

PATIENT'S RIGHTS

A-0115

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.13 Condition of Participation: Patient's Rights

A hospital must protect and promote each patient's rights.

Interpretive Guidelines §482.13

These requirements apply to all Medicare or Medicaid participating hospitals including short-term, acute care, surgical, specialty, psychiatric, rehabilitation, long-term, children's and cancer, whether or not they are accredited. This rule does not apply to critical access hospitals. (See Social Security Act (the Act) §1861(e).)

These requirements, as well as the other Conditions of Participation in 42 CFR 482, apply to all parts and locations (outpatient services, provider-based entities, inpatient services) of the Medicare participating hospital.

Survey Procedures §482.13

Survey of the Patients' Rights Condition of Participation (CoP) should be coordinated by one surveyor. However, each surveyor, as he/she conducts his/her survey assignments, should assess the hospital's compliance with the Patients' Rights CoP.

A-0116

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§482.13(a) Standard: Notice of Rights

Interpretive Guidelines §482.13(a)

The hospital must ensure the notice of rights requirements are met.

A-0117

(Rev. 75, Issued: 12-02-11, Effective: 12-02-11, Implementation: 12-02-11)

§482.13(a)(1) A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

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Interpretive Guidelines §482.13(a)(1)

The hospital must inform each patient, or when appropriate, the patient's representative as allowed by State law, of the patient's rights. Whenever possible, this notice must be provided before providing or stopping care. All patients, inpatient or outpatient, must be informed of their rights as hospital patients. The patient's rights include all of those discussed in this condition, as well as any other rights for which notice is required under State or Federal law or regulations for hospital patients. (See 42 CFR 482.11.) The patient's rights should be provided and explained in a language or manner that the patient (or the patient's representative) can understand. This is consistent with the guidance related to Title VI of the Civil Rights Act of 1964 issued by the Department of Health and Human Services - "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons" (August 8, 2003, 68 FR 47311). In accordance with §482.11, hospitals are expected to comply with Title VI and may use this guidance to assist it in ensuring patient's rights information is provided in a language and manner that the patient understands. Surveyors do not assess compliance with these requirements on limited English proficiency, but may refer concerns about possible noncompliance to the Office for Civil Rights in the applicable Department of Health and Human Services Regional Office.

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 required notice of patients' rights in addition to the patient. 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 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

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executed by the patient and designating an individual to make medical decisions for the patient when incapacitated, then the hospital must, when presented with the document, provide the required notice of its policies to the designated representative. 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 required notice to the individual, 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

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- 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, along with the specific basis for the refusal.

In addition, according to the regulation at 42 CFR 489.27(a), (which cross references the regulation at 42 CFR 405.1205), each Medicare beneficiary who is an inpatient (or his/her representative) must be provided the standardized notice, "An Important Message from Medicare" (IM), within 2 days of admission. Medicare beneficiaries who have not been admitted (e.g., patients in observation status or receiving other care on an outpatient basis) are not required to receive the IM. The IM is a standardized, OMB-approved form and cannot be altered from its original format. The IM is to be signed and dated by the patient to acknowledge receipt. See Exhibit 16 for a copy of the IM. Furthermore, 42 CFR 405.1205(c) requires that hospitals present a copy of the signed IM in advance of the patient's discharge, but not more than two calendar days before the patient's discharge. In the case of short inpatient stays, however, where initial delivery of the IM is within 2 calendar days of the discharge, the second delivery of the IM is not required.

The hospital must establish and implement policies and procedures that effectively ensure that patients and/or their representatives have the information necessary to exercise their rights.

Survey Procedures §482.13(a)(1)

- Determine the hospital's policy for notifying all patients of their rights, both inpatient and outpatient;

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- Determine that the hospital's policy provides for determining when a patient has a representative and who that representative is, consistent with this guidance and State law.
- Determine that the information provided to the patients by the hospital complies with Federal and State law;
- Review records and interview staff to examine how the hospital communicates information about their rights to diverse patients, including individuals who need assistive devices or translation services. Does the hospital have alternative means, such as written materials, signs, or interpreters (when necessary), to communicate patients' rights?
- Review records and interview staff and patients or patients' representatives (as appropriate) to examine how the hospital determines whether the patient has a representative, who that representative is, and whether notice of patients' rights is provided as required to patients' representatives.
- Ask patients to tell you what the hospital has told them about their rights;
- Does staff know what steps to take to inform a patient about their patients' rights, including those patients' with special communication needs?; and
- Review a sample of inpatient medical records for Medicare beneficiaries, to determine whether the records contain a signed and dated IM provided within 2 days of the admission of the patient. For patients whose discharge occurred more than 2 days after the initial IM notice was issued, determine whether the hospital provided another copy of the IM to the patient prior to discharge in a timely manner.

A-0118

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.13(a)(2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.

