governing body must appoint the administrator responsible for the management of the RNHCI.**

**Guideline: §403.738(b)(2)**

Review agreements with outside agencies to ensure that entities entering into affiliations with the RNHCI for purposes of management and operations meet the ownership requirements at §403.720(a)(7) and §403.738(c).

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**R181****§403.738(c) Standard: Affiliations and Disclosure**

**(1) An affiliation is permissible if it is between one of the following:**

- (i) An individual serving as an uncompensated director, trustee, officer, or other member of the governing body of an RNHCI and a provider of medical treatment or services.**
- (ii) An individual who is a director, trustee, officer, employee, or staff member of an RNHCI and another individual, with whom he or she has a family relationship, who is affiliated with (or has an ownership interest in) a provider of medical treatment or services.**
- (iii) The RNHCI and an individual or entity furnishing goods or services as a vendor to both providers of medical treatment or services and RNHCIs.**

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**R182**

**(2) The RNHCI complies with the disclosure requirements of §§420.206 and 455.104 of this chapter.**

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**R183**

**(3) The RNHCI furnishes written notice, including the identity of each new individual or company, to CMS at the time of a change, if a change occurs in any of the following:**

- (i) Persons with an ownership or control interest, as defined in §§420.201 and 455.101 of this chapter.**
- (ii) The officers, directors, agents, or managing employees.**
- (iii) The religious entity, corporation, association, or other company responsible for the management of the RNHCI.**
- (iv) The RNHCI's administrator or director of nonmedical nursing services.**

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**R184**

**(4) RNHCIs must comply with the Federal, State, and Local laws pertaining to “privacy of individual identifiable health information (45 CFR 164).”**

**Procedures: §403.738(a)(4)**

Determine whether the facility is in compliance with Federal, State and local laws.  
(refer to R176, R177, and R178)

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**R190**

**§403.740 Condition of Participation: Staffing**

**The RNHCI must be staffed with qualified experienced personnel who are present in sufficient numbers to meet the needs of the patients.**

**Intent: §403.740**

The intent of the regulation is that all areas of the RNHCI are staffed with sufficient, qualified personnel. To be an efficient and well-run institution, all staff, including those not directly involved in patient care, must work to improve the overall quality of the facility.

Staff are available and know how to respond to individual patients' needs and emergencies at all times. The RNHCI has sufficient staff to provide needed care and services.

**Guideline: §403.740**

The test of adequacy of staffing is how well the facility has organized itself to detect and react appropriately to potential emergencies, such as fire, injuries, etc.

Do not look at numbers alone. The RNHCI is responsible for organizing and evaluating its activities, assignments and available staff in such a way that maximizes the benefit to the patient. During the course of the onsite survey, you should be able to observe behavioral evidence of such organization.

**Probe: §403.740**

Is there observational or other evidence to suggest that patients' needs are not being met (e.g., demonstrate need for toileting, changing) while staff do laundry, housekeeping, cooking, or other tasks?

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## **R191**

### **§403.740(a) Standard: Personnel Qualifications**

**The RNHCI must ensure that staff who supervise or furnish services to patients are qualified to do so and that staff allowed to practice without direct supervision have specific training to furnish these services.**

#### **Guideline: §403.740(a)**

In order to determine whether RNHCI staff are “qualified,” in the absence of specific Federal, State, or local laws, review staff records for evidence of work experience and training (including, but not limited to, educational or life experience) with respect to duties currently performed.

This standard applies to all such individuals who furnish services, whether or not they are employed or compensated by the RNHCI or, if they are compensated, whether salaried or contractors.

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## **R192**

### **§403.740(b) Standard: Education, Training, and Performance Evaluation**

**(1) The RNHCI must ensure that staff (including contractors and other individuals working under arrangement) have the necessary education and training concerning their duties so that they can furnish services competently. This education includes, but is not limited to, training related to the individual job description, performance expectations, applicable organizational policies and procedures, and safety responsibilities.**

#### **Probe: §403.740(b)(1)**

How does the facility orient personnel (including contractual personnel) to RNHCI objectives, policies, procedures, and programs?

How does coordination of care among staff and/or contract personnel providing services to the facility occur?

Have staff received training (both upon hiring and on an ongoing basis) which results in the competencies needed to do their job?

Are staff aware and capable of meeting their job requirements?

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**R193**

**(2) Staff must demonstrate, in practice, the skills and techniques necessary to perform their duties and responsibilities.**

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**R194**

**(3) The RNHCI must evaluate the performance of staff and implement measures for improvement.**

**Guidelines: §403.740(b)(2) and (3)**

For effective service and safety of the patients, it is critical that all staff use the skills and techniques necessary to do their jobs correctly.

**Procedures and Probes: §403.740(b)(2) and (3)**

Observe whether or not staff are knowledgeable about the needs of each patient with whom they are assigned to work. Staff should be able to demonstrate in practice the results of training for the patients for whom they are responsible.

Determine the extent to which staff demonstrate competency in providing care for the patients for whom they are responsible.

If you identify questionable patient care practices by staff:

- Interview staff with respect to the practice; and
- Determine the purpose of the practice.

How has the facility addressed areas of weakness identified in its evaluation of its staff and incorporated actions to improve staff and the facility's overall performance?

How does the facility orient personnel (including contractual personnel) to objectives, policies, procedures, and programs?

How does coordination of care among staff and/or contract personnel providing services to the facility occur on an ongoing basis?

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**R200**

***(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)***

**§403.742 Condition of Participation: Physical Environment**

A RNHCI must be designed, constructed, and maintained to ensure the safety of the patients, staff, and the public.

### **§403.742(a) Standard: Buildings**

The physical plant and the overall environment must be maintained in a manner that ensures the safety and well-being of the patients. The RNHCI must have the following:

***Interpretive Guidelines §403.742:***

*Guidance pending and will be updated in future release*

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#### **R202**

***(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)***

**(1) Procedures for the proper storage and disposal of trash.**

***Interpretive Guidelines §403.742(a)(1):***

*Guidance pending and will be updated in future release*

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#### **R203**

***(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)***

**(2) Proper ventilation and temperature control and appropriate lighting levels to ensure a safe and secure environment.**

***Interpretive Guidelines §403.742(a)(2):***

*Guidance pending and will be updated in future release*

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#### **R206**

***(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)***

**(3) An effective pest control program.**

***Interpretive Guidelines §403.742(a)(3):***

*Guidance pending and will be updated in future release*

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#### **R207**

***(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)***

**(4) A preventive maintenance program to maintain essential mechanical, electrical, and fire protection equipment operating in an efficient and safe manner.**

***Interpretive Guidelines §403.742(a)(4):***

*Guidance pending and will be updated in future release*

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## **R208**

***(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)***

**(5) A working call system for patients to summon aid or assistance.**

***Interpretive Guidelines §403.742(a)(5):***

*Guidance pending and will be updated in future release*

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## **R209**

### **§403.742(b) Standard: Patient Rooms**

**Patient rooms must be designed and equipped for adequate care, comfort, and privacy of the patient.**

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## **R210**

**(1) Patient rooms must meet the following conditions:**

**(i) Accommodate no more than four patients.**

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## **R211**

**(ii) Measure at least 80 square feet per patient in multiple patient rooms and at least 100 square feet in single patient rooms.**

**Guideline: §403.742(b)(1)(ii)**

The measurement of the square footage should be based upon the useable living space of the room. Therefore, the minimum square footage in patient rooms should be measured based upon the floor's measurements exclusive of toilets and bath areas, closets, lockers, wardrobes, alcoves, or vestibules. However, if the height of the alcoves or vestibules reasonably provides useful living area, then the corresponding floor area may be included in the calculation.

