Prepublication Requirements

• Issued February 19, 2021 •

Home Health Changes related to CMS Final Rule

The Joint Commission has approved the following revisions for prepublication. While revised requirements are published in the semiannual updates to the print manuals (as well as in the online E-dition®), accredited organizations and paid subscribers can also view them in the monthly periodical The Joint Commission Perspectives®. To begin your subscription, call 800-746-6578 or visit http://www.jcrinc.com.

Please note: Where applicable, this report shows current standards and EPs first, with deleted language struck-through. Then, the revised requirement follows in bold text, with new language underlined.

APPLICABLE TO THE HOME CARE ACCREDITATION PROGRAM

Effective March 14, 2021

Human Resources (HR) Chapter

HR.01.01.01

The organization defines and verifies staff qualifications.

Element(s) of Performance for HR.01.01.01

11. For home health agencies and hospices that elect to use The Joint Commission deemed status option: The organization defines personnel qualifications as required by Centers for Medicare & Medicaid Services’ regulations (at 42 CFR 484.115 for home health agencies and at 42 CFR 418.114 and 42 CFR 418.76(a) for hospices).

Note: The following terms are defined in the Glossary: administrator, audiologist, clinical manager, qualified home health aide, qualified hospice aide, occupational therapist, occupational therapy assistant, physical therapist, physical therapist assistant, physician, practical (vocational) nurse, public health nurse, registered nurse, skilled professional services, social worker, social work assistant, speech-language pathologist.

11. For home health agencies and hospices that elect to use The Joint Commission deemed status option: The organization defines personnel qualifications as required by Centers for Medicare & Medicaid Services' regulations (at 42 CFR 484.115 for home health agencies and at 42 CFR 418.114 and 42 CFR 418.76(a) for hospices).

Note: The following terms are defined in the Glossary: administrator, audiologist, clinical manager, clinical nurse specialist, nurse practitioner, qualified home health aide, qualified hospice aide, occupational therapist, occupational therapy assistant, physician, practical (vocational) nurse, public health nurse, registered nurse, skilled professional services, social worker, social work assistant, speech-language pathologist.

Key: D indicates that documentation is required; R indicates an identified risk area;
HR.01.02.07

The organization determines how staff function within the organization.

**Element(s) of Performance for HR.01.02.07**

13. For home health agencies that elect to use The Joint Commission deemed status option: Skilled professionals have responsibility for, but are not limited to, the following:
- Participation in the patient’s coordination of care
- Ongoing interdisciplinary assessment of the patient
- Development and evaluation of the plan of care in partnership with the patient, representative (if any), and caregiver(s)
- Providing services that are ordered by the physician as indicated in the plan of care
- Patient, caregiver, and family counseling
- Patient and caregiver education
- Preparing clinical notes
- Communication with all physicians involved in the plan of care and other health care practitioners (as appropriate) related to the current plan of care
- Participation in the organization’s quality assessment and performance improvement (QAPI) program
- Participation in organization-sponsored in-service training

Note: See glossary for the definition of skilled professional services.

13. For home health agencies that elect to use The Joint Commission deemed status option: Skilled professionals have responsibility for, but are not limited to, the following:
- Participation in the patient’s coordination of care
- Ongoing interdisciplinary assessment of the patient
- Development and evaluation of the plan of care in partnership with the patient, representative (if any), and caregiver(s)
- Providing services that are ordered by the physician or allowed practitioner as indicated in the plan of care
- Patient, caregiver, and family counseling
- Patient and caregiver education
- Preparing clinical notes
- Communication with all physicians or allowed practitioners involved in the plan of care
- Participation in the organization’s quality assessment and performance improvement (QAPI) program
- Participation in organization-sponsored in-service training

Note: See glossary for the definition of skilled professional services.

Information Management (IM) Chapter

**IM.02.02.03**

The organization retrieves, disseminates, and transmits health information in useful formats.

**Element(s) of Performance for IM.02.02.03**
10. For home health agencies that elect to use The Joint Commission deemed status option: The home health agency transmits test data to either the Quality Improvement and Evaluation System (QIES)—Assessment Submission and Processing (ASAP) System or Centers for Medicare & Medicaid Services' Outcome and Assessment Information Set (OASIS) contractor.

