SR.2 The dietary manual shall be approved by a dietitian (full-time, part-time or contracted) and the medical staff at least every five years.

SR.3 The dietary manual shall be a document that is communicated, controlled and available to all staff and practitioners who are directly or indirectly responsible for ensuring that appropriate nutritional services are implemented.

Interpretive Guidelines:

A therapeutic diet manual must be approved by the dietitian and the medical staff. This therapeutic diet manual should be reviewed and under no circumstance should the publication or revision date be more than five years old. The therapeutic diet manual must be readily available to all medical, nursing and food service personnel.

Surveyor Guidance:

Review the therapeutic diet manual to determine that it is current and readily available to all appropriate staff. The therapeutic diet manual should include the diets currently available to patients and meet current national standards, such as RDA or DRI. The therapeutic diet manual should be referenced as necessary when such diets are prescribed.

Verify that the therapeutic diet manual has been approved by the medical staff and a qualified dietitian.

PATIENT RIGHTS (PR)

PR.1 NONDISCRIMINATION

SR.1 The organization will comply with the nondiscrimination provisions of Section 1557 of the Affordable Care Act (ACA) and will not deny access to health care because of race, color, national origin, sex, age, or disability.

SR.2 The organization will recognize all state-sanctioned marriages and spouses for purposes of compliance with the Conditions of Participation, regardless of any laws to the contrary of the state or locality where the organization is located.

Interpretive Guidelines:

In compliance with Section 1557 of the Affordable Care Act:

The hospital will post information notifying patients about their rights

The hospital will post information notifying patients with limited English proficiency (LEP) about the right to receive communication assistance.

- *The hospital is also required to post taglines in the top 15 languages spoken by individuals with LEP in the states in which the covered entity operates, advising consumers of the availability of free language assistance services.*

Except where CMS regulations explicitly require an interpretation in accordance with State law, wherever the text of a regulation or associated guidance uses the terms "marriage" or "spouse" or includes a reference to a patient's "representative," "surrogate," "support person," "next-of-kin," or similar term in such a manner as would normally implicitly or explicitly include a spouse, the terms are to be interpreted consistent with the guidance noted below:

"spouse" means an individual who is married to another individual as a result of marriage lawful where it was entered into, including a lawful same-sex marriage, regardless of whether the jurisdiction where the hospital is located, or in which the spouse lives, permits such marriages to occur or recognizes such marriages.

"marriage" means a marriage lawful where entered into, including a lawful same-sex marriage, regardless of whether the jurisdiction where the hospital is located, or in which the spouse lives, permits such marriages to occur or recognizes such marriages;

"family" includes, but is not limited to, an individual's "spouse" (see above); and,

"relative" when used as a noun, includes, but is not limited to, an individual's "spouse" (see above).

PR.2 SPECIFIC RIGHTS

The organization shall protect and promote each patient's rights. The organization shall inform, whenever possible, each patient and/or legal representative of the patient's rights in advance of providing or discontinuing care. The written listing of these rights shall be provided to the patient and /or family and shall include policies and procedures that address the following:

SR.1 Beneficiary Notices:

SR.1a Of non-coverage and right to appeal premature discharge; and,

SR.1b Medicare Outpatient Observation Notice (MOON).

SR.2 Patient participation and means for making informed decisions regarding his/her plan of care;

SR.3 The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services

deemed medically unnecessary or inappropriate.

SR.4 Prompt notification of the patient and his/her representative of patient choice and to promptly notify the patient's physician of admission;

SR.5 Personal privacy;

SR.6 Provision of care in a safe setting;

SR.7 Freedom from all forms of abuse or harassment;

SR.8 Confidentiality of clinical records;

SR.9 Patient access to clinical records as quickly as record keeping system permits; and,

SR.9a The hospital must not impede the legitimate efforts of individuals to gain access to their own clinical records and must actively seek to meet these requests as quickly as the record keeping system permits.

SR.10 Procedure for submission of a written or verbal grievance (See PR.6, Grievance Procedure).

SR.11 Pain Management

SR.12 Patient visitation rights

SR.12a The hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation.

SR.12b The hospital must: Inform each patient (or representative, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her other rights under 42 CFR Section 482.13(a).

SR.12c Inform each patient (or representative, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.

SR.12d Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, sexual orientation, gender identity, or disability.

SR.12e Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

SR.13 Other rights defined within the Patient Rights requirements (PR.1 – PR.8).

Interpretive Guidelines:

This standard requires that whenever possible, the hospital informs each patient and/or legal representative of the patient's rights in advance of providing or discontinuing care. The hospital will inform both inpatients and outpatients of their rights to include the elements as described in PR.1, SR.1 – SR.10.

The MOON is a standardized notice to inform beneficiaries (including Medicare health plan enrollees) that they are an outpatient receiving observation services and are not an inpatient of the hospital.

The MOON is mandated by the Federal Notice of Observation Treatment and Implication for Care Eligibility Act (NOTICE Act), passed on August 6, 2015. The NOTICE Act requires all hospitals to provide written and oral notification under specified guidelines.

All organizations are required to provide the MOON beginning no later than March 8, 2017.

https://www.cms.gov/Medicare/Medicare-General-Information/BNI/index.html?redirect=/bni/

Each Medicare beneficiary who is an inpatient is provided with a standardized notice, the "Important Message from Medicare, within two days of their admission. The Important Message (IM) template provided by CMS is to be used by the hospital, signed and dated by the patient when it is delivered to the beneficiary. In addition, a copy of the IM is to be presented to the beneficiary within two days before discharge.

The hospital has the responsibility to establish and implement policies and procedures that effectively ensure that patients and/or legal representative have the information necessary to exercise their rights under the Federal law. This responsibility includes, and is not limited to, providing all notices required by statute and regulation regarding patients' rights. The hospital may decide it is most effective to bundle the patients' rights and advance directives notice with these existing notices.

The hospital will provide for interpretation for certain individuals who speak languages other than English, use alternative communication techniques or aides for those who are deaf or blind, or take other steps as needed to effectively communicate with the patient.

The hospital's obligation to inform requires that the hospital present information in a manner and form that can be understood (e.g., the use of large print materials, specialized programs to inform individuals who are deaf or blind, use of interpreters).

The hospital must include the patient or their legal representative in the development, implementation and revision of his/her plan of care.

A patient may elect to delegate his or her right to make informed decisions to another person. To the degree permitted by State law, and to the maximum extent practical, the hospital must respect the patient's wishes and follow these accordingly. If the patient is unconscious or otherwise incapacitated and unable to make a decision, the hospital must consult the patient's advance directives, medical durable power of attorney or patient representative, if any of these individuals are available. In the advance directive or the medical power of attorney, the patient may provide guidance as to his or her wishes in certain situations or may delegate decision-making to another individual as permitted by State law. If such an individual has been selected by the patient, or if a person willing and able under applicable State law is available to make treatment decisions, relevant information should be provided to the representative so that informed health care decisions can be made for the patient. However, as soon as the patient is able to be informed of his or her rights, the hospital should provide such information to the patient.

The patient's (or patient's representatives, as allowed by law) right to participate in the development and implementation of his or her plan of care includes at a minimum, the right to: information regarding the patient's health status, diagnosis and prognosis, participate in the development and implementation of his/her inpatient treatment/care plan or outpatient treatment/care plan, including providing consent to, or refusal of, medical or surgical interventions; participate in the development and implementation of his/her discharge plan; and, participate in the development and implementation of his/her pain management plan. The patient or his or her representative should receive information provided in a manner that it is understood and to assure that the patient can effectively exercise the right to make informed decisions.

The patient and/or legal representative has the right to request or refuse treatment. This standard stresses, however, that the patient's right to make decisions about health care is not equivalent to an ability to demand treatment or services that are deemed medically inappropriate or unnecessary.

The right to personal privacy includes, at a minimum, that patients have privacy during personal hygiene activities (e.g., toileting, bathing, dressing), during medical/nursing treatments, and when requested by the patient as appropriate. The right to personal privacy would also include limiting the release or disclosure of patient information such as the patient's presence in the facility or location in the hospital, or personal information such as name, age, address, income, health information without prior consent from the patient. The hospital should have procedures in place, in accordance with State law, to provide appropriate information to patient families or significant others in those situations where the patient is unable to make their wishes known.

If an individual requires assistance during toileting, bathing, and other personal hygiene activities, staff should assist, giving utmost attention to the individual's need for privacy. Privacy should be afforded when the MD/DO or other staff visits the patient to discuss clinical care issues or conduct any examination.

A patient's right to privacy may be limited in situations where a person must be continuously observed, such as when restrained or in seclusion when immediate and serious risk to harm him/ herself (such as when the patient is under

suicide precautions or special observation status) or others exists.

The hospital staff should follow current standards of practice for patient environmental safety, infection control, and security. The hospital must protect vulnerable patients, including newborns and children.

The hospital must ensure that patients are free from all forms of abuse, neglect, or harassment. The hospital must have mechanisms/methods in place that ensure patients are free of all forms of abuse, neglect, or harassment.

The hospital must assure that any incidents of abuse, neglect or harassment are reported and analyzed, and the appropriate corrective, remedial or disciplinary action occurs, in accordance with applicable local, State, or Federal law.

Definition: Abuse is defined as the willful infliction of injury, unreasonable confinement, intimidation, or punishment, with resulting physical harm, pain, or mental anguish. This includes staff neglect or indifference to infliction of injury or intimidation of one patient by another. Neglect, for the purpose of this requirement, is considered a form of abuse and is defined as the failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness.

The hospital must have sufficient safeguards in place to ensure that access to all information regarding patients is limited to those individuals designated by law, regulation, and policy; or duly authorized as having a need to know. No unauthorized access or dissemination of clinical records is permitted. Clinical records are kept secure and are only viewed when necessary by those persons having a part in the patient's care.

Confidentiality applies to both central records and clinical record information that may be kept at other locations in the hospital, such as, patient units, radiology, laboratories, patient clinics, record storage areas, data systems, etc.

Care in a Safe Setting

In order to provide care in a safe setting, hospitals must identify patients at risk for intentional harm to self or others, identify environmental safety risks for such patients, and provide education and training for staff and volunteers.

Patients at risk of suicide (or other forms of self-harm) or exhibit violent behaviors toward others receive healthcare services in both inpatient and outpatient locations of hospitals. The focus for a ligature "resistant" or ligature "free" environment is that of psychiatric units of acute care hospitals and psychiatric hospitals and does not apply to non-psychiatric units of acute care hospitals that provide care to those at risk of harm to self or others, e.g. emergency departments, intensive care units, medical -surgical units, and other inpatient and outpatient locations.

It is important to note that not all patients with psychiatric conditions or a history of a psychiatric condition are cared for in psychiatric hospitals or psychiatric units of acute care hospitals. Therefore, non-psychiatric settings of all hospitals where patients with psychiatric conditions may be cared for must also identify patients at risk for intentional harm to self or others and mitigate environmental safety risks. Psychiatric patients requiring medical care in a non-psychiatric setting (medical inpatient units, ED, ICU, etc.) must be protected when demonstrating suicidal ideation or harm to others. The protection would be that of utilizing safety measures such as 1:1 monitoring with continuous visual observation, removal of sharp objects from the room/area, or removal of equipment that can be used as a weapon. Although all risks cannot be eliminated, hospitals are expected to demonstrate how they identify patients at risk of self -harm or harm to others and steps they are taking to minimize those risks in accordance with nationally recognized standards and guidelines.

The potential risks include but are not limited to those from ligatures, sharps, harmful substances, access to medications, breakable windows, accessible light fixtures, plastic bags (for suffocation), oxygen tubing, bell cords, etc.

Identifying Patients at Risk

There are numerous models and versions of patient risk assessment tools available to identify patients at risk for harm to self or others. No one size fits all tool is available. Therefore, the type of patient risk assessment tool used should be appropriate to the patient population, care setting and staff competency. All hospitals are expected to implement a patient risk assessment strategy, but it is up to the hospital to implement the appropriate strategies. For example, a patient risk assessment strategy in a post-partum unit would most likely not be the same risk assessment strategy utilized in the emergency department.

Environmental Safety Risks

Just as all hospitals must implement a patient risk assessment strategy, all hospitals must implement an environmental risk assessment strategy. Environmental risk assessment strategies may not be the same in all hospitals or hospital

units. The hospital must implement environmental risk assessment strategies appropriate to the specific care environment and patient population. That does not mean that a unit which does not typically care for patients with psychiatric conditions is not expected to conduct environmental risk assessments. It means that the risk assessment must be appropriate to the unit and should consider the possibility that the unit may sometimes care for patients at risk for harm to self or others. Examples of Environmental Risk Assessment Tool content may include prompts for staff to assess items such as, but not limited to:

- *Ligature risks include but are not limited to, hand rails, door knobs, door hinges, shower curtains, exposed plumbing/pipes, soap and paper towel dispensers on walls, power cords on medical equipment or call bell cords, and light fixtures or projections from ceilings, etc.*
- *Unattended items such as utility or housekeeping carts that contain hazardous items (mops, brooms, cleaning agents, hand sanitizer, etc.)*
- *Unsafe items brought to patients by visitors in locked psychiatric units of hospitals and psychiatric hospitals.*
- *Windows that can be opened or broken*
- *Unprotected lighting fixtures*
- *Inadequate staffing levels to provide appropriate patient observation and monitoring*

A ligature risk (point) is defined as anything which could be used to attach a cord, rope, or other material for the purpose of hanging or strangulation. Ligature points include shower rails, coat hooks, pipes, and radiators, bedsteads, window and door frames, ceiling fittings, handles, hinges and closures. (CQC Brief Guide: Ligature points – Review date: June 2017). The most common ligature points and ligatures are doors, hooks/handles, windows, and belts or sheets/towels. The use of shoelaces, doors, and windows increased over time. (Hunt et al 2012; Ligature points used by psych inpatients.)

The presence of ligature risks in the physical environment of a psychiatric patient compromises the patient's safety. This is particularly an issue for a patient with suicidal ideation. The hospital Patient's Rights Condition of Participation (CoP) at 482.13(c)(2) and NIAHO requirements provide all patients with the right to care in a safe setting. Psychiatric patients receiving care and treatment in a hospital setting are particularly vulnerable. The presence of ligature risks in the psychiatric patient's physical environment compromise their right to receive care in a safe setting. Safety risks in a psychiatric setting include but are not limited to furniture that can be easily moved or be thrown; sharp objects accessible by patients; areas out of the view of staff; access to plastic bags (for suffocation); oxygen tubing; equipment used for vital signs or IV Fluid administration; breakable windows; access to medications; access to harmful medications; accessible light fixtures; non-tamper proof screws; etc.

Psychiatric patients requiring medical care in a non-psychiatric setting (medical inpatient units, ED, ICU, etc.) must be protected when demonstrating suicidal ideation. The protection would be that of utilizing safety measures such as 1:1 monitoring with continuous visual observation, removal of sharp objects from the room/area, or removal of equipment that can be used as a weapon.

Hospital staff must be trained to identify environmental safety risks regardless of whether or not the hospital has chosen to implement the use of an environmental risk assessment tool to identify potential or actual risks in the patient care environment.

Education and Training

Hospitals must provide the appropriate level of education and training to staff regarding the identification of patients at risk of harm to self or others, the identification of environmental patient safety risk factors and mitigation strategies. Staff includes direct employees, volunteers, contractors, per diem staff and any other individuals providing clinical care under arrangement. Hospitals have the flexibility to tailor the training to the particular services staff provide and the patient populations they serve. Hospitals are expected to provide education and training to all new staff initially upon orientation and whenever policies and procedures change. However, CMS recommends initial training and then ongoing training at least every two years thereafter.

Correction of Environmental Risks

Regulations at 488.28 require that the deficiencies be corrected within 60 days from receipt of the deficiency report.