### 10.01.15 Required Documentation
The medical records must contain documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia. 482.24(c)(4)(iv)

All patient medical records, both inpatient and outpatient, must document:
- Complications;
- Hospital-acquired infections;
- Unfavorable reactions to drugs; and
- Unfavorable reactions to anesthesia.

### CHART REVIEW
& INTERVIEW
Through interview and review of medical records, determine that each record contains reports of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia.

### DOCUMENT REVIEW
Verify that the hospital has assured that the medical staff has specified which procedures and treatments require written patient consent.

Verify that the hospital’s standard informed consent form contains the elements listed as the minimum elements of a properly executed informed consent.

Compare the hospital’s standard informed consent form to the hospital’s policies on informed consent, to verify that the form is consistent with the policies. If there is applicable State law, verify that the form is consistent with the requirements of that law.

### CHART REVIEW
Review a minimum of six random medical records of patients who have, are undergoing, or are about to undergo a procedure or treatment that requires informed consent. Verify that each medical record contains informed consent forms.

Verify that each completed informed consent form contains the information for each of the elements listed above as the minimum elements of a properly executed informed consent, as well...
policies as well as applicable State and Federal law or regulation. A properly executed informed consent form contains the following minimum elements:

1. Name of the hospital where the procedure or other type of medical treatment is to take place;
2. Name of the specific procedure, or other type of medical treatment for which consent is being given;
3. Name of the responsible practitioner who is performing the procedure or administering the medical treatment;
4. Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient’s legal representative; (Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity. Hospitals are free to delegate to the responsible practitioner, who uses the available clinical evidence as informed by the practitioner’s professional judgment, the determination of which material risks, benefits and alternatives will be discussed with the patient.)
5. Signature of the patient or the patient’s legal representative; and
6. Date and time the informed consent form is signed by the patient or the patient’s legal representative.
7. If there is applicable State law governing the content of the informed consent form, then the hospital’s form must comply with those as any additional elements required by State law and/or the hospital’s policy.

**INTERVIEW**

Interview the staff and medical staff regarding the process for patient verbalization of understanding. Interview patients, if possible regarding the informed consent process to validate implementation.
### MEDICAL RECORDS (HEALTH INFORMATION) SERVICES

<table>
<thead>
<tr>
<th>STANDARD / ELEMENT</th>
<th>EXPLANATION</th>
<th>SCORING PROCEDURE</th>
<th>SCORE</th>
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<tbody>
<tr>
<td>8</td>
<td>A well-designed informed consent form might also include the following additional information:</td>
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<td>9</td>
<td>Name of the practitioner who conducted the informed consent discussion with the patient or the patient’s representative.</td>
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<td>10</td>
<td>Date, time, and signature of the person witnessing the patient or the patient’s legal representative signing the consent form.</td>
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<td>11</td>
<td>Indication or listing of the material risks of the procedure or treatment that were discussed with the patient or the patient’s representative;</td>
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<td>12</td>
<td>Statement, if applicable, that physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital’s policies and, in the case of residents, based on their skill set and under the supervision of the responsible practitioner.</td>
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<tr>
<td>13</td>
<td>Statement, if applicable, that qualified medical practitioners who are not physicians who will perform important parts of the surgery or administration of anesthesia will be performing only tasks that are within their scope of practice, as determined under State law and regulation, and for which they have been granted privileges by the hospital.</td>
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**Patient Safety Initiative:**
In recent years, informed consent forms have largely become legal documents that protect institutions rather than provide information for shared decision-making. Because an estimated 40 million people in

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2012 - 2013

Healthcare Facilities Accreditation Program (HFAP)
Accreditation Requirements for Healthcare Facilities
the United States are marginally or functionally illiterate and a much larger number are medically illiterate, policies should be implemented to ensure the use of clear informed consent forms that most patients and their families can readily understand.

Similarly, providing informed consent should be viewed as an interactive process between healthcare providers and patients, not merely a form for which a signature must be obtained.

Policy
Hospitals must assure that the practitioner(s) responsible for the surgery obtains informed consent from patients in a manner consistent with hospital policy. The hospital has a policy that describes the informed consent process including:

a. Who may obtain the patient’s informed consent;

b. Which procedures require informed consent;

c. The circumstances under which surgery is considered an emergency and may be undertaken without an informed consent;

d. The circumstances when a patient’s legal representative, rather than the patient, may give informed consent for surgery;

e. The content of the informed consent form and instructions for completing it;

f. The process used to obtain informed consent, including how informed consent is to be documented in the medical record;

g. Mechanisms that ensure that the informed consent form is properly executed and is in the patient’s medical record prior to the surgery (except in an emergency); and

h. If the informed consent process and informed
### 10.01.17 Adequacy of Available Information

All records must document the following, as appropriate: All practitioners’ orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient’s condition. 482.24(c)(4)(vi)

#### Patient Safety Initiative
When relying on memory to transcribe medical records, natural human limitations, often exacerbated by environmental circumstances, can result in errors of recall, increasing the risk of error and of an adverse event.