Interpretive guidelines §482.13(a)(2)

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The patient should have reasonable expectations of care and services and the facility should address those expectations in a timely, reasonable, and consistent manner. Although 482.13(a)(2)(ii) and (iii) address documentation of facility time frames for a response to a grievance, the expectation is that the facility will have a process to comply with a relatively minor request in a more timely manner than a written response. For example, a change in bedding, housekeeping of a room, and serving preferred food and beverage may be made relatively quickly and would not usually be considered a "grievance" and therefore would not require a written response.

The hospital must inform the patient and/or the patient's representative of the internal grievance process, including whom to contact to file a grievance (complaint). As part of its notification of patient rights, the hospital must provide the patient or the patient's representative a phone number and address for lodging a grievance with the State agency. The hospital must inform the patient that he/she may lodge a grievance with the State agency (the State agency that has licensure survey responsibility for the hospital) directly, regardless of whether he/she has first used the hospital's grievance process.

A **“patient grievance”** is a formal or informal written or verbal complaint that is made to the hospital by a patient, or the patient’s representative, regarding the patient's care (when the complaint is not resolved at the time of the complaint by staff present), abuse or neglect, issues related to the hospital's compliance with the CMS Hospital Conditions of Participation (CoPs), or a Medicare beneficiary billing complaint related to rights and limitations provided by 42 CFR 489.

- "Staff present" includes any hospital staff present at the time of the complaint or who can quickly be at the patient's location (i.e., nursing, administration, nursing supervisors, patient advocates, etc.) to resolve the patient's complaint.
- If a patient care complaint cannot be resolved at the time of the complaint by staff present, is postponed for later resolution, is referred to other staff for later resolution, requires investigation, and/or requires further actions for resolution, then the complaint is a grievance for the purposes of these requirements. A complaint is considered resolved when the patient is satisfied with the actions taken on their behalf.

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- Billing issues are not usually considered grievances for the purposes of these requirements. However, a Medicare beneficiary billing complaint related to rights and limitations provided by 42 CFR 489 is considered a grievance.
- A written complaint is always considered a grievance. This includes written complaints from an inpatient, an outpatient, a released/discharged patient, or a patient's representative regarding the patient care provided, abuse or neglect, or the hospital's compliance with CoPs. For the purposes of this requirement, an email or fax is considered "written."
- Information obtained from patient satisfaction surveys usually does not meet the definition of a grievance. If an identified patient writes or attaches a written complaint on the survey and requests resolution, then the complaint meets the definition of a grievance. If an identified patient writes or attaches a complaint to the survey but has not requested resolution, the hospital must treat this as a grievance if the hospital would usually treat such a complaint as a grievance.
- Patient complaints that are considered grievances also include situations where a patient or a patient's representative telephones the hospital with a complaint regarding the patient's care or with an allegation of abuse or neglect, or failure of the hospital to comply with one or more CoPs, or other CMS requirements. Those post-hospital verbal communications regarding patient care that would routinely have been handled by staff present if the communication had occurred during the stay/visit are not required to be defined as a grievance.
- All verbal or written complaints regarding abuse, neglect, patient harm, or hospital compliance with CMS requirements are considered grievances for the purposes of these requirements.
- Whenever the patient or the patient's representative requests that his or her complaint be handled as a formal complaint or grievance or when the patient requests a response from the hospital, the complaint is considered a grievance and all the requirements apply.
- Data collected regarding patient grievances, as well as other complaints that are not defined as grievances (as determined by the hospital), must be incorporated in the hospital's Quality Assessment and Performance Improvement (QAPI) Program.

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Survey Procedures §482.13(a)(2)

- Review the hospital's policies and procedures to assure that its grievance process encourages all personnel to alert appropriate staff concerning any patient grievance. Does the hospital adhere to its policy/procedure established for grievances?
- Interview patients or the patient's legal representative to determine if they know how to file a complaint (grievance) and who to contact if they have a complaint (grievance).
- Is the hospital following its grievance policies and procedures?
- Does the hospital's process assure that grievances involving situations or practices that place the patient in immediate danger are resolved in a timely manner?
- Does the patient or the patient's representative know that he/she has the right to file a complaint with the State agency as well as or instead of utilizing the hospital's grievance process?
- Has the hospital provided the telephone number for the State agency to all patients/patient representatives?
- Are beneficiaries aware of their right to seek review by the QIO for quality of care issues, coverage decisions, and to appeal a premature discharge?

A-0119

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.13(a)(2) (Continued)

[The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.]
The hospital's governing body must approve and be responsible for the effective operation of the grievance process, and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee.

Interpretive guidelines §482.13(a)(2)

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The hospital's grievance process must be approved by the governing body. The hospital's governing body is responsible for the effective operation of the grievance process. This includes the hospital's compliance with all of the CMS grievance process requirements. The hospital's governing body must review and resolve grievances, unless it delegates this responsibility in writing to a grievance committee. A committee is more than one person. The committee membership should have adequate numbers of qualified members to review and resolve the grievances the hospital receives (this includes providing written responses) in a manner that complies with the CMS grievance process requirements.