Medication Management (MM) Chapter

**MM.04.01.01**

Medication orders or prescriptions are clear and accurate.
Note: For more information on verbal and telephone orders, refer to Standards RC.02.03.07 and PC.02.01.03.

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<tr>
<th>Element(s) of Performance for MM.04.01.01</th>
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<tbody>
<tr>
<td>28. For home health agencies that elect to use The Joint Commission deemed status option: Influenza and pneumococcal vaccines are administered per an organization policy developed in consultation with a physician, and after an assessment of the patient to determine any contraindications.</td>
</tr>
<tr>
<td>28. For home health agencies that elect to use The Joint Commission deemed status option: Influenza and pneumococcal vaccines are administered per an organization policy developed in consultation with a physician or allowed practitioner and after an assessment of the patient to determine any contraindications.</td>
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Provision of Care, Treatment, and Services (PC) Chapter

**PC.01.02.03**

The organization assesses and reassesses the patient and his or her condition according to defined time frames.

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<td>10. For home health agencies that elect to use The Joint Commission deemed status option: The initial assessment visit must be held within 48 hours of referral, or within 48 hours of the patient's return home, or on the physician-ordered start-of-care date.</td>
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<td>10. For home health agencies that elect to use The Joint Commission deemed status option: The initial assessment visit must be held within 48 hours of referral, or within 48 hours of the patient's return home, or on the physician's or allowed practitioner's ordered start-of-care date.</td>
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Key: ☐ indicates that documentation is required; ☐ indicates an identified risk area;
13. For home health agencies that elect to use The Joint Commission deemed status option: The comprehensive assessment updated and revised (including administration of the Outcome and Assessment Information Set [OASIS]) as frequently as the patient’s condition warrants due to a major decline or improvement in the patient’s health status, but no less frequently than the following:
- The last 5 days of every 60 days beginning with the start-of-care date, unless there is a patient-elected transfer
- A significant change in condition, or a discharge and return to the same home health agency within the 60-day episode
- Within 48 hours of the patient’s return to the home from a hospital admission of 24 hours or more for any reason other than diagnostic tests or the patient has a physician-ordered resumption date
- At discharge

PC.01.02.05
Qualified staff or licensed independent practitioners assess and reassess the patient.

Element(s) of Performance for PC.01.02.05

5. For home health agencies that elect to use The Joint Commission deemed status option: When physical therapy, speech-language pathology, or occupational therapy is the only service ordered by a physician, a physical therapist, speech-language pathologist or occupational therapist may complete the comprehensive assessment and determine eligibility for the Medicare home health benefit, including homebound status. The occupational therapist may complete the comprehensive assessment if the need for occupational therapy establishes program eligibility. (See also PC.01.02.03, EP 11)

5. For home health agencies that elect to use The Joint Commission deemed status option: When physical therapy, speech-language pathology, or occupational therapy is the only service ordered by a physician or allowed practitioner, a physical therapist, speech-language pathologist or occupational therapist may complete the comprehensive assessment and determine eligibility for the Medicare home health benefit, including homebound status. The occupational therapist may complete the comprehensive assessment if the need for occupational therapy establishes program eligibility. (See also PC.01.02.03, EP 11)

PC.01.03.01
The organization plans the patient’s care.
Element(s) of Performance for PC.01.03.01

10. For home health agencies that elect to use The Joint Commission deemed status option: The individualized plan of care specifies the care and services necessary to meet the needs identified in the comprehensive assessment and addresses the following:
   - All pertinent diagnoses
   - Mental, psychosocial, and cognitive status
   - Types of services, supplies, and equipment required
   - The frequency and duration of visits
   - The patient’s prognosis
   - The patient’s potential for rehabilitation
   - The patient’s functional limitations
   - The patient’s permitted activities
   - The patient’s nutritional requirements
   - All medications and treatments
   - Safety measures to protect against injury
   - A description of the patient’s risk for emergency department visits and hospital readmission, and all necessary interventions to address the underlying risk factors
   - Patient-specific interventions and education
   - Measurable outcomes and goals identified by the organization and patient as a result of implementing and coordinating the plan of care
   - Patient and caregiver education and training to facilitate timely discharge
   - Information related to any advance directives
   - Identification of the disciplines involved in providing care
   - Any other relevant items, including additions, revisions and deletions
10. For home health agencies that elect to use The Joint Commission deemed status option: The individualized plan of care specifies the care and services necessary to meet the needs identified in the comprehensive assessment and addresses the following:
   - All pertinent diagnoses
   - Mental, psychosocial, and cognitive status
   - Types of services, supplies, and equipment required
   - The frequency and duration of visits
   - The patient’s prognosis
   - The patient’s potential for rehabilitation
   - The patient’s functional limitations
   - The patient’s permitted activities
   - The patient’s nutritional requirements
   - All medications and treatments
   - Safety measures to protect against injury
   - A description of the patient’s risk for emergency department visits and hospital readmission, and all necessary interventions to address the underlying risk factors
   - Patient-specific interventions and education
   - Measurable outcomes and goals identified by the organization and patient as a result of implementing and coordinating the plan of care
   - Patient and caregiver education and training to facilitate timely discharge
   - Information related to any advance directives
   - Identification of the disciplines involved in providing care
   - Any other relevant items, including additions, revisions, and deletions that the home health agency, physician, or allowed practitioner may choose to include

