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§482.13(b)(2) 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.

Interpretive Guidelines §482.13(b)(2)

The right to make informed decisions means that the patient or patient's representative is given the information needed in order to make "informed" decisions regarding his/her care.

Patient's Representative:

A patient may wish to delegate his/her right to make informed decisions to another person (as allowed under State law).

Hospitals are expected to take reasonable steps to determine the patient's wishes concerning designation of a representative. Unless prohibited by applicable State law:

- When a patient who is not incapacitated has designated, either orally to hospital staff or in writing, another individual to be his/her representative, the hospital must provide the designated individual with the information required to make an informed decision about the patient's care. The hospital must also seek the written consent of the patient's representative when informed consent is required for a care decision. The explicit designation of a representative by the patient takes precedence over any non-designated relationship and continues throughout the patient's inpatient stay or outpatient visit, unless expressly withdrawn, either orally or in writing, by the patient.
- In the case of a patient who is incapacitated, when an individual presents the hospital with an advance directive, medical power of attorney or similar document executed by the patient and designating an individual to make medical decisions for the patient when incapacitated, the hospital must, when presented with the document, provide the designated individual the information required to make informed decisions about the patient's care. The hospital must also seek the consent of the designated individual when informed consent is required for a care decision. The explicit designation of a representative takes precedence over any non-designated relationship and continues throughout the patient's inpatient stay or outpatient visit, unless the patient ceases to be incapacitated and expressly withdraws the designation, either orally or in writing.
- When a patient is incapacitated or otherwise unable to communicate his or her wishes, there is no written advance directive on file or presented, and an individual asserts that he or she is the patient's spouse, domestic partner (whether or not formally established and including a same-sex domestic partner), parent (including someone who has stood in loco parentis for the patient who is a minor child), or other family member and thus is the patient's representative, the hospital is expected to accept this assertion, without demanding supporting documentation, and provide the individual the information required to make informed decisions about the patient's care. The hospital must also seek the consent of the individual when informed consent is required for a care decision. Hospitals are expected to treat the individual as the patient's representative unless:
 - More than one individual claims to be the patient's representative. In such cases, it would be appropriate for the hospital to ask each individual for documentation supporting his/her claim to be the patient's representative. The hospital should make its determination of who is the patient's representative based upon the hospital's determination of who the patient would most want to make decisions on his/her behalf. Examples of documentation a hospital might consider could include, but are not limited to, the following: proof of a legally recognized marriage, domestic partnership, or civil union; proof of a joint household; proof of shared or co-mingled finances; and any other documentation the hospital considers evidence of a special relationship that indicates familiarity with the patient's

preferences concerning medical treatment;

- Treating the individual as the patient's representative without requesting supporting documentation would result in the hospital violating State law. State laws, including State regulations, may specify a procedure for determining who may be considered to be the incapacitated patient's representative, and may specify when documentation is or is not required; or
- The hospital has reasonable cause to believe that the individual is falsely claiming to be the patient's spouse, domestic partner, parent or other family member.

Hospitals are expected to adopt policies and procedures that facilitate expeditious and non-discriminatory resolution of disputes about whether an individual is the patient's representative, given the critical role of the representative in exercising the patient's rights.

A refusal by the hospital of an individual's request to be treated as the patient's representative, based on one of the above-specified familial relationships, must be documented in the patient's medical record must, along with the specific basis for the refusal.

Informed Decisions

The right to make informed decisions regarding care presumes that the patient or the patient's representative has been provided information about his/her health status, diagnosis, and prognosis. Furthermore, it includes the patient's or the patient's representative's participation in the development of his/her plan of care, including providing consent to, or refusal of, medical or surgical interventions, and in planning for care after discharge from the hospital. The patient or the patient's representative should receive adequate information, provided in a manner that the patient or the patient's representative can understand, to assure that the patient or the patient's representative can effectively exercise the right to make informed decisions.

Hospitals must establish processes to assure that each patient or the patient's representative is given information on the patient's health status, diagnosis, and prognosis.

Giving informed consent to a treatment or a surgical procedure is one type of informed decision that a patient or patient's representative may need to make regarding the patient's plan of care. Hospitals must utilize an informed consent process that assures patients or their representatives are given the information and disclosures needed to make an informed decision about whether to consent to a procedure, intervention, or type of care that requires consent. See the guidelines for 42 CFR 482.51(b)(2) pertaining to surgical services informed consent and the guidelines for 42 CFR 482.24(c)(2)(v) pertaining to medical records for further detail.

Informed decisions related to care planning also extend to discharge planning for the patient's post-acute care. See the guidelines at 42 CFR 482.43(c) pertaining to discharge planning for discussion of pertinent requirements.

Hospitals must also establish policies and procedures that assure a patient's right to request or refuse treatment. Such policies should indicate how the patient's request will be addressed. However, hospitals are under no obligation to fulfill a patient's request for a treatment or service that the responsible practitioner has deemed medically unnecessary or even inappropriate.

Required Hospital Disclosures to Patients:

Physician Ownership

In addition, there are certain provisions of the Medicare provider agreement rules concerning disclosures that certain hospitals are required to make which are enforced under 42 CFR 482.13(b)(2):

- 42 CFR 489.3 defines a “physician-owned hospital” as any participating hospital in which a physician or immediate family member of a physician (as defined in §411.351) has an ownership or investment interest in the hospital, except for those satisfying an exception found at §411.356(a) or (b). Surveyors are not required to make an independent determination regarding whether a hospital meets the Medicare definition of “physician-owned,” but they must ask whether the hospital is physician-owned.
- 42 CFR 489.20(u)(1) requires that all physician-owned hospitals provide written notice to their patients at the beginning of each patient’s hospital inpatient stay or outpatient visit stating that the hospital is physician-owned, in order to assist the patient in making an informed decision about his or her care, in accordance with the requirements of §482.13(b)(2).
 - A planned inpatient stay or outpatient visit which is subject to the notice requirement begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission for inpatient care or for an outpatient service subject to notice. An unplanned inpatient stay or outpatient visit subject to the notice requirement begins at the earliest point at which the patient presents to the hospital.
- The notice must disclose, in a manner reasonably designed to be understood by all patients, that the hospital is physician-owned and that a list of owners or investors who are physicians or immediate family members of physicians is available upon request. If the patient (or someone on behalf of the patient) requests this list, the hospital must provide it at the time of the request.
 - However, the notice requirement does not apply to any physician-owned hospital that does not have at least one referring physician (as defined at §411.351) who has an ownership or investment interest in the hospital or who has an immediate family member who has an ownership or investment interest in the hospital. In such cases, the hospital must sign an attestation statement that it has no referring physician with an ownership or investment interest or whose immediate family member has an ownership or investment interest in the hospital. The hospital must maintain this attestation in its records.
- 42 CFR 489.20(u)(2) provides that physician-owned hospitals must require each physician owner who is a member of the hospital’s medical staff to agree, as a condition of obtaining/retaining medical staff membership or admitting privileges, to disclose in writing to all patients they refer to the hospital their ownership or investment interest in that hospital or that of any immediate family member. The hospital must require that this disclosure be made at the time of the referral and the requirement should be reflected in the hospital’s policies and procedures governing privileges for physician owners.
 - The hospital may exempt from this disclosure requirement any physician owner who does not refer any patients to the hospital.
- 42 CFR 489.12 permits CMS to refuse to enter into a provider agreement with a physician-owned hospital applicant that does not have procedures in place to notify

patients of physician ownership in the hospital as required under §489.20(u).

- 42 CFR 489.53(c) permits CMS to terminate a provider agreement with a physician-owned hospital if the hospital fails to comply with the requirements at §489.20(u).

MD/DO 24/7 On-Site Presence

42 CFR 489.20(w) mandates that **if** there is no doctor of medicine or osteopathy present in the hospital 24 hours per day, seven days per week, the hospital must provide written notice of this to all inpatients at the beginning of a planned or unplanned inpatient stay, and to outpatients for certain types of planned or unplanned outpatient visits. The purpose of this requirement is to assist the patient in making an informed decision about his/her care, in accordance with 42 CFR 482.13(b)(2). Hospitals that have an MD/DO on-site 24/7 (including residents who are MDs or DOs) do not need to issue any disclosure notice about emergency services capability.

- The notice must be provided to all inpatients and to those outpatients who are under observation or who are having surgery or any other procedure using anesthesia.
- The notice must be provided at the beginning of the planned or unplanned inpatient stay, or outpatient visit subject to notice.
 - A planned inpatient stay or outpatient visit which is subject to the notice requirement begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission for inpatient care or for an outpatient service subject to notice. An unplanned inpatient stay or outpatient visit which is subject to the notice requirement begins at the earliest point at which the patient presents to the hospital.
- Individual notices are not required in the hospital's dedicated emergency department (DED) (as that term is defined in 42 CFR 489.24(b)), but the DED must post a notice conspicuously, in a place or places likely to be noticed by all individuals entering the DED. The posted notice must state that the hospital does not have a doctor of medicine or a doctor of osteopathy present in the hospital 24 hours per day, 7 days per week, and must indicate how the hospital will meet the medical needs of any patient with an emergency medical condition, as defined in 42 CFR 489.24(b) [the EMTALA definition], at a time when there is no doctor of medicine or doctor of osteopathy present in the hospital. If an emergency department patient is determined to require admission, then the individual notice requirements of 42 CFR 489.20(w) would apply to that patient.
- Before admitting an inpatient or providing outpatient services requiring notice, the hospital must obtain a signed acknowledgement from the patient stating that he/she understands that a doctor of medicine or doctor of osteopathy may not be present at all times services are furnished to him/her.
 - In the event of an unplanned surgery or inpatient admission to treat an emergency medical condition, it may in some cases be necessary in the interest of the patient's safety to proceed with treatment before the required notice can be given and acknowledgement can be obtained. In such circumstances, the hospital must provide notice and obtain acknowledgement as soon as possible after the patient's stay or visit begins.
- For a hospital that participates in Medicare with multiple campuses providing inpatient services (e.g., a main provider campus and separate satellite, remote, and/or provider-based locations) under one CMS Certification Number, a separate determination is