Survey Procedures §482.13(a)(2)

- Determine if the hospital's governing body approved the grievance process.
- Is the governing body responsible for the operation of the grievance process, or has the governing body delegated the responsibility in writing to a grievance committee?
- Determine how effectively the grievance process works. Are patient's or the patient representative's concerns addressed in a timely manner? Are patients informed of any resolution to their grievances? Does the hospital apply what it learns from the grievance as part of its continuous quality improvement activities?
- Is the grievance process reviewed and analyzed through the hospital's QAPI process or some other mechanisms that provides oversight of the grievance process?

A-0120

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.13(a)(2) (Continued)

[The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The hospital's governing body must approve and be responsible for the effective operation of the grievance process, and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee.] The grievance process must include a mechanism for timely

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referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization. At a minimum:

Interpretive Guidelines §482.13(a)(2)

Quality Improvement Organizations (QIOs) are CMS contractors charged with reviewing the appropriateness and quality of care rendered to Medicare beneficiaries in the hospital setting. The QIOs are also tasked with reviewing utilization decisions. Part of this duty includes reviewing discontinuation of stay determinations based upon a beneficiary's request. The regulations state the functions of the QIOs in order to make Medicare beneficiaries aware of the fact that if they have a **complaint regarding quality of care**, disagree with a **coverage decision**, or they wish to appeal a premature discharge, they may contact the QIO to lodge a complaint. The hospital is required to have procedures for referring Medicare beneficiary concerns to the QIOs; additionally, CMS expects coordination between the grievance process and existing grievance referral procedures so that beneficiary complaints are handled timely and referred to the QIO at the beneficiary's request.

This regulation requires coordination between the hospital's existing mechanisms for utilization review notice and referral to QIOs for Medicare beneficiary concerns (See 42 CFR Part 489.27). This requirement does not mandate that the hospital automatically refer each Medicare beneficiary's grievance to the QIO; however, the hospital must inform all beneficiaries of this right, and comply with his or her request if the beneficiary asks for QIO review.

Medicare patients have the right to appeal a premature discharge (see Interpretive Guidelines for 42 CFR 482.13(a)). Pursuant to 42 CFR 412.42(c)(3), a hospital must provide a hospital-issued notice of non-coverage (HINN) to any fee-for-service beneficiary that expresses dissatisfaction with an impending hospital discharge. Medicare Advantage (MA) organizations are required to provide enrollees with a notice of non-coverage, known as the Notice of Discharge and Medicare Appeal Rights (NODMAR), only when a beneficiary disagrees with the discharge decision or when the MA organization (or hospital, if the MA

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organization has delegated to it the authority to make the discharge decision) is not discharging the enrollee, but no longer intends to cover the inpatient stay.

Survey Procedures §482.13(a)(2)

- Review patient discharge materials. Is the hospital in compliance with 42 CFR §489.27?
- Does the hospital grievance process include a mechanism for timely referral of Medicare patient concerns to the QIO? What time frames are established?
 - Interview Medicare patients. Are they aware of their right to appeal premature discharge?

A-0121

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

[At a minimum:]

§482.13(a)(2)(i) The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.

Interpretive Guidelines §482.13(a)(2)(i)

The hospital's procedure for a patient or the patient's representative to submit written or verbal grievances must be clearly explained. The patient or patient's representative should be able to clearly understand the procedure.

Survey Procedures §482.13(a)(2)(i)

- Review the information provided to patients that explains the hospital's grievance procedures. Does it clearly explain how the patient is to submit either a verbal or written grievance?
- Interview patients or patient representatives. Does the patient, or (if he/she is incapacitated) his/her representative, know about the grievance process and how to submit a grievance?

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(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

[At a minimum:]

§482.13(a)(2)(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.

Interpretive Guidelines §482.13(a)(2)(ii)

The hospital must review, investigate, and resolve each patient's grievance within a reasonable time frame. For example, grievances about situations that endanger the patient, such as neglect or abuse, should be reviewed immediately, given the seriousness of the allegations and the potential for harm to the patient(s). However, regardless of the nature of the grievance, the hospital should make sure that it is responding to the substance of each grievance while identifying, investigating, and resolving any deeper, systemic problems indicated by the grievance.

Document when a grievance is so complicated that it may require an extensive investigation. We recognize that staff scheduling as well as fluctuations in the numbers and complexity of grievances can affect the timeframes for the resolution of a grievance and the provision of a written response. On average, a time frame of 7 days for the provision of the response would be considered appropriate. We do not require that every grievance be resolved during the specified timeframe although most should be resolved. 42 CFR 482.13(a)(2)(iii) specifies information the hospital must include in their response.

If the grievance will not be resolved, or if the investigation is not or will not be completed within 7 days, the hospital should inform the patient or the patient's representative that the hospital is still working to resolve the grievance and that the hospital will follow-up with a written response within a stated number of days in accordance with the hospital's grievance policy. The hospital must attempt to resolve all grievances as soon as possible.