Key: ☐ indicates that documentation is required; ☐ indicates an identified risk area;
12. For home health agencies that elect to use The Joint Commission deemed status option: When a physician refers a patient under a plan of care that cannot be completed until after an evaluation visit, the staff consults with the physician to approve additions or modifications to the original plan of care.

12. For home health agencies that elect to use The Joint Commission deemed status option: When a physician or allowed practitioner refers a patient under a plan of care that cannot be completed until after an evaluation visit, the staff consults with the physician or allowed practitioner to approve additions or modifications to the original plan of care.

56. For home health agencies that elect to use The Joint Commission deemed status option: Revisions related to plans for the patient’s discharge must be communicated to the patient, representative, caregiver, all physicians issuing orders for the organization’s plan of care, and the patient’s primary care practitioner or other health care professional who will be responsible for providing care and services (if any) to the patient after discharge from the organization. (See also PC.04.01.03, EP 3)

56. For home health agencies that elect to use The Joint Commission deemed status option: Revisions related to plans for the patient’s discharge must be communicated to the patient, representative, caregiver, all physicians or allowed practitioners issuing orders for the organization’s plan of care, and the patient’s primary care practitioner or other health care professional who will be responsible for providing care and services (if any) to the patient after discharge from the organization. (See also PC.04.01.03, EP 3)

PC.02.01.03

The organization provides care, treatment, or services in accordance with orders or prescriptions, as required by law and regulation.

Element(s) of Performance for PC.02.01.03

1. Prior to providing care, the organization obtains or renews orders (verbal or written) from a licensed independent practitioner in accordance with professional standards of practice and law and regulation.

1. Prior to providing care, the organization obtains or renews orders (verbal or written) from a physician or allowed practitioner in accordance with professional standards of practice and law and regulation.

8. For home health agencies that elect to use The Joint Commission deemed status option: The organization follows physician orders when administering medications or providing care, treatment, or services.

8. For home health agencies that elect to use The Joint Commission deemed status option: The organization follows physician or allowed practitioner orders when administering medications or providing care, treatment, or services.
9. For home health agencies and hospices that elect to use The Joint Commission deemed status option: The home health aide or hospice aide provides services that are ordered by the physician in the plan of care, consistent with the aide’s training, and that the aide is permitted to perform under state law.

9. For home health agencies and hospices that elect to use The Joint Commission deemed status option: The home health aide or hospice aide provides services that are ordered by the physician or allowed practitioner in the plan of care, consistent with the aide’s training, and that the aide is permitted to perform under state law.

**PC.02.01.05**
The organization provides interdisciplinary, collaborative care, treatment, or services.

**Element(s) of Performance for PC.02.01.05**

10. For home health agencies that elect to use The Joint Commission deemed status option: The individualized plan of care must be reviewed and revised by the physician responsible for the home health plan of care and the home health agency as frequently as the patient’s condition or needs require, but no less frequently than once every 60 days, beginning with the start of care date.

10. For home health agencies that elect to use The Joint Commission deemed status option: The individualized plan of care must be reviewed and revised by the physician or allowed practitioner responsible for the home health plan of care and the home health agency as frequently as the patient’s condition or needs require, but no less frequently than once every 60 days, beginning with the start of care date.