made for each campus or satellite location with inpatient services as to whether the disclosure notice is required. For example, if a hospital has a main campus and a satellite location and a physician is present 24/7 on the main campus but not at the satellite location, the hospital is required to provide the disclosure notice only at the satellite location. No notice is required for patients presenting to the main provider campus in this case. In this same example, if the hospital also has a provider-based, off-campus ambulatory (i.e., same-day) surgery department, no notice is required at that off-campus surgery site, since the hospital's main campus does have an MD/DO present 24/7.

- 42 CFR 489.53(c) permits CMS to terminate a provider agreement with a hospital if the hospital fails to comply with the requirements at §489.20(w) when it does not have an MD or DO on-site 24/7.

Survey Procedures §482.13(b)(2)

- Is there a hospital policy addressing the patient's or the patient's representative (as appropriate) right to make informed decisions?
 - Does the hospital's policy provide for determining when a patient has a representative who may exercise the patient's right to make informed decisions, and who that representative is, consistent with this guidance and State law?
- Is there a hospital policy addressing the patient's right to have information on his/her medical status, diagnosis, and prognosis? Does it articulate the hospital's process for assuring that patients have this information?
- Is there a hospital policy addressing how the patient will be involved in his/her care planning and treatment?
- Is there evidence that the hospital routinely complies with its policies? Evidence would be obtained through review of medical records, interviewing current patients and/or interviewing hospital personnel to determine their understanding of the hospital's informed decision-making policies and how they are implemented. Review of evidence would be designed to determine whether patients/patient representatives are provided adequate information about the patient's medical status, diagnosis, and prognosis, and then allowed to make informed decisions about their care planning and treatment.

Assessing Required Disclosures:

Physician Ownership

- If the hospital indicates that it is physician-owned but is exempt under §489.20(v) from the disclosure requirement of §489.20(u)(2), ask to see the signed attestation that it does not have any referring physicians with an ownership/investment interest or whose immediate family member has an ownership/investment interest in the hospital. (As with any other on-the-spot correction of a deficiency during a survey, creation of an attestation at the time of a survey does not mean that there was no deficiency and that the hospital would not be cited.)
- If the hospital is physician-owned but not exempt from the physician ownership disclosure requirements:
 - Verify that appropriate policies and procedures are in place to assure that necessary written notices are provided to all patients at the beginning of an inpatient or outpatient stay.

- Review the notice the hospital issues to each patient to verify that it discloses, in a manner reasonably designed to be understood by all patients, that the hospital meets the Federal definition of “physician-owned,” that a list of owners and investors who are physicians or immediate family members of physicians is available upon request, and that such a list is provided to the patient at the time the request is made by or on behalf of the patient.
- Determine through staff interviews, observation, and a review of policies and procedures whether the hospital furnishes its list of physician owners and investors at the time a patient or patient’s representative requests it.
- Determine through staff interviews and review of policies, procedures, and staff records whether a physician-owned hospital’s medical staff membership and admitting privileging requirements include a requirement that, as a condition of continued membership or admitting privileges, physician owners who refer patients to the hospital agree to provide written disclosure of their own or any immediate family member’s ownership or investment interest to all patients at the time of the referral to the hospital.

MD/DO 24/7 On-Site Presence

- Determine through interviews, observation, and medical record review whether an MD/DO is present in the hospital, at each campus or satellite location providing inpatient services 24 hours/day, seven days/week.
- For each required location where an MD/DO is not present:
 - Verify that the appropriate policies and procedures are in place to assure written notices that an MD/DO is not present at all times are provided at the beginning of an inpatient stay or outpatient stay to all inpatients and to all outpatients receiving observation services, surgery or another procedure requiring anesthesia.
 - Verify that there is signed acknowledgment by patients of such disclosure, obtained by the hospital prior to the patient’s admission or before applicable outpatient services were provided.
 - Ask a sample of inpatients and affected outpatients whether they were provided notice about an MD/DO not being present at all times in the hospital.
 - Verify that the hospital’s emergency department has signage with the appropriate disclosure information.
 - Review the notice the hospital issues to verify that it indicates how the hospital will meet the medical needs of any patient who develops an emergency medical condition at a time when no physician is present at that hospital, including any remote location or satellite.