The space occupied by movable wardrobes should be excluded from the useable square footage in a room, unless it is an item of the patient's own choice, and it is in addition to

the individual closet space in the patient's room. Non-permanent items of the patient's own choice should have no effect in the calculation of useable living space.

Protrusions such as columns, radiators, ventilation systems for heating and/or cooling should be ignored in computing the useable square footage of the room if the area involved is minimal (e.g., a baseboard heating or air conditioning system or ductwork that does not protrude more than 8 inches from the wall, or a column that is, not more than 8 inches on each side), and does not have an adverse effect on the patient's health and safety. If these protrusions are not minimal, they would be deducted from useable square footage computed in determining compliance with this requirement.

The swing or arc of any door that opens directly into the patient's room should not be excluded from the calculations of useable square footage in a room.

The facility layout may give square footage measurements. Carry a tape measure and take measurements if the room appears small.

Unless a variance has been applied for and approved as at §403.742(b)(3), are there at least 80 square feet per patient in multiple patient rooms and at least 100 square feet for single patient rooms?

Additional guidance is available from the Life Safety Code (LSC) specialist

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## **R212**

**(iii) Have direct access to an exit corridor.**

**Guideline: §403.742(b)(1)(iii)**

There is no authority under current regulations to approve a variance to this requirement.

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## **R213**

**(iv) Be designed or equipped to assure full visual privacy for each patient.**

**Guideline: §403.742(b)(1)(iv)**

“Full visual privacy” means that patients have a means of completely withdrawing from public view while occupying their bed (e.g., curtain, moveable screens, private room).

The guidelines do not intend to limit the provisions of privacy to solely one or more curtains, moveable screens or a private room. Facility operators are free to use other means to provide full visual privacy, with those means varying according to the needs and requests of patients. However, the requirement explicitly states that bedrooms must “be designed or equipped to assure full visual privacy for each patient.” For example, a patient with a bed by the window cannot be required to remain out of his or her room

while his/her roommate is having a dressing changed. Room design or equipment must provide privacy.

**Procedure: §403.742(b)(1)(iv)**

Surveyors will assess whether the means the facility is using to assure full-visual privacy meets this requirement without negatively affecting any other patient rights.

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**R214**

(v) **Have at least one window to the outside.**

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**R215**

(vi) **Have a floor at or above grade level.**

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**R216**

(2) **The RNHCI must furnish each patient with the following:**

(i) **A separate bed of proper size and height for the convenience of the patient.**

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**R217**

(ii) **A clean, comfortable mattress.**

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**R218**

(iii) **Bedding appropriate to the weather and climate.**

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**R219**

(iv) **Functional furniture appropriate to the patient's needs and individual closet space with clothes racks and shelves accessible to the patient.**

**Guideline: §403.742(b)(2)(iv)**

“Functional furniture appropriate to the patients’ needs” means that the furniture in each patient’s room contributes to the patient attaining or maintaining his/her highest practicable level of independence. In general, furnishings include places to put clothing away in an organized manner that will let it remain clean, free of wrinkles, and accessible to the patient while protecting it from casual access by others, and places to put personal effects.

There may be instances in which individual patients determine that certain items are not necessary (e.g., both the patient and spouse use wheelchairs. They visit more easily without another chair in the room.) In this case, the patient's wishes could determine the furniture needs.

"Shelves accessible to the patient" means that the patient, if able, or a staff person at the direction of the patient, can get to their clothes whenever they choose.

**Probe: §403.742(b)(2)(iv)**

Is there functional furniture appropriate to the patients' needs?

Is there individual closet space with accessible clothes racks and shelves?

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**R220**

**(3) CMS may permit variances in requirements specified in paragraphs (b)(1)(i) and (ii) of this section relating to rooms on an individual basis when the RNHCI adequately demonstrates in writing that the variances meet the following:**

**(i) Are in accordance with the special needs of the patients.**

**(ii) Will not adversely affect patients' health and safety.**

**Guideline: §403.742(b)(3)**

A variance must be in accordance with the special needs of the patients and must not adversely affect the health or safety of patients. Facility hardship is not part of the basis for granting a variance.