Survey Procedures §482.13(a)(2)(ii)

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What time frames are established to review and respond to patient grievances? Are these time frames clearly explained in the information provided to the patient that explains the

hospital's grievance process? On average, does the hospital provide a written response to most of its grievances within the timeframe specified in its policy?

A-0123

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

[At a minimum:]

§482.13(a)(2)(iii) In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

Interpretive Guidelines §482.13(a)(2)(iii)

The written notice of the hospital's determination regarding the grievance must be communicated to the patient or the patient's representative in a language and manner the patient or the patient's legal representative understands.

The hospital may use additional tools to resolve a grievance, such as meeting with the patient and his family. The regulatory requirements for the grievance process are minimum standards, and do not inhibit the use of additional effective approaches in handling patient grievances. However, in all cases the hospital must provide a written notice (response) to each patient's grievance(s). The written response must contain the elements listed in this requirement.

When a patient communicates a grievance to the hospital via email the hospital may provide its response via email pursuant to hospital policy. (Some hospitals have policies against communicating to patients over email.) If the patient requests a response via email, the hospital may respond via email. When the email response contains the information stated in this requirement, the email meets the requirement for a written response. The hospital must maintain evidence of its compliance with these requirements.

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A grievance is considered resolved when the patient is satisfied with the actions taken on their behalf.

There may be situations where the hospital has taken appropriate and reasonable actions on the patient's behalf in order to resolve the patient's grievance and the patient or the patient's representative remains unsatisfied with the hospital's actions. In these situations, the hospital may consider the grievance closed for the purposes of these requirements. The hospital must maintain documentation of its efforts and demonstrate compliance with CMS requirements.

In its written response, the hospital is not required to include statements that could be used in a legal action against the hospital, but the hospital must provide adequate information to address each item stated in this requirement. The hospital is not required to provide an exhaustive explanation of every action the hospital has taken to investigate the grievance, resolve the grievance, or other actions taken by the hospital.

Survey Procedures §482.13(a)(2)(iii)

Review the hospital's copies of written notices (responses) to patients. Are all patients provided a written notice? Do the notices comply with the requirements?

A-0129

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.13(b) Standard: Exercise of Rights

Interpretive Guidelines §482.13(b)

The hospital must ensure that the exercise of patients' rights requirements are met.

A-0130

(Rev. 75, Issued: 12-02-11, Effective: 12-02-11, Implementation: 12-02-11)

§482.13(b)(1) The patient has the right to participate in the development and implementation of his or her plan of care.

Interpretive Guidelines §482.13(b)(1)

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This regulation requires the hospital to actively include the patient in the development, implementation and revision of his/her plan of care. It requires the hospital to plan the patient's care, with patient participation, to meet the patient's psychological and medical needs.

The patient's (or patient's representatives, as allowed by State law) right to participate in the development and implementation of his or her plan of care includes at a minimum, the right to: participate in the **development and implementation** of his/her **inpatient treatment/care plan, outpatient treatment/care plan**, participate in the development and implementation of his/her **discharge plan**, and participate in the development and implementation of his/her **pain management plan**.

Hospitals are expected to take reasonable steps to determine the patient's wishes concerning designation of a representative to exercise the patient's right to participate in the development and implementation of the patient's plan of care. 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 involve the designated representative in the development and implementation of the patient's plan of care. 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, when presented with the document, must involve the designated representative in the development and implementation of the patient's plan of care. 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.

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- 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 must involve the individual as the patient's representative in the development and implementation of the patient's plan of care, 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.

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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, along with the specific basis for the refusal.

Survey Procedures §482.13(b)(1)

- Does the hospital have policies and procedures to involve the patient or the patient's representative (as appropriate) in the development and implementation of his/her inpatient treatment/care plan, outpatient treatment/care plan, discharge plan, and pain management plan?
- Review records and interview staff and patients, or patients' representatives (as appropriate), to determine how the hospital involves the patient or the patient's representative (as appropriate) in the development and implementation of his/her plan of care?
- Does the hospital's policy provide for determining when a patient has a representative who may exercise the patient's right to participate in developing and implementing his/her plan of care, and who that representative is, consistent with this guidance and State law?
- Is there evidence that the patient or the patient's representative was included or proactively involved in the development and implementation of the patient's plan of care?
- Were revisions in the plan of care explained to the patient and/or the patient's representative (when appropriate)?

A-0131

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§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

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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

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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

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- 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

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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 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

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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).

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- 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

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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.

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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:

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- 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.

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- 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.

A-0132

(Rev. 75, Issued: 12-02-11, Effective: 12-02-11, Implementation: 12-02-11)

§482.13(b)(3) The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with §489.100 of this part (Definition), §489.102 of this part (Requirements for providers), and §489.104 of this part (Effective dates).

Interpretive Guidelines §482.13(b)(3)

An advance directive is defined at §489.100 as “a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State), relating to the provision of health care when the individual is incapacitated.” The patient (inpatient or outpatient) has the right to formulate advance directives, and to have hospital staff implement and comply with their advance directive. The regulation at 42 CFR 489.102 specifies the rights of a patient (as permitted by State law) to make medical care decisions, including the right to accept or refuse medical or surgical treatment and the right to formulate, at the individual's option, advance directives.

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In the advance directive, the patient may provide guidance as to his/her wishes concerning provision of care in certain situations; alternatively the patient may delegate decision-making authority to another individual, as permitted by State law. (In addition, the patient may use the advance directive to designate a “support person,” as that term is used in §482.13(h), for purposes of exercising the patient’s visitation rights.) When a patient who is incapacitated has executed an advance directive designating a particular individual to make medical decisions for him/her 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. (See also the requirements at §482.13(b)(2).) The hospital must also seek the consent of the patient’s representative when informed consent is required for a care decision. The explicit designation of a representative in the patient’s advance directive takes precedence over any non-designated relationship and continues throughout the patient’s inpatient stay or, as applicable, outpatient visit, unless the patient ceases to be incapacitated and expressly withdraws the designation, either orally or in writing.

§489.102 also requires the hospital to:

- Provide written notice of its policies regarding the implementation of patients’ rights to make decisions concerning medical care, such as the right to formulate advance directives. If an individual is incapacitated or otherwise unable to communicate, the hospital may provide the advance directive information required under §489.102 to the individual’s “family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law.” (§489.102(e)) The guidance concerning the regulation at §482.13(a)(1) governing notice to the patient or the patient’s representative of the patient’s rights applies to the required provision of notice concerning the hospital’s advance directive policies. Although both inpatients and outpatients have the same rights under §482.13(a)(1), §489.102(b)(1) requires that notice of the hospital’s advance directive policy be provided at the time an individual is admitted as an inpatient. However, in view of the broader notice requirements at §482.13(a)(1), the hospital should also provide the advance directive notice to outpatients (or their representatives) who are in the emergency department, who are in an observation status, or who are undergoing same-day surgery. The notice should be presented at

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the time of registration. Notice is not required for other outpatients, given that they are unlikely to become incapacitated.

- The notice must include a clear and precise statement of limitation if the hospital cannot implement an advance directive on the basis of conscience. At a minimum, a statement of limitation should:

- Clarify any differences between institution-wide conscience objections and those that may be raised by individual physicians or other practitioners;
- Identify the State legal authority permitting such an objection; and
- Describe the range of medical conditions or procedures affected by the conscience objection.

It should be noted that this provision allowing for certain conscience objections to implementing an advance directive is narrowly focused on the directive's content related to medical conditions or procedures. This provision would not allow a hospital or individual physician or practitioner to refuse to honor those portions of an advance directive that designate an individual as the patient's representative and/or support person, given that such designation does not concern a medical condition or procedure.

Issuance of the written notice of the hospital's advance directive policies to the patient or the patient's representative must be documented in the patient's medical record.

- Document in a prominent part of the patient's medical record whether or not the patient has executed an advance directive;
- Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;
- Ensure compliance with requirements of State law concerning advance directives and inform individuals that complaints concerning the advance directive requirements may be filed with the State survey and certification agency;

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- Provide for the education of staff concerning its policies and procedures on advance directives. The right to formulate advance directives includes the right to formulate a psychiatric advance directive (as allowed by State law); and
- Provide community education regarding advance directives and the hospital must document its efforts.

A **psychiatric advance directive** is akin to a traditional advance directive for health care. This type of advance directive might be prepared by an individual who is concerned that at some time he or she may be subject to involuntary psychiatric commitment or treatment. The psychiatric advance directive may cover a range of subjects, and may name another person who is authorized to make decisions for the individual if he or she is determined to be legally incompetent to make his/her own choices. It may also provide the patient's instructions about hospitalization, alternatives to hospitalization, the use of medications, types of therapies, and the patient's wishes concerning restraint or seclusion. The patient may designate who should be notified upon his/her admission to the hospital, as well as who should not be permitted to visit him or her. State laws regarding the use of psychiatric advance directives vary.

In accordance with State law, a psychiatric advance directive should be accorded the same respect and consideration that a traditional advance directive for health care is given. Hospitals should carefully coordinate how the choices of a patient balance with the rights of other patients, staff, and individuals in the event that a dangerous situation arises.

However, even if State law has not explicitly spoken to the use of psychiatric advance directives, consideration should be given to them inasmuch as this regulation also supports the patient's right to participate in the development and implementation of his or her plan of care. When the patient is, for whatever reason, unable to communicate his/her wishes, the preferences expressed in the psychiatric advance directive can give critical insight to the MD/DOs, nurses, and other staff as they develop a plan of care and treatment for the patient.

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Survey Procedures §482.13(b)(3)

- Review the hospital's advance directive notice. Does it advise inpatients or applicable outpatients, or their representatives, of the patient's right to formulate an advance directive and to have hospital staff comply with the advance directive (in accordance with State law)? Does it include a clear, precise and valid statement of limitation if the hospital cannot implement an advance directive on the basis of conscience?
- Review the records of a sample of patients for evidence of hospital compliance with advance directive notice requirements. Does every inpatient or applicable outpatient record contain documentation that notice of the hospital's advance directives policy was provided at the time of admission or registration? Is there documentation of whether or not each patient has an advance directive? For those patients who have reported an advance directive, has a copy of the patient's advance directive been placed in the medical record?
- What mechanism does the hospital have in place to allow patients to formulate an advance directive or to update their current advance directive? Is there evidence that the hospital is promoting and protecting each patient's right to formulate an advance directive?
- Determine to what extent the hospital complies, as permitted under State law, with patient advance directives that delegate decisions about the patient's care to a designated individual.
- Determine to what extent the hospital educates its staff regarding advance directives.
- Interview staff to determine their knowledge of the advance directives of the patients in their care.
- Determine to what extent the hospital provides education for the patient population (inpatient and outpatient) regarding one's rights under State law to formulate advance directives.

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(Rev. 75, Issued: 12-02-11, Effective: 12-02-11, Implementation: 12-02-11)

§482.13(b)(4) - The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.

Interpretive Guidelines §482.13(b)(4)

Identifying Who Is to Be Notified

For every inpatient admission, the hospital must ask the patient whether the hospital should notify a family member or representative about the admission. If the patient requests such notice and identifies the family member or representative to be notified, the hospital must provide such notice promptly to the designated individual. The explicit designation of a family member or representative by the patient takes precedence over any non-designated relationship.

The hospital must also ask the patient whether the hospital should notify his/her own physician. In the case of scheduled admissions, the patient's own physician likely is already aware of the admission. However, if the patient requests notice to and identifies the physician, the hospital must provide such notice promptly to the designated physician, regardless of whether the admission was scheduled in advance or emergent.

When a patient is incapacitated or otherwise unable to communicate and to identify a family member or representative to be notified, the hospital must make reasonable efforts to identify and promptly notify a family member or patient's representative. If an individual who has accompanied the patient to the hospital, or who comes to or contacts the hospital after the patient has been admitted, 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, the hospital is expected to accept this assertion, without demanding supporting documentation, and provide this individual information about the patient's admission, unless:

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- More than one individual claims to be the patient's family member or representative. In such cases it would not be inappropriate for the hospital to ask each individual for documentation supporting his/her claim to be the patient's family member or 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 family member or 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 family member or 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 should be notified as the patient's family member or representative, given the critical role of the representative in exercising the patient's rights. Hospitals may also choose to provide notice to more than one family member.

When a patient is incapacitated and the hospital is able through reasonable efforts to identify the patient's own physician – e.g., through information obtained from a family member, or from review of prior admissions or outpatient encounters, or through access to the patient's records in a regional system of electronic patient medical records in which the hospital participates – the hospital must promptly notify the patient's physician of the admission.

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Prompt Notice

The hospital must provide the required notice promptly. "Promptly" means as soon as possible after the physician's or other qualified practitioner's order to admit the patient has been given. Notice may be given orally in person, by telephone, by e-mail or other electronic means, or by other methods that achieve prompt notification. It is not acceptable for the hospital to send a letter by regular mail.

Medical Record Documentation

The hospital must document that the patient, unless incapacitated, was asked no later than the time of admission whether he or she wanted a family member/representative notified, the date, time and method of notification when the patient requested such, or whether the patient declined to have notice provided. If the patient was incapacitated at the time of admission, the medical record must indicate what steps were taken to identify and provide notice to a family member/representative and to the patient's physician.

Survey Procedures §482.13(b)(4)

- Determine if the hospital has policies that address notification of a patient's family or representative and physician when the patient is admitted as an inpatient.
- Ask the hospital who is responsible for providing the required notice. Interview person(s) responsible for providing the notice to determine how they identify the persons to be notified and the means of notification. What do they do in the case of an incapacitated person to identify a family member/representative and the patient's physician?
- Review a sample of inpatient medical records. Do the medical records provide evidence that the patient was asked about notifying a family member/representative and his/her physician? Is there a record of when and how notice was provided? Was notice provided promptly? Is there a record of the patient declining to have notice provided to a family member/representative and his/her physician? Is there documentation of whether the patient was incapacitated at the time of admission, and if so, what steps were taken to identify a family member/representative and the patient's physician?

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§482.13(c) Standard: Privacy and Safety

Interpretive Guidelines §482.13(c)

The hospital must ensure the privacy and safety requirements are met.

A-0143

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§482.13(c)(1) - The patient has the right to personal privacy.

Interpretive Guidelines §482.13(c)(1)

The underlying principle of this requirement is the patient's basic right to respect, dignity, and comfort while in the hospital.

Physical Privacy

“The right to personal privacy” includes at a minimum, that patients have physical privacy to the extent consistent with their care needs during personal hygiene activities (e.g., toileting, bathing, dressing), during medical/nursing treatments, and when requested as appropriate.

People not involved in the care of the patient should not be present without his/her consent while he/she is being examined or treated. 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 or treatment.