12. For home health agencies that elect to use The Joint Commission deemed status option: The home health agency promptly alerts the relevant physician(s) to any changes in the patient’s condition or needs that suggest that outcomes are not being achieved and/or there is a need to alter the plan of care.

12. For home health agencies that elect to use The Joint Commission deemed status option: The home health agency promptly alerts the relevant physician(s) or allowed practitioner(s) to any changes in the patient’s condition or needs that suggest that outcomes are not being achieved and/or there is a need to alter the plan of care.

**PC.02.02.01**
The organization coordinates the patient’s care, treatment, or services based on the patient’s needs.

**Element(s) of Performance for PC.02.02.01**
31. For home health agencies that elect to use The Joint Commission deemed status option: The home health agency coordinates the patient’s care in the following ways:
   - Coordinates communication with all physicians or allowed practitioners involved in the plan of care
   - Integrates orders from all physicians or allowed practitioners involved in the plan of care so all services and interventions provided are coordinated
   - Involves the patient, representative (if any), and caregiver(s), as appropriate, in the coordination of care activities in order to meet patient needs

31. For home health agencies that elect to use The Joint Commission deemed status option: The home health agency coordinates the patient’s care in the following ways:
   - Coordinates communication with all physicians or allowed practitioners involved in the plan of care
   - Integrates orders from all physicians or allowed practitioners involved in the plan of care so all services and interventions provided are coordinated
   - Involves the patient, representative (if any), and caregiver(s), as appropriate, in the coordination of care activities in order to meet patient needs

PC.04.01.01

The organization follows a process that addresses the patient’s need for continuing care, treatment, or services after discharge or transfer.

Element(s) of Performance for PC.04.01.01

Key: ☑ indicates that documentation is required; ☐ indicates an identified risk area;
29. For home health agencies that elect to use The Joint Commission deemed status option: The home health agency may only transfer or discharge a patient for the following reasons:

- The organization and the physician responsible for the home health plan of care agree that the organization can no longer meet the patient's needs based on the patient's acuity
- The patient or payer will no longer pay for the services provided by the organization
- The organization and the physician responsible for the home health plan of care agree that the patient no longer needs the organization's services because the measurable outcomes and goals set forth in the plan of care (in accordance with 42 CFR 484.60(a)(2)(xiv)) have been achieved (See also PC.01.02.01, EP 25)
- The patient refuses services or elects to be transferred or discharged
- The home health agency has a policy that addresses discharge or transfer for cause when the patient's (or other persons in the patient's home) behavior is disruptive, abusive, or uncooperative to the extent that delivery of care to the patient or the ability of the organization to operate effectively is seriously impaired (See also PC.04.01.01, EP 30)
- The patient dies
- The organization ceases to operate

29. For home health agencies that elect to use The Joint Commission deemed status option: The home health agency may only transfer or discharge a patient for the following reasons:

- The organization and the physician or allowed practitioner responsible for the home health plan of care agree that the organization can no longer meet the patient's needs based on the patient's acuity
- The patient or payer will no longer pay for the services provided by the organization
- The organization and the physician or allowed practitioner responsible for the home health plan of care agree that the patient no longer needs the organization's services because the measurable outcomes and goals set forth in the plan of care (in accordance with 42 CFR 484.60(a)(2)(xiv)) have been achieved (See also PC.01.02.01, EP 25)
- The patient refuses services or elects to be transferred or discharged
- The home health agency has a policy that addresses discharge or transfer for cause when the patient's (or other persons in the patient's home) behavior is disruptive, abusive, or uncooperative to the extent that delivery of care to the patient or the ability of the organization to operate effectively is seriously impaired (See also PC.04.01.01, EP 30)
- The patient dies
- The organization ceases to operate
30. For home health agencies that elect to use The Joint Commission deemed status option: The organization does the following before it discharges a patient for cause:
- Advise the patient, representative (if any), the physician(s) issuing orders for the home health plan of care, and the licensed independent practitioner primarily responsible for the patient after discharge (if any) that a discharge for cause is being considered
- Make efforts to resolve the problem(s) presented by the patient’s behavior, the behavior of other persons in the patient’s home, or situation
- Provide the patient and representative (if any), with contact information for other agencies or providers who may be able to provide care
- Document the problem(s) and efforts made to resolve the problem(s), and then enter this documentation into the patient record
(See also PC.04.01.01, EP 29)