**Procedure: §403.742(b)(3)**

The variances must be reviewed and considered for renewal whenever the facility is certified.

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**R224**

*(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)*

*§403.744 Condition of Participation: Life Safety From Fire*

*§403.744(a) General*

*An RNHCI must meet the following conditions:*

*Interpretive Guidelines: §403.744*

*Guidance pending and will be updated in future release.*

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## **R225**

*(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)*

**§403.744(a) General. An RNHCI must meet the following conditions:**

**(1) Except as provided in this section-**

- (i) The RNHCI 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).**

**Interpretive Guidelines: §403.744 (a)(1)(i)**

*Guidance pending and will be updated in future release.*

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## **R226**

*(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)*

**§403.744(a) General. An RNHCI must meet the following conditions:**

**(1) Except as provided in this section-**

- (ii) Notwithstanding paragraph (a)(1)(i) of this section, corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors.**

**Interpretive Guidelines: §403.744 (a)(1)(ii)**

*Guidance pending and will be updated in future release.*

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## **R227**

*(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)*

**§403.744 (a)(2) The RNHCI must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, staff, and the public; evacuation; and cooperation with fire fighting authorities.**

**Interpretive Guidelines: §403.744 (a)(2)**

*Guidance pending and will be updated in future release.*

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## **R228**

*(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)*

**§403.744 (a)(3) The RNHCI must maintain written evidence of regular inspection and approval by State or local fire control agencies.**

*Interpretive Guidelines: §403.744 (a)(3)*

*Guidance pending and will be updated in future release.*

## **R229**

*(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)*

**§403.744 (a)(4) The RNHCI may place alcohol based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.**

*Interpretive Guidelines: §403.744 (a)(4)*

*Guidance pending and will be updated in future release.*

## **R230**

*(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)*

**§403.744 (a)(5) When a sprinkler system is shut down for more than 10 hours the RHNCI must:**

- (i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or*
- (ii) Establish a fire watch until the system is back in service.*

*Interpretive Guidelines: §403.744 (a)(5)*

*Guidance pending and will be updated in future release.*

## **R231**

*(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)*

**§403.744 (a)(6) Building must have an outside window or outside door in every sleeping room, and for any building constructed after July 5, 2016 the sill height must not exceed 36 inches above the floor. Windows in atrium walls are considered outside windows for the purposes of this requirement.**

*Interpretive Guidelines: §403.744 (a)(6)*

*Guidance pending and will be updated in future release.*

## **R232**

*(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)*

### **§403.744(b) Exceptions**

**(1) *In consideration of a recommendation by the State survey agency or Accrediting Organization, or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon a RNHCI facility, but only if the waiver will not adversely affect the health and safety of the patients.***

**(2) If CMS finds that the fire and safety code imposed by State law adequately protects patients in the institution, the provisions of the Life Safety Code required in paragraph (a)(1) of this section do not apply in that State.**

***Interpretive Guidelines: §403.744(b)(1) and (2):***

*Guidance pending and will be updated in future release.*

## **R233**

*(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)*

***§403.744(c) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:***

***[http://www.archives.gov/Federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/Federal_register/code_of_federal_regulations/ibr_locations.html). If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the Federal Register to announce the changes.***

**(1) *National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, [www.nfpa.org](http://www.nfpa.org), 1.617.770.3000.***

- (i) *NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;***
- (ii) *TIA 12-1 to NFPA 101, issued August 11, 2011.***
- (iii) *TIA 12-2 to NFPA 101, issued October 30, 2012.***
- (iv) *TIA 12-3 to NFPA 101, issued October 22, 2013.***
- (v) *TIA 12-4 to NFPA 101, issued October 22, 2013.***