However, audio/video monitoring (does not include recording) of patients in medical-surgical or intensive-care type units would not be considered violating the patient's privacy, as long as there exists a clinical need, the patient/patient's representative is aware of the monitoring and the monitors or speakers are located so that the monitor screens are not readily visible or where speakers are not readily audible to visitors or the public. Video recording of patients undergoing medical treatment requires the consent of the patient or his/her representative.

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A patient's right to privacy may also be limited in situations where a person must be continuously observed to ensure his or her safety, such as when a patient is simultaneously restrained and in seclusion to manage violent or self-destructive behavior or when the patient is under suicide precautions.

Protecting Patient Personal Information

The right to personal privacy also includes limiting the release or disclosure of patient information. Patient information includes, but is not limited to, the patient's presence or location in the hospital; demographic information the hospital has collected on the patient, such as name, age, address, income; or information on the patient's medical condition. Such patient information may not be disclosed without informing the patient or the patient's representative in advance of the disclosure and providing the patient or the patient's representative an opportunity to agree, prohibit, or restrict the disclosure. Below is a summary of privacy issues that surveyors might encounter in hospital settings, and the related privacy requirements.

Permitted Disclosures:

A hospital is permitted to use and disclose patient information, without the patient's authorization, in order to provide patient care and perform related administrative functions, such as payment and other hospital operations.

- Payment operations include hospital activities to obtain payment or be reimbursed for the provision of health care to an individual.
- Hospital operations are administrative, financial, legal, and quality improvement activities of a hospital that are necessary to conduct business and to support the core functions of treatment and payment. These activities include, but are not limited to: quality assessment and improvement activities, case management and care coordination; competency assurance activities, conducting or arranging for medical reviews, audits, or legal services, including fraud and abuse detection and compliance programs; business planning, development, management, and administration and certain hospital-specific fundraising activities.

Hospitals must develop and implement policies and procedures that restrict access to and use of patient information based on the specific roles of the members of

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their workforce. These policies and procedures must identify the persons, or classes of persons, in the workforce who need access to protected health information to carry out their duties and the categories of protected health information to which access is needed.

One example of a permitted disclosure is a Facility Directory. It is common practice in many hospitals to maintain a directory of patient contact information. The hospital must inform the patient, or the patient's representative, of the individual information that may be included in a directory and the persons to whom such information may be disclosed. The patient, or the patient's representative, must be given the opportunity to restrict or prohibit any or all uses and disclosures. The hospital may rely on a patient's/representative's individual's informal permission to list in its facility directory the patient's name, general condition, religious affiliation, and location in the provider's facility. The provider may then disclose the patient's condition and location in the facility to anyone asking for the patient by name, and also may disclose religious affiliation to clergy. If the opportunity to prohibit or restrict uses and disclosures cannot be provided due to the patient's incapacity or emergency treatment circumstance, and there is no patient representative available, the hospital may disclose patient information for the facility's directory if such disclosure is in the patient's best interest. The hospital must provide the patient or the patient's representative an opportunity to prohibit or restrict disclosure as soon as it becomes practicable to do so. The hospital may use patient information to notify, or assist in the notification of, a family member, a personal representative of the patient, or another person responsible for the care of the patient of their location, general condition, or death. The hospital must have procedures in place, in accordance with State law, to provide appropriate information to patient families or others in those situations where the patient is unable to make their wishes known.

Incidental Uses and Disclosures May be Acceptable:

An incidental use or disclosure is a secondary use or disclosure of patient information that cannot reasonably be prevented, is limited in nature, and that occurs as a result of another use or disclosure that is permitted. Many customary health care communications and practices play an important role in ensuring the prompt delivery of effective care. Due to the nature of these communications and

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practices, as well as of the hospital environment, the potential exists for a patient's information to be disclosed incidentally. For example, a hospital visitor may overhear a health care professional's confidential conversation with another health care professional or the patient, or may glimpse a patient's information on a sign-in sheet or nursing station whiteboard. The regulation protecting patient privacy does not impede these customary and essential communications and practices and, thus, a hospital is not required to eliminate all risk of incidental use or disclosure secondary to a permitted use or disclosure, so long as the hospital takes reasonable safeguards and discloses only the minimum amount of personally identifiable information necessary. For example, hospitals may:

- Use patient care signs (e.g. "falls risk" or "diabetic diet") displayed at the bedside or outside a patient room;
- Display patient names on the outside of patient charts; or
- Use "whiteboards" that list the patients present on a unit, in an operating room suite, etc.

Hospitals are expected to review their practices and determine what steps are reasonable to safeguard patient information while not impeding the delivery of safe patient care or incurring undue administrative or financial burden as a result of implementing privacy safeguards.

Examples of reasonable safeguards could include, but are not limited to:

- Requesting that waiting customers stand a few feet back from a counter used for patient registration;
- Use of dividers or curtains in areas where patient and physician or other hospital staff communications routinely occur;
- Health care staff speaking quietly when discussing a patient's condition or treatment in a semi-private room;
- Utilizing passwords and other security measures on computers maintaining personally identifiable health information; or

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- Limiting access to areas where white boards or x-ray light boards are in use, or posting the board on a wall not readily visible to the public, or limiting the information placed on the board.