30. For home health agencies that elect to use The Joint Commission deemed status option: The organization does the following before it discharges a patient for cause:
- Advise the patient, representative (if any), the physician or allowed practitioner issuing orders for the home health plan of care, and the primary care practitioner or other health care professional responsible for the patient after discharge (if any) that a discharge for cause is being considered
- Make efforts to resolve the problem(s) presented by the patient’s behavior, the behavior of other persons in the patient’s home, or situation
- Provide the patient and representative (if any), with contact information for other agencies or providers who may be able to provide care
- Document the problem(s) and efforts made to resolve the problem(s), and then enter this documentation into the patient record
(See also PC.04.01.01, EP 29)

Record of Care, Treatment, and Services (RC) Chapter

**RC.01.01.01**

The organization maintains complete and accurate patient records.

**Element(s) of Performance for RC.01.01.01**
5. The patient record includes the following:
- Information needed to support the patient's diagnosis and condition
- Information needed to justify the patient's care, treatment, or services
- Information that documents the course and result of the patient's care, treatment, or services
- Information about the patient's care, treatment, or services that promotes continuity of care among providers

Note: For home health agencies that elect to use The Joint Commission deemed status option: Each patient's record is available to the physician(s) issuing orders for the home health plan of care and to staff as needed.
- Information that documents the patient's response to care, treatment, or services provided

RC.01.02.01

Entries in the patient record are authenticated.

Element(s) of Performance for RC.01.02.01

4. Entries in the patient record are authenticated by the author. Information introduced into the patient record through transcription or dictation is authenticated by the author.

Note 1: Authentication can be verified through electronic signatures, written signatures or initials, rubber-stamp signatures, or computer key. The Centers for Medicare & Medicaid Services (CMS) permits the use of rubber-stamp signatures in accordance with the Rehabilitation Act of 1973 for authors with a physical disability who can provide proof of their inability to sign their signature due to a disability.

Note 2: For paper-based records, signatures entered for purposes of authentication after transcription or for verbal orders are dated when required by law or regulation or organization policy. For electronic records, electronic signatures will be date-stamped.
Prepublication Requirements continued
February 19, 2021

**RC.02.01.01**

The patient record contains information that reflects the patient's care, treatment, or services.

**Element(s) of Performance for RC.02.01.01**

2. The patient record contains the following clinical information:
   - Any medications administered, including dose
   - Any activity restrictions
   - Any changes in the patient's condition
   - Any summaries of the patient's care, treatment, or services furnished to the patient's physician or licensed independent practitioner(s)
   - The patient's medical history
   - Any allergies to medications
   - Any adverse drug reactions
   - The patient's functional status
   - Any diet information or any dietary restrictions
   - Diagnostic and therapeutic tests, procedures, and treatments, and their results
   - Any specific notes on care, treatment, or services
   - The patient's response to care, treatment, or services
   - Any assessments relevant to care, treatment, or services
   - Physician orders
   - Any information required by organization policy, in accordance with law and regulation
   - A list of medications, including dose, strength, frequency, route, date and time of administration for prescription and nonprescription medications, herbal products, and home remedies that relate to the patient's care, treatment, or services
   - The plan(s) of care
   - For DMEPOS suppliers serving Medicare beneficiaries: The DMEPOS prescription, any certificates of medical necessity (CMN), and pertinent documentation from the beneficiary's prescribing physician. (See also PC.01.02.01, EP 1; PC.01.03.01, EP 23; RC.02.01.01, EP 3)

Note 1: For organizations that provide personal care and support services: The plan of care may be a part of the service agreement or service contract, a list of duties to be carried out by the personal care or support service staff, or another separate document.

Note 2: For organizations that provide personal care and support services: The patient record contains the documentation on the list noted above that applies to the care, treatment, or services provided by the personal care and support staff.