**(2) *[Reserved]***

## **R234**

*(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)*

**§ 403.745 Condition of participation: Building Safety.**

- (a) *Standard: Building Safety. Except as otherwise provided in this section the RNHCI must meet the applicable provisions and must proceed in accordance with the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6).*
- (b) *Standard: Exceptions. Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to a RNHCI.*
- (c) *Waiver. If application of the Health Care Facilities Code required under paragraph (a) of this section would result in unreasonable hardship for the RNHCI, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of individuals.*
- (d) *Incorporation by reference. The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html). If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the Federal Register to announce the changes.*
- (1) *National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, [www.nfpa.org](http://www.nfpa.org), 1.617.770.3000.*
- (i) *NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.*
- (ii) *TIA 12-2 to NFPA 99, issued August 11, 2011.*
- (iii) *TIA 12-3 to NFPA 99, issued August 9, 2012.*
- (iv) *TIA 12-4 to NFPA 99, issued March 7, 2013.*
- (v) *TIA 12-5 to NFPA 99, issued August 1, 2013.*
- (vi) *TIA 12-6 to NFPA 99, issued March 3, 2014.*
- (2) *[Reserved]*

## **R235**

### **§403.746 Condition of Participation: Utilization Review**

**The RNHCI must have in effect a written utilization review plan to assess the necessity of services furnished. The plan must provide that records be maintained of all meetings, decisions, and actions by the utilization review committee.**

**Guideline: §403.746**

Determine that the RNHCI has a written utilization review plan to assess the necessity of services furnished by the RNHCI and its staff to Medicare and Medicaid patients. Verify through review of records and reports, and interviews with the Utilization Review (UR) chairperson and/or members, that UR activities are being performed as described in the plan. Review the minutes of the UR committee to verify that they include procedures for evaluating admissions as stated in §403.746(a).

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**R236**

**§403.746(a) Standard: Utilization Review Plan**

**The utilization review plan must contain written procedures for evaluating the following:**

- (1) Admissions.**
  - (2) Duration of care.**
  - (3) Continuing care of an extended duration.**
  - (4) Items and services furnished.**
- 

**R237**

**§403.746(b) Standard: Utilization Review Committee**

**The committee is responsible for evaluating each admission and ensuring that the admission is necessary and appropriate. The utilization review plan must be carried out by the utilization review committee, consisting of the governing body, administrator or other individual responsible for the overall administration of the RNHCI, the supervisor of nursing staff, and other staff as appropriate.**

**Guideline: §403.746(b)**

Review the Utilization Review plan and the determinations involving all admissions or extended stays.

Verify that the composition of the UR committee is appropriate.

## Transmittals Issued for this Appendix

Rev #	Issue Date	Subject	Impl Date	CR#
<u>R200SOMA</u>	02/21/2020	Revisions to the State Operations Manual (SOM) Appendix A - Hospitals, Appendix AA – Psychiatric Hospitals, Appendix B – Home Health Agency, Appendix D - Portable X-Ray, Appendix G - Rural Health Clinics/Federally Qualified Health Centers, Appendix H- End Stage Renal Disease Facilities (ESRD), Appendix K – Comprehensive Outpatient Rehabilitation Facility, Appendix L - Ambulatory Surgical Centers, Appendix M – Hospice, Appendix U - Religious Nonmedical Healthcare Institutions, Appendix W - Critical Access Hospitals (CAHs), Appendix X-Organ Transplant Program and Appendix Z - Emergency Preparedness	02/21/2020	N/A
<u>R171SOMA.pdf</u>	11/17/2017	Revisions to State Operations Manual (SOM), Appendix U - Survey Procedures and Interpretive Guidelines for Responsibilities of Medicare Participating Religious Nonmedical Healthcare Institutions	11/20/2017	N/A
<u>R01SOM</u>	05/21/2004	Initial Release of Pub 100-07	N/A	N/A