Survey Procedures §482.13(c)(1)

- Conduct observations/interview patients or their representatives to determine if patients are provided reasonable privacy during examinations or treatments, personal hygiene activities and discussions about their health status/care and other appropriate situations.
- Review hospital policy and interview staff concerning their understanding of the use of patient information in the facility directory. Does the policy address the opportunity for the patient or patient's representative to restrict or prohibit use of patient information in emergent and non-emergent situations?
- Review hospital policy and conduct observations/interview staff to determine if reasonable safeguards are used to reduce incidental disclosures of patient information.
- If audio and/or visual monitoring is utilized in the med/surg or ICU setting, conduct observations to determine that monitor screens and/or speakers are not readily visible or audible to visitors or the public.

A-0144

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.13(c)(2) - The patient has the right to receive care in a safe setting.

Interpretive Guidelines §482.13(c)(2)

The intention of this requirement is to specify that each patient receives care in an environment that a reasonable person would consider to be safe. For example, 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. Additionally, this standard is intended to provide protection for the patient's emotional health and safety as well as his/her physical safety. Respect, dignity and comfort would be components of an emotionally safe environment.

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Survey Procedures §482.13(c)(2)

- Review and analyze patient and staff incident and accident reports to identify any incidents or patterns of incidents concerning a safe environment. Expand your review if you suspect a problem with safe environment in the hospitals.
- Review QAPI, safety, infection control and security (or the committee that deals with security issues) committee minutes and reports to determine if the hospital is identifying problems, evaluating those problems and taking steps to ensure a safe patient environment.
- Observe the environment where care and treatment are provided.
- Observe and interview staff at units where infants and children are inpatients. Are appropriate security protections (such as alarms, arm banding systems, etc.) in place? Are they functioning?
- Review policy and procedures on what the facility does to curtail unwanted visitors or contaminated materials.
- Access the hospital's security efforts to protect vulnerable patients including newborns and children. Is the hospital providing appropriate security to protect patients? Are appropriate security mechanisms in place and being followed to protect patients?

A-0145

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.13(c)(3) - The patient has the right to be free from all forms of abuse or harassment.

Interpretive Guidelines §482.13(c)(3)

The intent of this requirement is to prohibit all forms of abuse, neglect (as a form of abuse) and harassment whether from staff, other patients or visitors. 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.

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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 following components are suggested as necessary for effective abuse protection:

- **Prevent.** A critical part of this system is that there are adequate staff on duty, especially during the evening, nighttime, weekends and holiday shifts, to take care of the individual needs of all patients. (See information regarding meaning of adequate at those requirements that require the hospital to have adequate staff. Adequate staff would include that the hospital ensures that there are the number and types of qualified, trained, and experienced staff at the hospital and available to meet the care needs of every patient.)
- **Screen.** Persons with a record of abuse or neglect should not be hired or retained as employees.
- **Identify.** The hospital creates and maintains a proactive approach to identify events and occurrences that may constitute or contribute to abuse and neglect.
- **Train.** The hospital, during its orientation program, and through an ongoing training program, provides all employees with information regarding abuse and neglect, and related reporting requirements, including prevention, intervention, and detection.
- **Protect.** The hospital must protect patients from abuse during investigation of any allegations of abuse or neglect or harassment.
- **Investigate.** The hospital ensures, in a timely and thorough manner, objective investigation of all allegations of abuse, neglect or mistreatment.
- **Report/Respond.** The hospital must assure that any incidents of abuse, neglect or harassment are reported and analyzed, and the appropriate corrective, remedial or

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disciplinary action occurs, in accordance with applicable local, State, or Federal law.

As a result of the implementation of this system, changes to the hospital's policies and procedures should be made accordingly.

Survey Procedures §482.13(c)(3)

- Examine the extent to which the hospital has a system in place to protect patients from abuse, neglect and harassment of all forms, whether from staff, other patients, visitors or other persons. In particular, determine the extent to which the hospital addresses the following issues.
 - Are staffing levels across all shifts sufficient to care for individual patient's needs?
 - Does the hospital have a written procedure for investigating allegations of abuse and neglect including methods to protect patients from abuse during investigations of allegations?
 - How does the hospital substantiate allegations of abuse and neglect?
 - Do incidents of substantiated abuse and neglect result in appropriate action?
 - Has the hospital implemented an abuse protection program? Does it comply with Federal, State and local laws and regulations? Is it effective?
 - Are appropriate agencies notified in accordance with State and Federal laws regarding incidents of substantiated abuse and neglect?
 - Can staff identify various forms of abuse or neglect?
 - Do staff members know what to do if they witness abuse and neglect?
 - What evidence is there that allegations of abuse and neglect are thoroughly investigated?
 - Does the hospital conduct criminal background checks as allowed by State law for all potential new hires?
 - Is there evidence the hospital employs people with a history of abuse, neglect or harassment?