Key: ☐ indicates that documentation is required; ☐ indicates an identified risk area;
2. The patient record contains the following clinical information:
   - Any medications administered, including dose
   - Any activity restrictions
   - Any changes in the patient’s condition
   - Any summaries of the patient’s care, treatment, or services furnished to the patient’s physician or allowed practitioner
   - The patient’s medical history
   - Any allergies to medications
   - Any adverse drug reactions
   - The patient’s functional status
   - Any dietary information or any dietary restrictions
   - Diagnostic and therapeutic tests, procedures, and treatments, and their results
   - Any specific notes on care, treatment, or services
   - The patient’s response to care, treatment, or services
   - Any assessments relevant to care, treatment, or services
   - User or allowed practitioner orders
   - Any information required by organization policy, in accordance with law and regulation
   - A list of medications, including dose, strength, frequency, route, date and time of administration for prescription and nonprescription medications, herbal products, and home remedies that relate to the patient’s care, treatment, or services
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   Note 1: For organizations that provide personal care and support services: The plan of care may be a part of the service agreement or service contract, a list of duties to be carried out by the personal care or support service staff, or another separate document.
   Note 2: For organizations that provide personal care and support services: The patient record contains the documentation on the list noted above that applies to the care, treatment, or services provided by the personal care and support staff.
3. For home health agencies that elect to use The Joint Commission deemed status option: The patient record contains the following:
- Identifying information
- The name of the physician
- The patient’s current comprehensive assessment, and the assessments from the most recent home health admission
- Any medication, dietary, treatment, and activity orders
- All interventions, including medication administration, treatments, and services, and responses to those interventions
- Patient’s responses to all interventions, medications, treatments and services
- Goals in the patient’s plans of care and the patient’s progress toward achieving them
- Any signed and dated clinical and progress notes
- Contact information for the patient, the patient’s representative (if any) and the patient’s primary caregiver
- Contact information for the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the home health agency
- Any copies of summary reports sent to the attending physician
- A completed discharge summary
(See also PC.04.02.01, EP 3 and RC.02.01.01, EP 2)

3. For home health agencies that elect to use The Joint Commission deemed status option: The patient record contains the following:
- Identifying information
- The name of the physician or allowed practitioner
- The patient’s current comprehensive assessment, and the assessments from the most recent home health admission
- Any medication, dietary, treatment, and activity orders
- All interventions, including medication administration, treatments, and services, and responses to those interventions
- Patient’s responses to all interventions, medications, treatments and services
- Goals in the patient’s plans of care and the patient’s progress toward achieving them
- Any signed and dated clinical and progress notes
- Contact information for the patient, the patient’s representative (if any) and the patient’s primary caregiver
- Contact information for the physician or allowed practitioner who will be responsible for providing care and services to the patient after discharge from the home health agency
- Any copies of summary reports sent to the attending physician or allowed practitioner
- A completed discharge summary
(See also PC.04.02.01, EP 3 and RC.02.01.01, EP 2)

**RC.02.03.07**

Qualified staff receive and record verbal orders.

**Element(s) of Performance for RC.02.03.07**
3. For home health agencies that elect to use The Joint Commission deemed status option: Verbal orders are documented in the patient record and signed, dated, and timed by a registered nurse or qualified practitioner responsible for furnishing or supervising the ordered care, treatment, or services. Note: The Centers for Medicare & Medicaid Services (CMS) permits the use of rubber-stamp signatures in accordance with the Rehabilitation Act of 1973 for authors with a physical disability who can provide proof of their inability to sign their signature due to a disability.

3. For home health agencies that elect to use The Joint Commission deemed status option: Physician or allowed practitioner verbal orders are documented in the patient record and signed, dated, and timed by a registered nurse or qualified practitioner responsible for furnishing or supervising the ordered care, treatment, or services. Note: The Centers for Medicare & Medicaid Services (CMS) permits the use of rubber-stamp signatures in accordance with the Rehabilitation Act of 1973 for authors with a physical disability who can provide proof of their inability to sign their signature due to a disability.

Rights and Responsibilities of the Individual (RI) Chapter

RI.01.02.01

The organization respects the patient's right to participate in decisions about his or her care, treatment, or services.

Element(s) of Performance for RI.01.02.01

16. For home health agencies that elect to use The Joint Commission deemed status option: The home health agency advises the patient, representative (if any), caregiver, and all physicians issuing orders for the plan of care when there is any revision in the plan of care due to a change in patient health status before the change is made.

16. For home health agencies that elect to use The Joint Commission deemed status option: The home health agency advises the patient, representative (if any), caregiver, and all physicians or allowed practitioners issuing orders for the plan of care when there is any revision in the plan of care due to a change in patient health status before the change is made.