The requirement means that the stated information is necessary to monitor the patient’s condition and that this and other necessary information must be in the patient’s medical record.

In order for necessary information to be used it must be promptly filed in the medical record so that health care staff involved in the patient’s care can access/retrieve this information in order to monitor the patient’s condition and provide appropriate care.

The medical record must contain:
- All practitioner’s orders (properly authenticated);

#### CHART REVIEW
Verify that the patient records contain appropriate documentation of practitioners’ orders, interventions, findings, assessments, records, notes, reports and other information necessary to monitor the patient’s condition.

Is necessary information included in patient records in a prompt manner so that health care staff involved in the care of the patient has access to the information necessary to monitor the patient’s condition?

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<thead>
<tr>
<th>1 = Compliant</th>
<th>2 = Not Compliant</th>
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**COMMENTS:**
### MEDICAL RECORDS (HEALTH INFORMATION) SERVICES

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<thead>
<tr>
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<tbody>
<tr>
<td>• All nursing notes (including nursing care plans);</td>
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<td>• All reports of treatment (including complications and hospital-acquired infections);</td>
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<td>• All medication records (including unfavorable reactions to drugs);</td>
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<td>• All radiology reports;</td>
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<td>• All laboratory reports;</td>
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<tr>
<td>• All vital signs; and</td>
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<tr>
<td>• All other information necessary to monitor the patient’s condition.</td>
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#### 10.01.18 Discharge Summary,

The medical records must contain a discharge summary with outcome of hospitalization, disposition of case and provisions for follow-up care.

482.24(c)(4)(vii)

All patient medical records must contain a discharge summary. A discharge summary discusses the outcome of the hospitalization, the disposition of the patient, and provisions for follow-up care. Follow-up care provisions include any post hospital appointments, how post hospital patient care needs are to be met, and any plans for post-hospital care by providers such as home health, hospice, nursing homes, or assisted living.

The MD/DO or other qualified practitioner with admitting privileges in accordance with State law and hospital policy, who admitted the patient is responsible for the patient during the patient’s stay in the hospital. This responsibility would include developing and entering the discharge summary.

Other MD/DOs who work with the patient’s MD/DO and who are covering for the patient’s MD/DO and who are knowledgeable about the patient’s condition, the patient’s care during the hospitalization, and the patient’s discharge plans may write the discharge summary at the responsible MD/DO’s request.

#### CHART REVIEW

1. Determine that each record contains evidence of a discharge summary to assure proper continuity of care.
2. Verify that a discharge summary is included to assure that proper continuity of care is required.
3. For patient stays under 48 hours, the final progress notes may serve as the discharge summary and must contain the outcome of hospitalization, the case disposition, and any provisions for follow-up care.
4. Verify that a final diagnosis is included in the discharge summary.

#### DISCHARGE SUMMARIES MUST BE COMPLETED WITHIN 7 DAYS OF DISCHARGE. (See standard 10.01.33)

2012 - 2013 Healthcare Facilities Accreditation Program (HFAP)
Accreditation Requirements for Healthcare Facilities
In accordance with hospital policy, and 42 CFR Part 482.12(c)(1)(i) the MD/DO may delegate writing the discharge summary to other qualified health care personnel such as nurse practitioners and MD/DO assistants to the extent recognized under State law or a State’s regulatory mechanism.

Whether delegated or non-delegated, we would expect the person who writes the discharge summary to authenticate, date, and time their entry and additionally for delegated discharge summaries we would expect the MD/DO responsible for the patient during his/her hospital stay to co-authenticate and date the discharge summary to verify its content. The discharge summary requirement would include outpatient records. For example:

- The outcome of the treatment, procedures, or surgery;
- The disposition of the case;
- Provisions for follow-up care for an outpatient surgery patient or an emergency department patient who was not admitted or transferred to another hospital.

10.01.19 Medical Record Delinquency.

All medical records must contain a final diagnosis. All medical records must be complete within 30 days of discharge or outpatient care.

CHART REVIEW
Select a sample of patients who have been discharged for more than 30 days. Request their medical records. Are those records complete? Does each record have the patient’s final diagnosis?

COMMENTS: